EUROPEAN
COMMISSION

Brussels, 2.6.2016
SWD(2016) 127 final/2

CORRIGENDUM

This document corrects document SWD(2016) 127 final of 21.4.2016

Incorrect data sets in A.1.3, A.1.28, and A.1.30. of Annex 1 have been replaced and the Table of Contents amended accordingly.

The text shall read as follows:

**COMMISSION STAFF WORKING DOCUMENT**

**on the implementation of Directives 2004/23/EC, 2006/17/EC and 2006/86/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells**

***Accompanying the document***

**REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS on the implementation of Directives 2004/23/EC, 2006/17/EC and 2006/86/EC setting standards of quality and safety for human tissues and cells**

{COM(2016) 223 final}
{SWD(2016) 128 final}

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## ABBREVIATIONS

ART = assisted reproductive technologies
ATMP = advanced therapies medicinal products
CMV = cytomegalovirus
DBM = demineralised bone matrix
EBV = Epstein–Barr virus
EBMT = European Group for Blood and Marrow Transplantation
EC = European Commission
ECDC = European Centre for Disease Prevention and Control
EEA = European Economic Area
EU = European Union
GMP = good manufacturing practices
GTP = good tissue practices
HBV = hepatitis B virus
HCV = hepatitis C virus
HSC = haematopoietic stem cells
HIV = human immunodeficiency virus
HFEA = Human Fertility and Embryology Authority
HLA = human leukocyte antigen
HTA = Human Tissue Authority
HTLV = human T-cell lymphotropic virus
IgM = immunoglobulin M
ISO = International Organization for Standardization
JACIE = Joint Accreditation Committee-ISCT & EBMT
NAT = nucleic acid amplification test
PBSC = peripheral blood stem cells
RATC = Rapid Alerts for Tissues and Cells
SAE = serious adverse event
SAR = serious adverse reaction
SARE = serious adverse reactions and events
SOP = standard operating procedures

Member State and country codes: http://publications.europa.eu/code/en/en-370100.htm

# 1. INTRODUCTION

This Staff Working Document accompanying the Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on the implementation of Directives 2004/23/EC, 2006/17/EC and 2006/86/EC setting standards of quality and safety for human tissues and cells summarises the results of a Commission survey on the implementation of the EU tissue and cell legislation conducted in 2013. The data reported was from 2011.

The implementation survey was answered by all Member States except Greece, and also by two EEA countries, Liechtenstein and Norway.[1] The individual country responses are included in Annex 1 to this document. Only Greece did not provide any information. Overall the cooperation with the Member States was satisfactory reflecting the very good interaction between the Commission services and the Member States in this area.

This document addresses only the implementation of the EU tissues and cells legislation, whereas the outcome of the verification of completeness of transposition performed by the Commission is summarised in the overall Report on the implementation of the EU tissue and cell legislation. Information on the application of the principle of voluntary and unpaid donation (VUD) is presented in a separate Staff Working Document also accompanying the abovementioned Report.

The implementation section of this document follows the structure of Directive 2004/23/EC, and includes three main chapters which address the obligations of Member States' authorities, donor selection and evaluation, and quality and safety of tissues and cells.

# 2. IMPLEMENTATION OF THE EU TISSUES AND CELLS LEGISLATION

The implementation survey covers a broad range of topics: 1. designation of competent authorities, 2. obligations of Member States' authorities, 3. donor selection and evaluation, and 4. quality and safety of tissues and cells. Each sub-section ends with comments summarising the main findings.

Overall, the implementation of the EU tissues and cells legislation by Member States is considered adequate. However, a number of Member States reported difficulties in the interpretation, implementation or enforcement of some of its requirements.

As the EU legislation in the tissue and cell sector does not provide for full harmonisation, Member States had various approaches when implementing its provisions. These differences facilitate successful integration of the requirements into national legislation but in some cases they may limit the mutual acceptance of authorisations with consequences on the cross-border movement of tissues and cells.

[1] In a number of cases clarification requests were sent to Member States, as replies were incomplete or difficult to reconcile with other information available to the Commission. It is important to note that the hyperlinks contain the original replies of Member States, whilst the report reflects the updated information provided by Member States. This can lead to certain discrepancies. In such cases this report contains the correct information.

## 2.1. Designation of Competent Authority or Authorities Responsible for the Implementation of Directive 2004/23/EC

In the 2010 Communication on the application of Directive 2004/23/EC[2] it was stated that all Member States had designated a competent authority in accordance with the provision laid down in Article 4(1), with 21 Member States having one competent authority responsible for all types of tissues and cells and five Member States (EL, FI, FR, PT, UK) with a specific competent authority for reproductive tissues and cells.

The 2013 survey revealed some organisational changes in the Member States (Table I, Figure 1):

- In 15 Member States (AT, BE, BG, DE, DK, EE, FI, HR, HU, IE, LU, LV, MT, SI, SK) and Liechtenstein, there is only one competent authority;
- Four Member States (CZ, ES, RO, UK) reported that two competent authorities were designated in their countries. In the Czech Republic, while the main competent authority is responsible for tissue establishments' authorisation and inspection, as well as vigilance, a second competent authority is in charge of granting import and export licences, European affairs and various aspects related to the national legislation. In the United Kingdom one competent authority is overseeing the traditional tissues and cells, and the other is responsible for the supervision in the Assisted Reproductive Technologies (ART) sector. In Romania one authority is mainly responsible for the accreditation of the tissue establishments, while a second one is in charge of inspections and vigilance. In Spain, the organisation is similar to the one in the United Kingdom, but the national ART competent authority has only a consultative role, whereas the authorisation, inspection and vigilance tasks were delegated to the regions;
- Six Member States (FR, LT, NL, PL, PT, SE) and Norway reported that three competent authorities were designated to oversee the tissues and cells field at national level;
- In France, Portugal and UK one of the competent authorities is responsible only for the oversight of the ART sector;
- Five Member States declared having regional competent authorities, namely DE, ES, FR, IT and SK. These authorities have been entrusted with tasks like accreditation/ authorisation/designation/licensing of tissue establishments, inspection and/or vigilance. In Italy regional authorities are responsible only for authorising the tissue

[2] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2009:0708:FIN:EN:PDF

establishments.

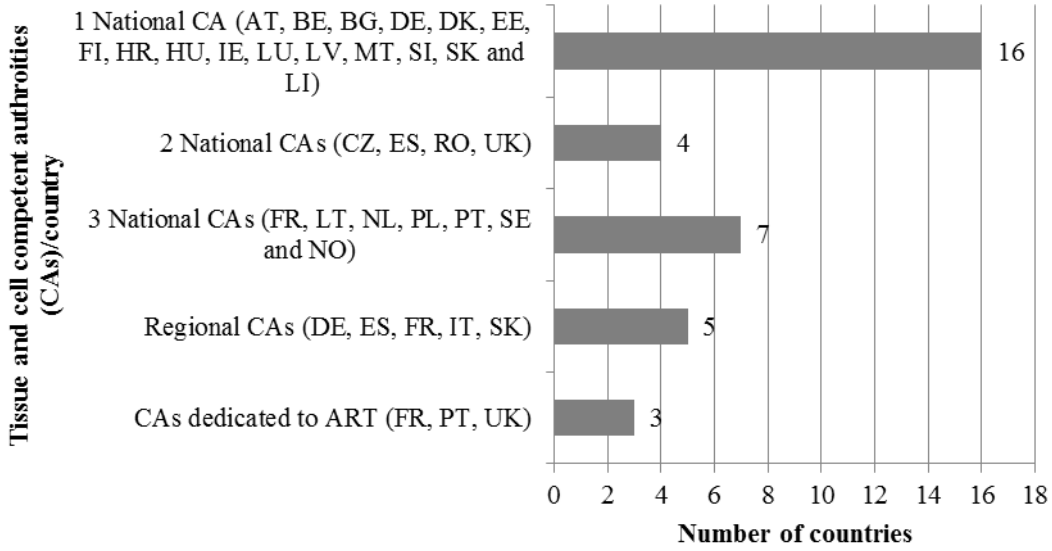



*Fig. 1. Tissues and cells competent authorities in the reporting EU Member States and EEA countries*

In two Member States the designated competent authorities do not cover all the categories of tissues and cells as requested by the Directives. This is the case of Poland[3] and Lithuania, where, due to an inappropriate transposition of the EU legislation in the ART sector, no competent authorities responsible for this particular field were reported.

In addition to the oversight of the tissues and cells sector, in most of the Member States, the tissues and cells competent authorities are also supervising other sectors/activities (Figure 2).

[3] In 2015 Poland has adopted new legislation for the ART sector and is in process of implementing it.

| Country | National competent authority 1 | National competent authority 2 | National competent authority 3 |
|---|---|---|---|
| AT | Federal Office for Safety in Health Care (BASG) / AGES Austrian Agency for Health and Food | | |
| BE | FAMHP: Federal Agency for Medicines and Health Products | | |
| BG | Bulgarian Executive Agency for Transplantation | | |
| CY | Ministry of Health, Cyprus | | |
| CZ | State Institute for Drug Control | Ministry of Health of the Czech Republic | |
| DE | Paul-Ehrlich-Institut, Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel | | |
| DK | Danish Health & Medicines Authority | | |
| EE | State Agency of Medicines | | |
| EL | no data reported | | |
| ES | Organizacion Nacional de Transplantes | | |
| FI | Finnish Medicines Agency | | |
| FR | Ministry of Health | Agence nationale de sécurité du médicament et des produits de santé (ANSM) | Agence de la biomédecine (ABM) |
| HR | Ministry of Health | | |
| HU | National Public Health and Medical Officer Service - Office of the Chief Medical Officer (NPHMOS-OCMO) | | |
| IE | Irish Medicines Board (IMB) | | |
| IT | Ministry of Health - National Transplant Centre | National Blood Centre | |
| LT | National Transplants Bureau under the Ministry of Health of the Republic of Lithuania | Ministry of Health of the Republic of Lithuania | State Health Care Accreditation Agency under the Ministry of Health |
| LU | Ministère de la Santé | | |
| LV | State Agency of Medicines of the Republic of Latvia | | |
| MT | Superintendence of Public Health, Ministry for Health, Malta | | |
| NL | Ministry of Health, Welfare and Sport (Ministerie voor Volksgezondheid, Welzijn en Sport, VWS) | Health Care Inspectorate (Inspectie voor de Gezondheidszorg, IGZ) | Dutch Transplantation Foundation (Nederlandse Transplantatie Stichting, NTS) |
| PL | National Centre for Tissue and Cell Banking | Polish Transplant Coordinating Center Poltransplant | Department of Mother and Child, Ministry of Health |
| PT | Instituto Português do Sangue e da Transplantação, IP (IPST) | Direção-Geral de Saúde | Conselho Nacional de Procriação Medicamente Assistida (CNPMA) |
| RO | National Transplant Agency | Ministry of Health - Public Health and Control in Public Health Directorate | |
| SE | Health and Social Care Inspectorate / Inspektionen för vård och Omsorg (IVO) | Medical Products Agency | The National Board of Health and Welfare |
| SI | Javna agencija Republike Slovenije za zdravila in medicinske pripomočke / Agency for Medicinal Products and Medical Devices of the Republic of Slovenia | | |
| SK | Ministry of Health of the Slovak Republic | | |
| UK | Human Tissue Authority (HTA) | Human Fertilisation and Embryology Authority (HFEA) | |
| | | | |
| LI | Amt für Gesundheit | | |
| NO | Norwegian directorate of health | Norwegian board of health supervision | Norwegian medicines agency |

*Table I. Tissues and cells national competent authorities*

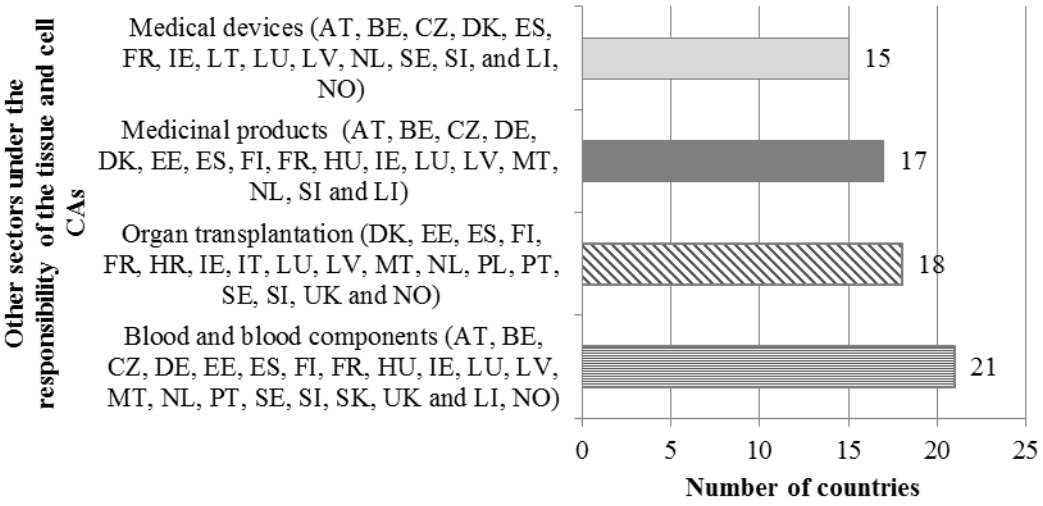



*Fig. 2. Other responsibilities of tissues and cells competent authorities*

Several Member States provided clarifications on the tasks and responsibilities of their national competent authorities. Germany and Ireland specified that they are also responsible for advanced therapy medicinal products and xenogenic medicinal products. Furthermore, some Member States reported that their competent authorities are also responsible for: cosmetic products, veterinary products (France, Ireland); tattoo inks, biocides, ancillary products, human breast milk (France); clinical trials approval, protection of animals (Ireland); data collection and traceability (Italy); licensing of import-export activities (Czech Republic, Poland); licensing organisations that remove, store, and use human tissue for purposes outside direct patient treatment (United Kingdom/HTA); public health regulation (Malta); policy development and implementation (Denmark, Ireland, United Kingdom); providing training programmes, international cooperation, relation with the media, research projects, transplant registries, promotion and education (Spain, Italy); enforcement (Ireland).

Certainly the designation of the competent authority or authorities in the field of human tissues and cells for human application is a prerogative of the Member States and EEA countries. As demonstrated by the reported data, many national competent authorities are ministries or agencies or delegated bodies in the health sector. In some countries the nominated organisations also work on research, education or labour issues. Some countries with federal organisations have entrusted some important responsibilities (e.g. authorisation and inspection of tissue establishments) to the regional authorities. Whereas some Member States preferred to pool national capability in one large national competent authority usually responsible for several/all healthcare sectors, other countries chose to develop expertise by creating/maintaining distinct organisations dedicated to oversee the human tissues and cells sector or a specific area of this sector (e.g. ART). Irrespective of organisational structure, the bi-annual meetings of the tissues and cells competent authorities allow for sharing best practices, with specialised authorities giving significant input in their particular area of expertise and the others contributing with integrative standpoints within the broader context of the healthcare sector, especially when analysing borderline issues like those with the medical devices and medicinal products sectors.

*Comments*

All Member States have appointed competent authorities for tissues and cells, which can be considered satisfactory. In some Member States more than one authority is responsible for the oversight of the tissue and cell sector. In these cases the division of tasks is based on the tissue types concerned (e.g. separate authority for the ART sector), geographic competences (federal/regional/local) or instruments used (e.g. authorisation/inspection). In some Member States the authorities for tissues and cells are also responsible for the oversight of other sectors (e.g. organs, blood, medicinal products), which can be beneficial from an efficiency point of view. Ultimately it is for the Member States to decide on the organisational set-up of their competent authorities. However, Member States need to ensure adequate coordination and communication between all authorities involved, e.g. to discuss borderline issues or ensure adequate follow-up in case of shortcomings.

Irrespective of the organisational set-up it is important that all authorities have adequate resources at their disposal and are independent from industry, from the professional sector and other influences. In this respect it could be problematic if one and the same person works for a national competent authority and – at the same time – for a national tissue establishment.

## 2.2 Obligations of Member States Authorities

Directive 2004/23/EC contains a number of obligations for competent authorities. They relate to (1) the supervision of procurement, (2) the authorisation of tissue establishments, (3) inspections and control measures, (4) traceability, (5) imports and exports, (6) reporting obligations and (7) notification of serious adverse events and reactions. The implementation of these obligations is set out in this section.

### *2.2.1 Supervision of human tissue and cell procurement*

Under Article 5 of the Directive 2004/23/EC, the competent authority or authorities must ensure that tissue and cell procurement and testing are carried out in conditions accredited, designated, authorised or licensed for this purpose and that it complies with the requirements laid down in Directive 2006/17/EC.

The survey showed that all reporting Member States authorise the conditions of procurement, as follows:

- Twelve Member States (BG, CY, CZ, DE, ES, FI, HR, HU, IE, LU, MT, SI) and Liechtenstein authorise the conditions of procurement by inspecting all procurement centres;
- Seven Member States (AT, DK, IT, PL, PT, SE, UK) reported inspecting some procurement centres;
- Nineteen Member States (AT, BE, BG, CY, DE, DK, EE, HR, HU, IT, LT, LU, LV, MT, NL, PL, PT, SE, UK) and Norway evaluate the documentation associated with the procurement made available by the tissue establishment working with procurement centres.

Additionally, Member States reported other practices:

- Procurement sites have to be listed on the tissue establishment's licence and inspected during routine inspections (Finland);

- Procurement activities are evaluated during the product evaluation, where documentation has to include a description of the procurement conditions (France);
- Procurement centres which operate through a third party agreement with a licensed establishment are not inspected by the national competent authority (United Kingdom).

Estonia specified that only tissue establishments and healthcare professionals having contracts with tissue establishments are allowed to procure tissues. Ireland reported that when procurement occurs in Ireland, the activity is inspected and the site requires a tissue establishment authorisation; if the procurement occurs outside Ireland, the relevant documentation is inspected onsite at the Irish tissue establishment. Similar to Ireland, in Belgium procurement can be carried out only by authorised tissue establishments. Romania reported that one competent authority is responsible for evaluating the documentation of all the procurement centres, while the other authority is responsible for their inspection. Spain informed that the task of supervising human tissue and cell procurement was entrusted to the regional competent authorities.

In 2011, 20 Member States and Liechtenstein and Norway, granted 640 authorisations for the conditions of procurement (Figure 3). Six Member States (FI, IE, LU, LV, PT, SE) did not grant any authorisation and in two Member States (Greece and Italy) such data were not available.

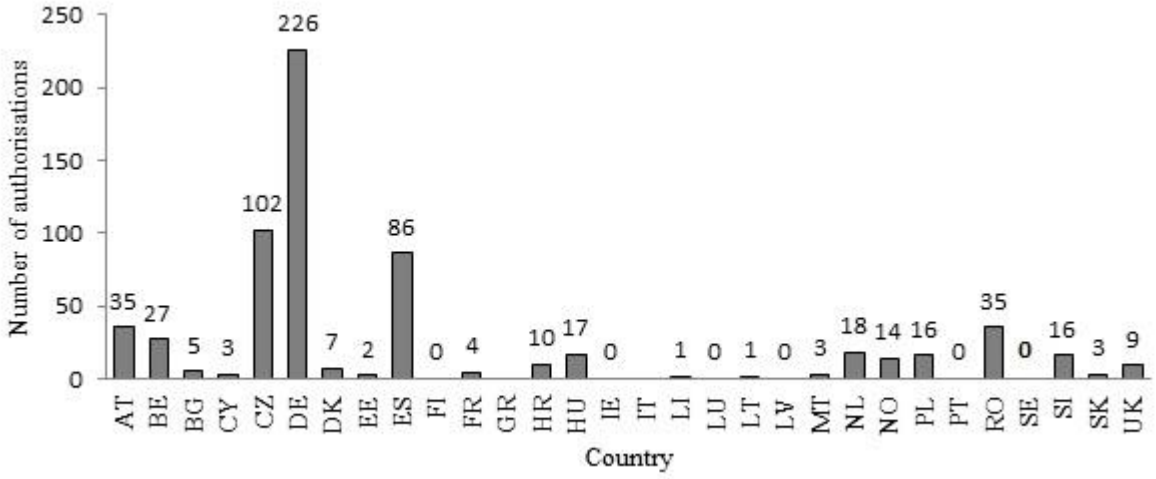



*Fig. 3. Number of authorisations for conditions of procurement granted in 2011*

Most of the Member States provided the number of centres carrying out procurement activities in 2011. Of the 4825 procurement organisations carrying out procurement activities, most of them are dedicated to the collection of haematopoietic stem cells, followed by procurement of replacement tissues and reproductive cells (Figure 4). It has to be underlined that a number of 332 procurement organisations harvesting cells or tissues to be used for advanced therapy medicinal product (ATMP) manufacturing were also reported. A detailed analysis of the procurement organisations per Member State and type of tissues procured is presented in Figures 5 - 8.

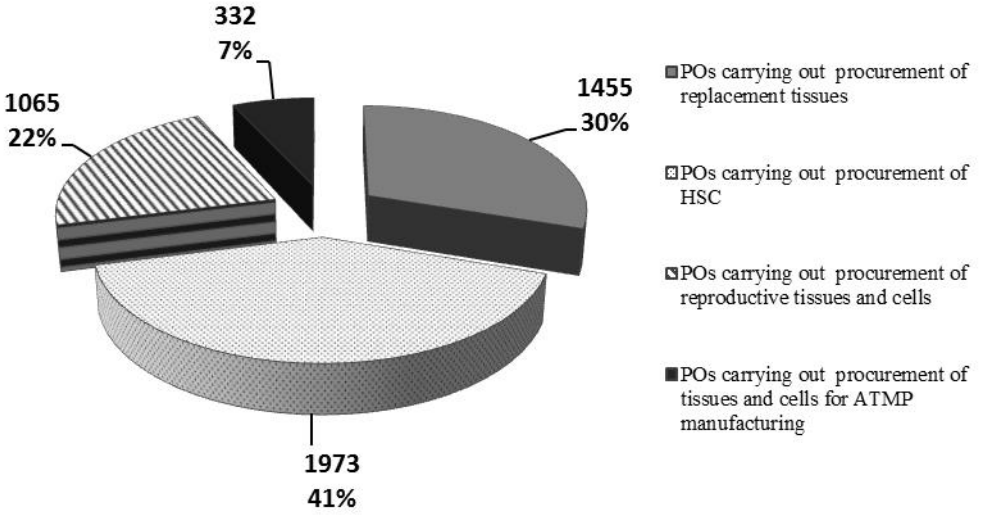



*Fig. 4. Number of procurement organisations reported by the EU and EEA countries (2011 data)*

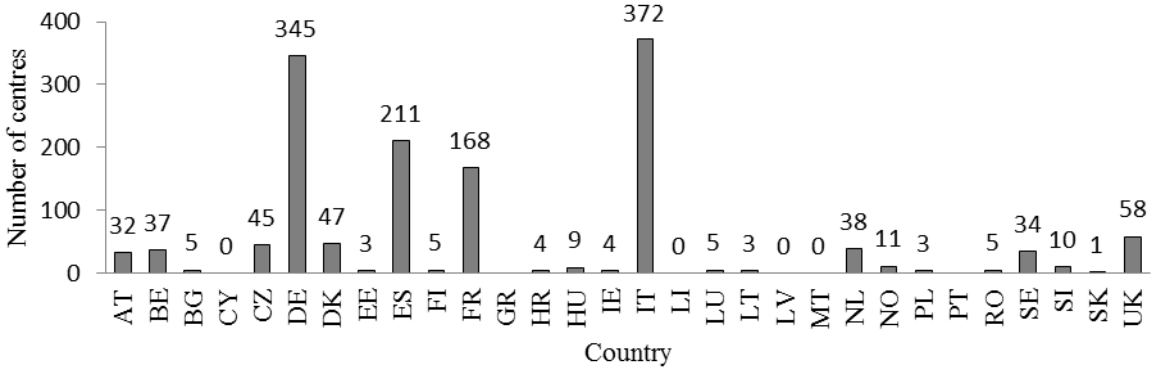



*Fig. 5. Number of centres carrying out procurement of replacement tissues (e.g. musculoskeletal, cardiovascular, ocular tissue, skin) in 2011*

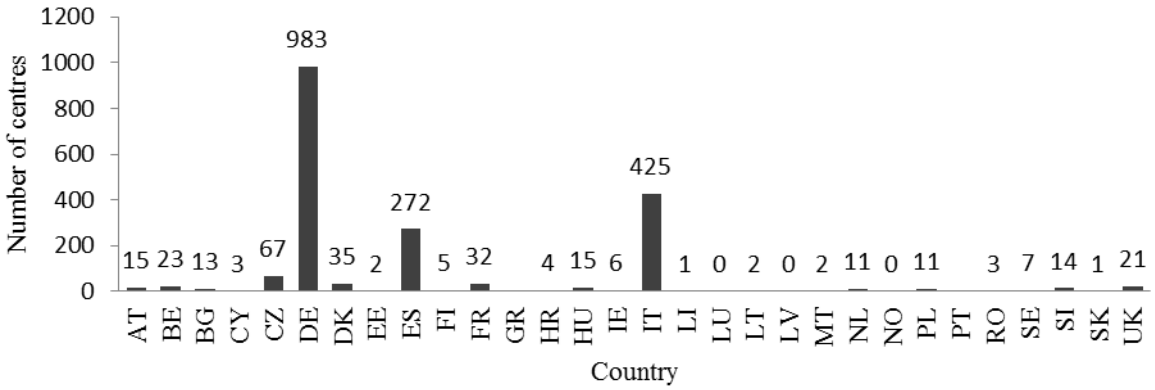


*Fig. 6. Number of centres carrying out procurement of HSC (e.g. bone marrow, peripheral blood stem cells, cord blood) in 2011*

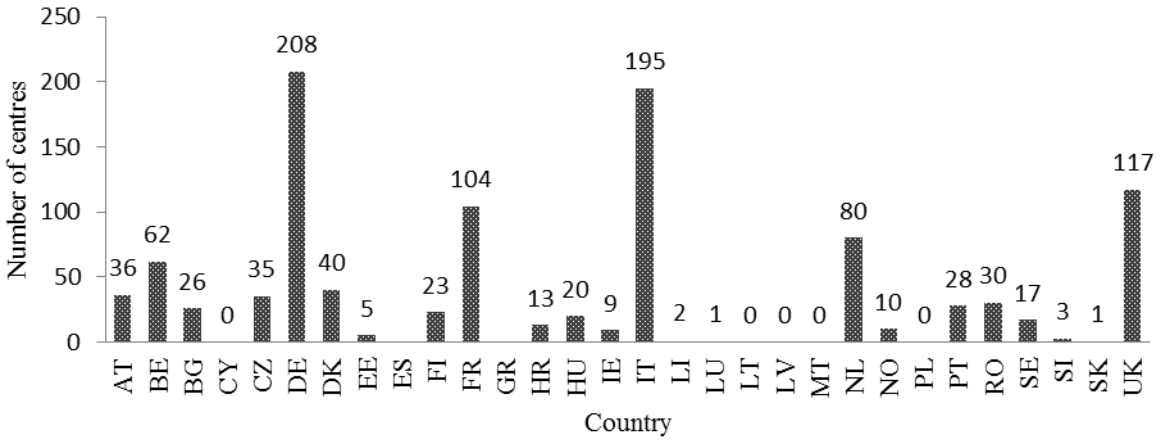



*Fig. 7. Number of centres carrying out procurement of reproductive tissues and cells in 2011*

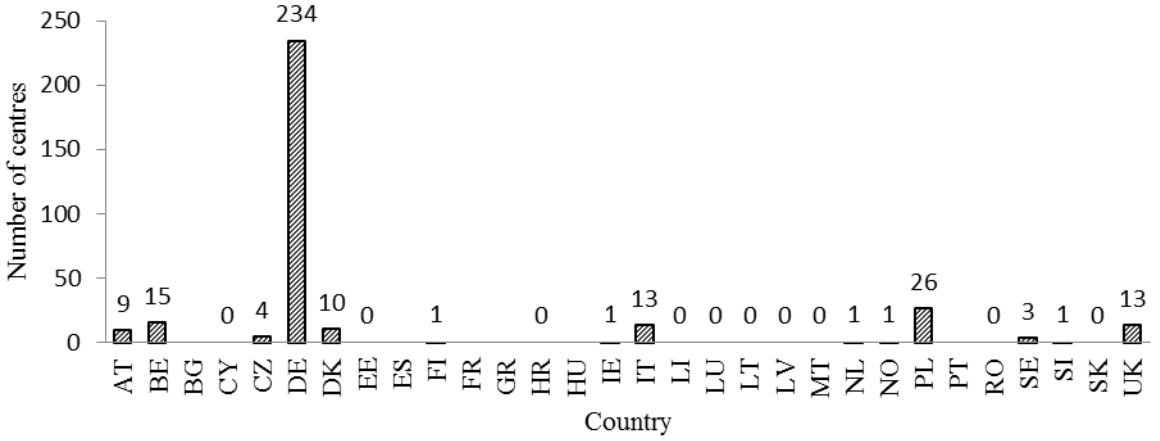



*Fig. 8. Number of centres carrying out procurement of tissues and/or cells for ATMP manufacturing in 2011*

The survey revealed that all reporting Member States ensure that centres carrying out procurement of human tissues and cells centres comply with the requirements of Article 5 of Directive 2004/23/EC and its implementing Directive 2006/17/EC. Their approaches vary, with Member States only inspecting the site/centre, others only analysing the mandatory documentation (Belgium, Denmark), and most of them performing both inspections and analysis of the mandatory documentation (Fig 9).

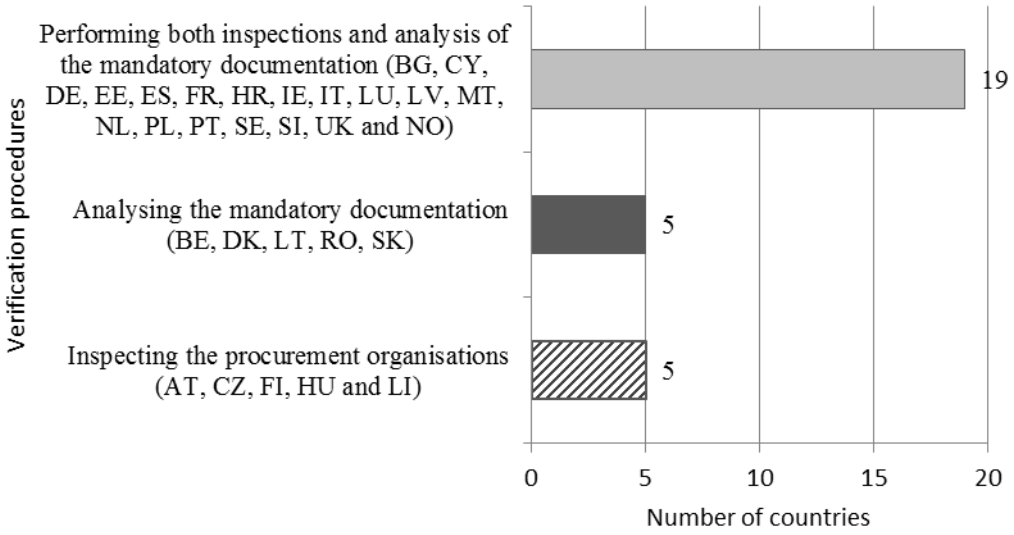



*Fig. 9. Member States' approaches for ensuring that centres carrying out procurement of human tissues and cells comply with the EU legal requirements*

Additional procedures were also reported. In Sweden tissue establishments perform audits of the procurement centre(s) and the audit reports are examined during the inspection of the tissue establishment. The competent authority in the United Kingdom (HTA) reported investigating allegations about non-compliance with procurement standards; moreover, to ensure continued compliance, correspondence is circulated to the sector (e.g. newsletter) and regular workshops are organised for updating the tissue establishments on the latest regulatory requirements.

According to Article 5(1) of Directive 2004/23/EC Member States have to ensure that testing is carried out in conditions accredited, designated, authorised or licensed for this purpose. The survey showed that only in 10 Member States (CZ, DE, DK, HR, LU, MT, NL, RO, UK) and Liechtenstein and Norway, the tissues and cells competent authorities are also responsible for the accreditation/designation/authorisation or licensing of testing laboratories. In all the other Member States this is the competence of other authorities (Table II), as follows:

- Ministry of Health (Cyprus, Slovenia);
- Regional authorities (DE, ES, FI, HU, IT);
- National accreditation organisations.

| Country | Name of the national accreditation organisation |
|---|---|
| BE | Scientific Institute for Public Health |
| BG | Bulgarian Service for Accreditation |
| EE | Estonian Accreditation Centre |
| FI | National Institute for Health and Welfare |
| FR | Comité Français d'Accréditation |
| IE | Irish National Accreditation Board |
| LV | Latvian National Accreditation Bureau |
| PL | National Chamber of Diagnostic Laboratories |
| PT | Direcao-General de Saude |
| SE | The Swedish Board for Accreditation and Conformity Assessment |
| SK | Slovak National Accreditation Service |
| UK | Clinical Pathology Accreditation (private organisation, providing a voluntary national accreditation service) |

*Table II. National accreditation organisation responsible for the accreditation/designation/ authorisation or licensing of testing laboratories*

Additionally, Malta, Romania and Liechtenstein reported that in their countries the tissues and cells competent authorities are responsible for the laboratories' accreditation, without being responsible for inspecting them. Austria reported having no national provisions on accreditation of testing laboratories.

The Member States' approaches for ensuring that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed in conformity with Article 5(2) of Directive 2004/23/EC are shown in Figure 10.

Concerning the inspection of the testing laboratories, while in the Czech Republic, Denmark and the United Kingdom the tissues and cells competent authorities are also responsible for the laboratories' accreditation, in Hungary, Portugal and Spain this task is not in their remit.

Eleven Member States also provided the number of qualified laboratories in their countries (2011 data) (Figure 11).

Overall, the answers to this section of the questionnaire showed that Member States pay strict attention to the procurement of human tissues and cells. This is underlined by the fact that several countries allow procurement to be performed only by tissue establishments (BE, DE, EE, IT, SE) or authorise the conditions of procurement by inspecting all procurement centres (BG, CY, CZ, DE, ES, FI, HR, HU, IE, LU, MT, SI and LI). Additionally, in most of the responding countries, the documentation associated with the procurement is analysed during tissue establishments' inspections.

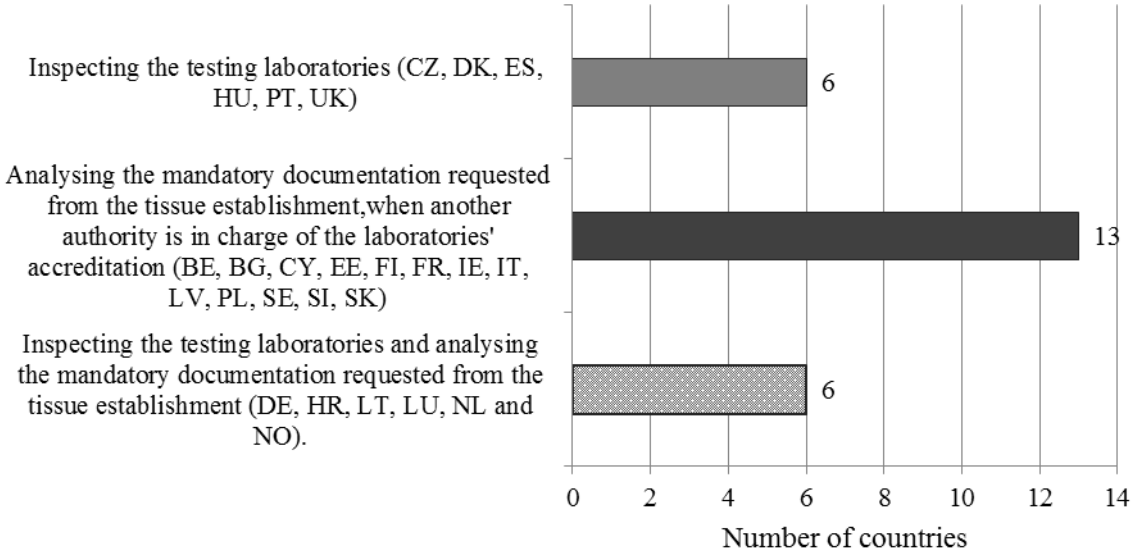



*Fig. 10. Member States approaches for ensuring that donors' testing is carried out in conformity with Article 5.2 of the Directive 2004/23/EC*

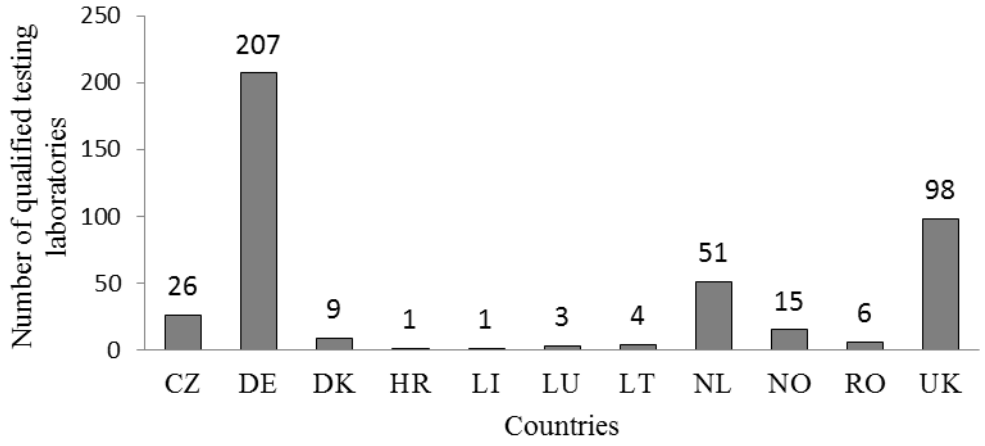



*Fig. 11. Number of qualified testing laboratories/Member State (Total number = 421 – 2011 data)*

*Comments*

The high number of procurement organisations shows that this activity is well developed across the Union, particularly in the larger Member States with tradition in this field (e.g. DE, FR, IT, UK). Furthermore, beside procurement of replacement tissues, haematopoietic stem cells and reproductive cells, some Member States also reported a significant number of centres carrying out procurement of tissue and cells for ATMP manufacturing.

Concerning testing, the survey showed that in most of the reporting countries accreditation/designation/authorisation or licensing of testing laboratories is not under the competence of tissues and cells authorities. In most of the cases the national accreditation organisations are also responsible for the inspection of the testing laboratories. However, only the countries in which tissues and cells competent authorities are also responsible for the

accreditation/designation/authorisation or licensing of testing laboratories provided data on the number of qualified laboratories on their territory. Wherever accreditation and inspections are undertaken by different authorities, a good communication and coordination between respective authorities needs to be ensured.

### *2.2.2. Accreditation/designation/authorisation/licensing of tissue establishments and tissue and cell preparation processes*

Under Article 6(1) of Directive 2004/23/EC, Member States must have in place an appropriate mechanism to ensure that all tissue establishments where activities of testing, processing, preservation, storage and distribution of human tissues and cells intended for human applications are undertaken have been accredited, designated, authorised or licensed by a competent authority for the purpose of those activities.

All Member States reported that for replacement tissues and cells (e.g. musculoskeletal tissue, cardiovascular tissues, ocular tissues, skin, haematopoietic stem cells) an accreditation/designation/authorisation/licensing system of tissue establishments is in place. In the ART sector, 25 Member States reported having an accreditation, designation, authorisation, licensing system also for the ART tissue establishments, while two Member States (Lithuania, Poland) are still in the process of organising their national oversight system for this area.

As reported by the Member States, inspections play a key role in the accreditation/ designation/authorisation/licensing process which varies from prior compulsory on-site inspections to desk-based review of documentation and routine inspections (Figure 12). In five Member States (ES-ART sector, FR, SE, SK, UK) and Norway inspection is not a prerequisite for the designation, authorisation, accreditation, or licensing of tissue establishments.

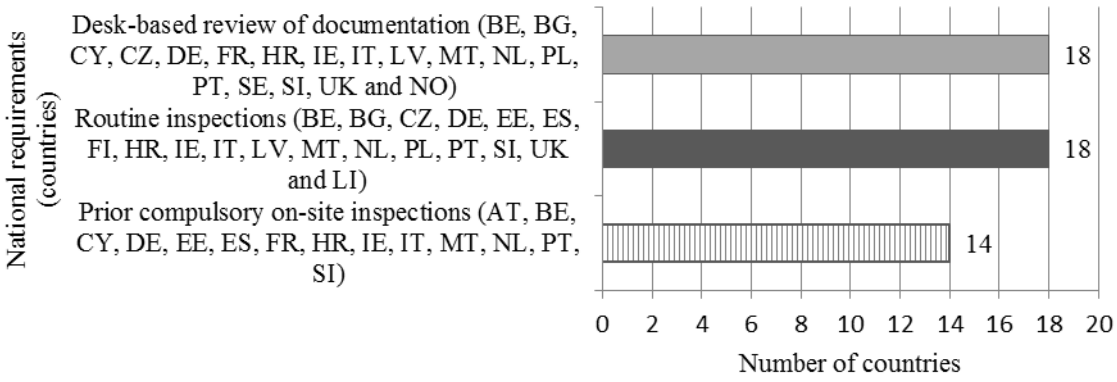



*Fig. 12. National requirements for accrediting/designating/authorising/licensing of tissue establishments*

Under Article 6(2), the competent authority or authorities must authorise the tissue and cell preparation processes which the tissue establishment is entitled to carry out.

Compared with the 2008 data when only three Member States were conducting inspections solely for the purpose of authorising preparation processes, this second survey reveals that 14

Member States are now organising such inspections (Figure 13). In the other Member States, in the absence of specific authorisation systems, tissue and cell preparation processes are either authorised by reviewing applications of the submitted documentation or during a general inspection for the purpose of authorising a tissue establishment.

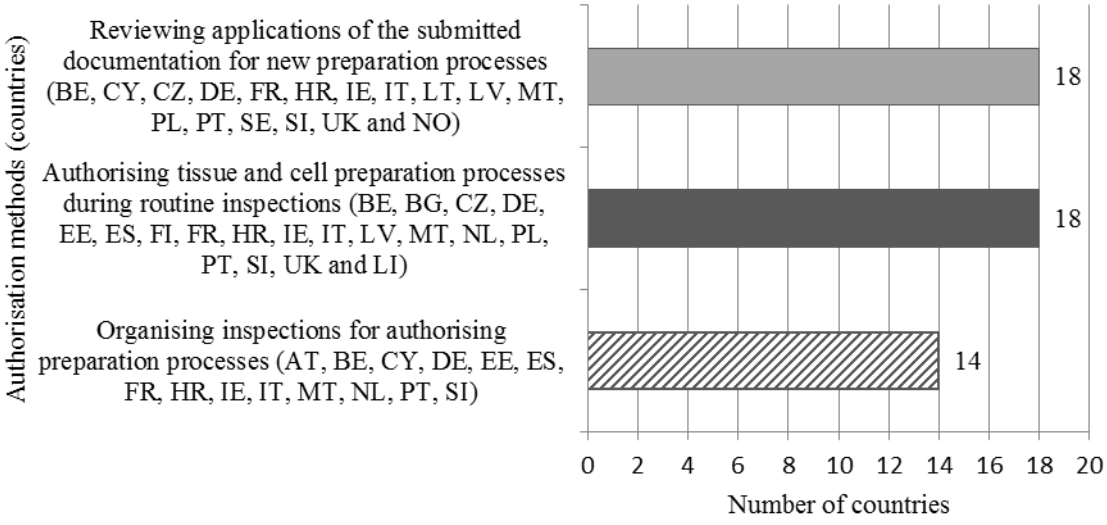



*Fig. 13. National systems for authorising tissue and cell preparation processes*

Two Member States, Croatia and the Netherlands, reported that a certification of the tissue establishment to a quality system standard provided by an external entity is also required. In other Member States (Cyprus, France and Spain), the certification by an external entity is optional, but recommended. In Italy there are different approaches depending on the type of tissues/cells: whereas haematopoietic stem cells centres are inspected in collaboration with JACIE and cord blood banks require ISO certification, for the other types of tissues and cells, no certification is required by law.

Compared to 2008 when 1716 tissue establishments were accredited/designated/ authorised/licensed, the current survey showed that at 31/12/2011 a total of 2047 tissue establishments were accredited, designated, authorised or licensed in the EU (Figures 14 and 15).

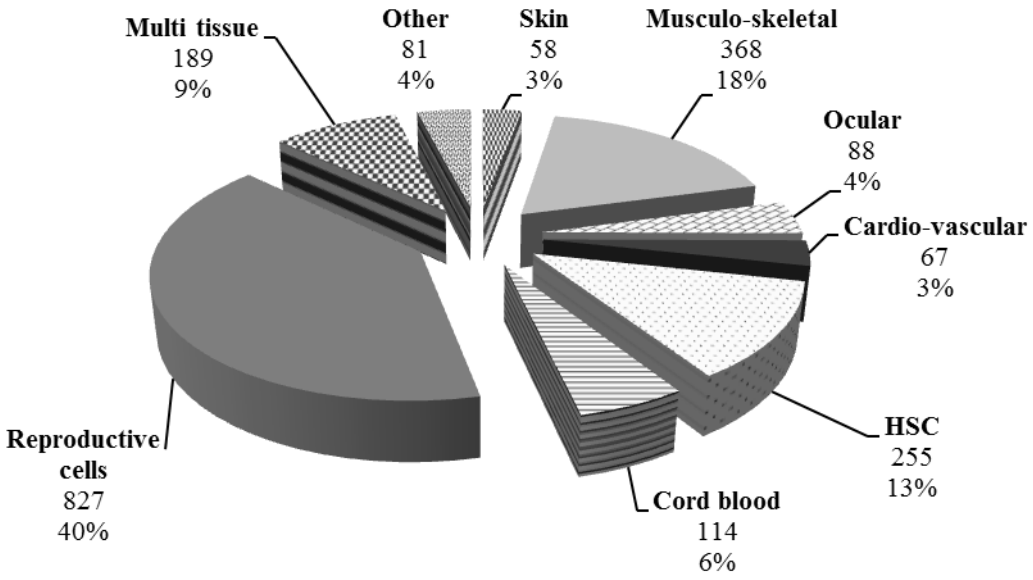



*Fig. 14. Number of accredited/designated/authorised/licensed tissue establishments per type of human tissues and cells (2011 data)*

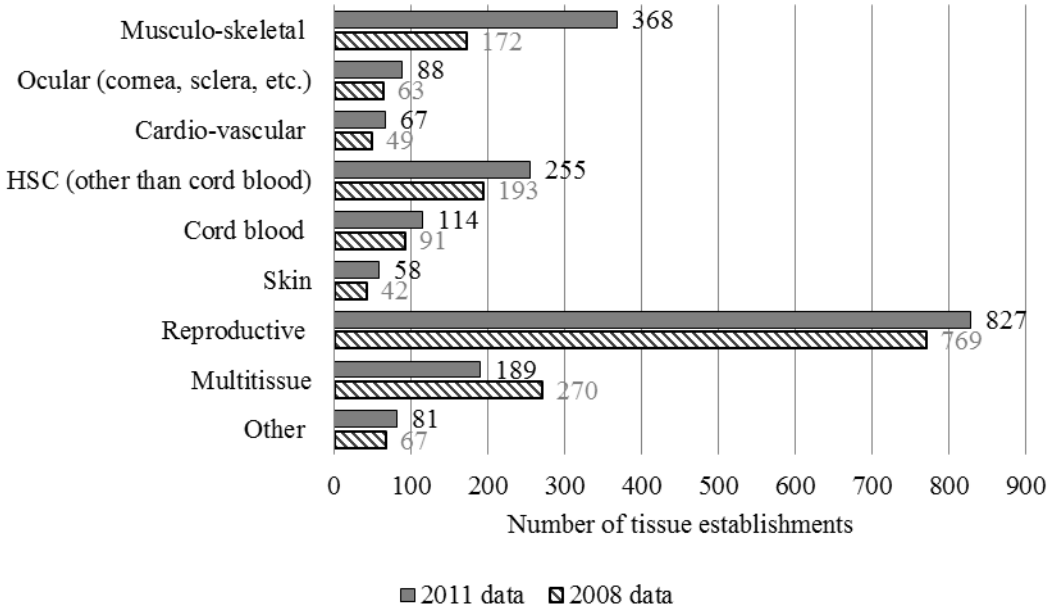



*Fig. 15. Number of accredited/designated/authorised/licensed tissue establishments per type of human tissues and cells (comparative data)*

The numbers of accredited/designated/authorised/licensed tissue establishments per country are presented in Figure 16. Only one Member State, namely Malta, reported having no authorised tissue establishments on their territory. Norway provided no information on the number of tissue establishments.

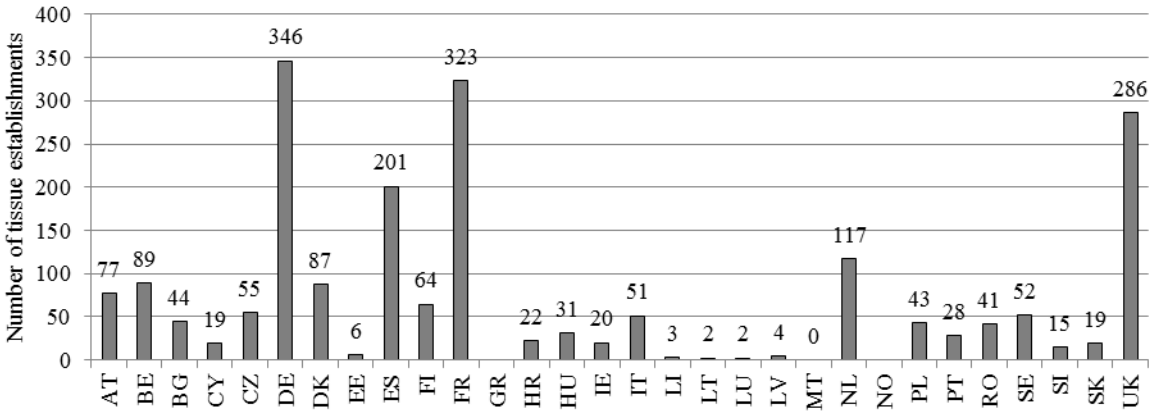



*Fig. 16. The number of accredited/designated/authorised/licensed tissue establishments/country (2011 data)*

Additionally in 2011, 1674 tissue establishments were authorised/re-authorised by competent authorities in 26 Member States (AT, BE, BG, CY, CZ, DE, DK, EE, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI, SK, UK ) and Liechtenstein. Eighteen Member States (AT, BE, BG, CY, CZ, DE, FR, HR, HU, IE, IT, LV, MT, PL, RO, SI, SK, UK) and Liechtenstein indicated that 528 tissue establishments were pending approval of authorisation/re-authorisation at 31/12/2011.

Information on the status of the tissue establishments (public vs. private) was provided by 25 Member States and Liechtenstein. The situation is summarised in Figures 17 and 18. Two other countries, Spain and Norway, indicated that such data are not available.

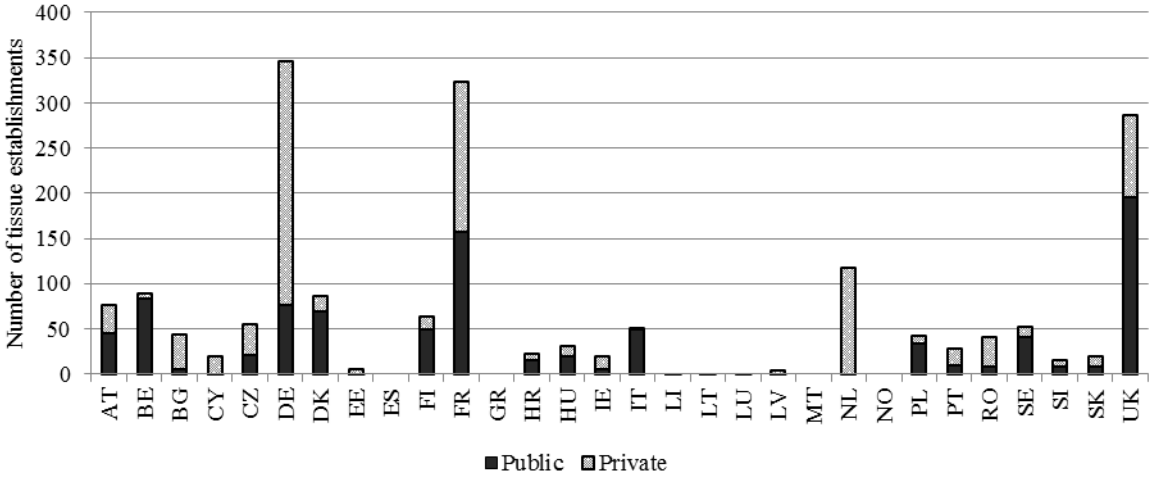



*Fig. 17.Tissue establishments' status (public vs. private)/country (2011 data)*

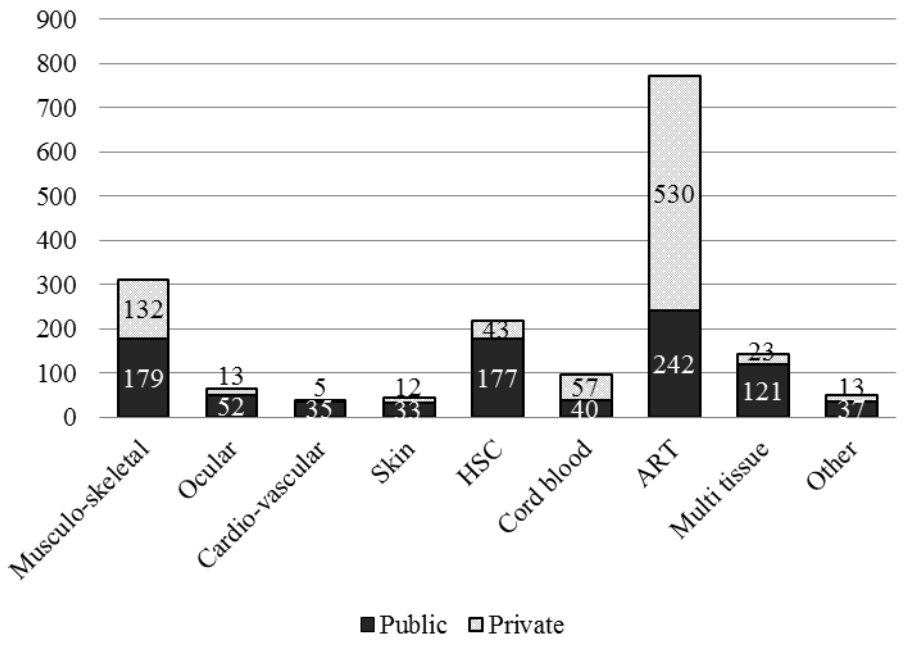



*Fig. 18.Tissue establishments' status (public vs. private)/type of tissue (2011 data)*

Overall, 916 public and 828 private accredited/designated/authorised/licensed tissue establishments were reported. As shown in Figure 18, only in the ART field and the cord blood sector the number of private tissue establishments exceeds the number of the public ones (69% and 59% respectively). Some interesting mixed models have emerged such as the tissue sector in Italy, where the private sector role is limited to that of a third party for processing or storage, with all donation, promotion and distribution activities remaining in public hands.

Under Article 6(5), competent authorities may agree to the direct distribution of tissues and cells for immediate transplantation to a recipient. Six Member States (CY, DE, DK, LT, FR, PT) indicated that in 2011 tissues and/or cells were distributed under the direct agreement of an competent authorities. In most of the cases, these were HSC (bone marrow, PBSC, cord blood, donor lymphocyte infusion), but also ocular tissues (Denmark, Portugal), heart valves (Portugal), musculoskeletal tissue (Lithuania, Portugal) and amniotic membrane (Portugal).

*Comments*

The importance of the tissue and cell sector was demonstrated by its development in the last three years, with an almost 20% increase in the number of authorised tissue establishments compared with the previous survey. In two areas (musculoskeletal tissues and reproductive cells) a significant rise in the tissue establishments' number was noted, whereas for other types of tissues and cells the number of authorised tissue establishments slightly decreased. Additionally, if for most types of tissues and cells the public sector prevails, in the field of ART approximately 60% of the ART establishments belong to the private sector. The development of the private sector is more significant in some Member States (e.g. the Netherlands), while in others (e.g. BG, CZ, DE, RO) is due to the expansion of private ART establishments and cord blood banks.

Summing up, the answers concerning the accreditation/designation/authorisation/licensing of tissue establishments and tissue and cell preparation processes showed that this core responsibility is well implemented across the Union. However, when the survey was launched, two Member States were still in the process of transposing into national legislation the requirements for safety and quality in the ART field, and one Member State had no operational competent authority and submitted no replies to the implementation questionnaire.

The survey showed that the authorisation process is quite heterogeneous, which may hinder the process of mutual acceptance of authorisations between EU Member States. Even though half of the responding Member States require a prior on-site inspection, most of the countries grant a tissue establishment authorisation/accreditation/licence based on a desk-based review of the documentation. Additionally, depending on the Member State's approach, tissue establishments' authorisations/accreditations/licences are granted for a limited or unlimited time interval.

A combination of approaches was also reported for authorising tissue and cell preparation processes. Numerous recent technological developments which generated new processing methodologies, unheard of a decade ago (e.g. pre-cutting of corneas with the transplant of only the anterior or posterior segment to one patient, decellularisation of skin and heart valves, new pathogen inactivation or sterilisation techniques) have increased the importance of robust preparation process authorisation. As suggested by some Member States, a more harmonised procedure and/or establishing an EU authorisation template for preparation process authorisation may contribute to reaching mutual acceptance between Member States.

While it is for Member States to decide which terminology to use for the initial permission to operate as a tissue establishment, it should be transparent and mutually clear for competent authorities that the requirements of the EU legislation have been met in every Member State. The differences in terminology used might create some confusion, in particular as some of these terms (e.g., accreditation) are also used to describe reviews by private, non-governmental entities.

Overall, the survey shows that it is important that all Member States continue improving their practices on authorisation, accreditation, licensing and designation according to the EU legislation.

### *2.2.3. Inspections and control measures*

Under Article 7(1) of Directive 2004/23/EC, Member States must ensure that the competent authority or authorities organise inspections and that the tissue establishments carry out appropriate control measures.

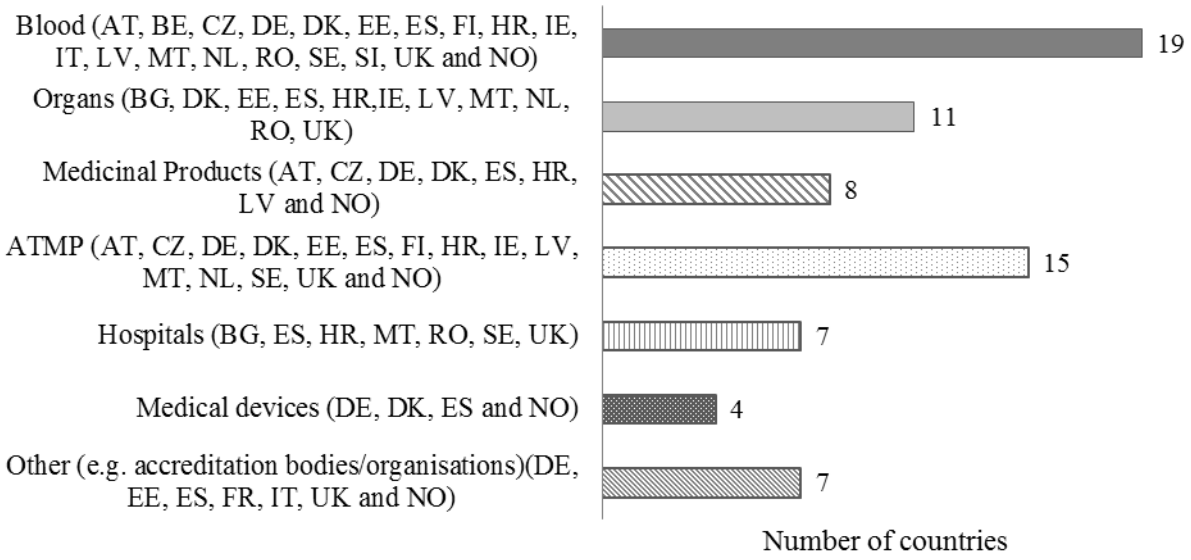
As reported in the first implementation survey, most of the countries have comprehensive inspection systems place. Twenty-four Member States (AT, BE, BG, CY, DE, DK, EE, ES, FI, FR, HR, HU, IE, IT, LU, LV, MT, NL, PL, PT, RO, SE, SI, UK) and Liechtenstein and Norway confirmed the existence of such systems (Table III).

| | |
|---|---|
| AT | Austrian Agency for Health and Food Safety (AGES) |
| BE | Directorate General Inspection of FAMHP |
| BG | National Transplant Agency - Department "Registers, information, control and development of transplant" |
| CY | Ministry of Health |
| CZ | Clinical Practice and Surveillance over Biological Material Processing (part of Inspection Division) |
| DE | Regional competent authorities in the German Länder supported by the Paul-Ehrlich-Institute. |
| DK | Danish Medicines and Medicines Authority |
| EE | State Agency of Medicines, Department of Biologicals within the structure of the agency. |
| ES | Regional competent authorities. |
| FI | Fimea's Inspectorate unit within the "Supervision and licenses Department" |
| FR | ANSM (INSBIO Department) - for non-reproductive tissues and cells. Regional agencies - for ART establishments |
| HR | Ministry of Health - Service for Blood, Tissues and Cells Inspection |
| HU | Officers of the National Public Health and Medical Officer Service - Office of the Chief Medical Officer, Department of Health Administration |
| IE | Irish Medicines Board - Compliance department |
| IT | CNT - Tissue and Cell section. For HPC and cord blood banks inspections are carried out in collaboration with CNS. |
| LI | Arzneimittelkontrolle, for coordination and the Swissmedic inspectorate by agreement. |
| LT | Legal and Supervisory Division of the National Transplant Bureau under the Ministry of Health of Lithuania |
| LU | Ministère de la santé - Division de la médecine curative. |
| LV | State Agency of Medicines - Pharmaceutical activities compliance evaluation department |
| MT | Superintendence of Public Health |
| NL | Health Care Inspectorate |
| NO | Norwegian Board of Health Supervision |
| PL | National Centre for Tissue and Cell Banking |
| PT | DGS - Departamento da Qualidade na Saúde, for non-reproductive tissues. Ministry of Health' administrative body for Health Inspections (IGAS) in collaboration with CNPMA, for ART establishments. |
| RO | Ministry of Health - State Sanitary Inspectorate |
| SE | The Health and Social Care Inspectorate |
| SI | Agency for Medicinal Products and Medical Devices |
| SK | In preparation |
| UK | HTA - Regulation directorate for tissue establishments handling non-reproductive tissues and cells and reproductive tissues. HFEA - Directorate of Compliance - for ART establishments |

*Table III. Competent authorities responsible for inspections (2011 data)*

One Member State, Slovakia, is currently developing/revising the inspection system at national level.

Most Member States reported that tissue establishment inspection schemes overlap or interact with inspections performed in other sectors (mostly blood, organs, medicinal products/advanced therapies (Figure 19). Only seven Member States (CY, HU, LT, LU, PL, PT, SK) and Liechtenstein indicated having in place national inspection schemes dedicated only to tissue establishments.




*19. Overlaps of the tissue establishment inspection schemes*

Twenty-five Member States provided data on the staffing of inspection departments within the national competent authorities (Figure 20) and the number of inspections performed in 2011 (Figures 21a and 22a), as well as their outcome (Figures 21b and 22b).

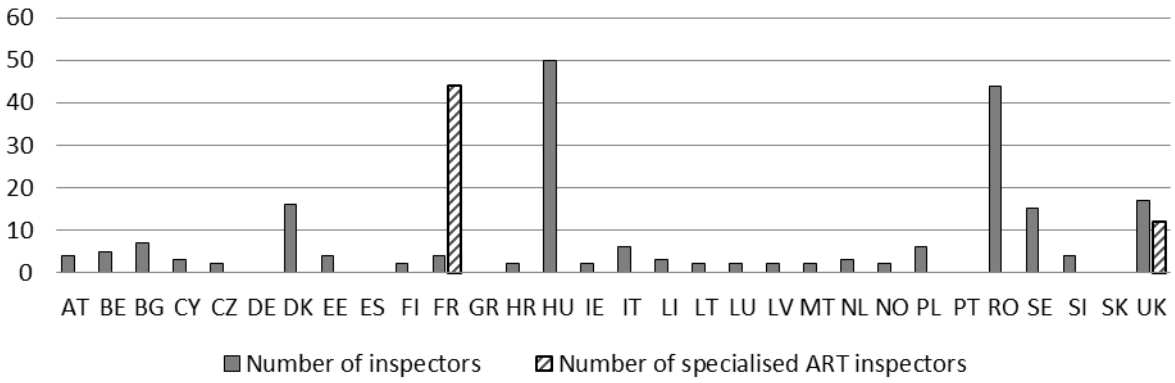



*Fig. 20. Number of inspectors/Member State (numbers provided by FR, HU, RO and SE include also the inspectors in the regional authorities)*

For Spain, where inspection was entrusted to the competent authorities in the autonomous regions, no data on either staffing or the number of inspections performed in 2011 were provided. Germany indicated that inspections are carried out by the regional competent authorities of the German *Länder*, supported by the national competent authority and provided data only on the number of inspections performed in 2011. Additionally, France specified that for the ART sector the regional agencies were given the task of inspecting the ART establishments, but the national authority is responsible for ensuring the appropriate training of the ART inspectors and for publishing an annual report on these inspections. Several Member States pointed out that inspections are carried out by inspectors of the national competent authority together with inspectors from the regional competent authorities (e.g. HU, IT, RO). Sweden reported that inspections are performed by the national competent authority together with inspectors from the regional offices. No information was received from Slovakia. Two Member States, France and the United Kingdom, provided data on the number of specialised inspectors for the ART establishments.

Regarding staffing, 13 Member States (BE, DK, EE, HR, IE, LU, LV, MT, PL, PT, RO, SE, SI) and Liechtenstein specified that inspectors responsible for the inspection of tissue establishments are also in charge of performing inspections in other sectors (e.g. blood, organs, medicinal products, sanitary inspections).

Regarding the number of inspections carried out in 2011, a number of 542 inspections of tissue establishments for non-reproductive tissues and cells was reported, as follows:

- 506 routine inspections;
- Four inspections following the communication of a serious adverse reaction (SAR) or event (SAE), and;
- 32 other inspections (enforcement inspections; inspections for new preparation processes; suspicion of illegal activities; verification of traceability and new activities; verification of corrective actions following a previous inspection; inspections due to a whistle-blower; inspection following moving to new premises).

Regarding the outcome of these inspections, in 48 cases (9%) no shortcomings were noted, minor or major shortcomings were identified in 331 (61%) cases and 150 cases (28%) respectively, whereas in five cases inspections were followed by either suspension (four cases) or revocation of authorisation and closure of the tissue establishment (one case) (Figure 21b).

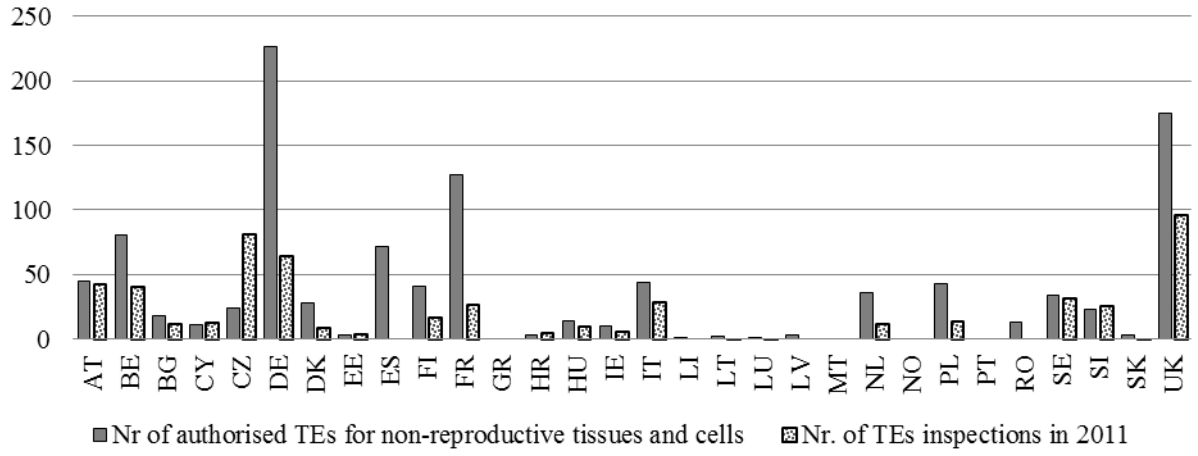



*Fig. 21a. Number of authorised tissue establishments for non-reproductive tissues and cells and the number of inspections carried out in 2011*

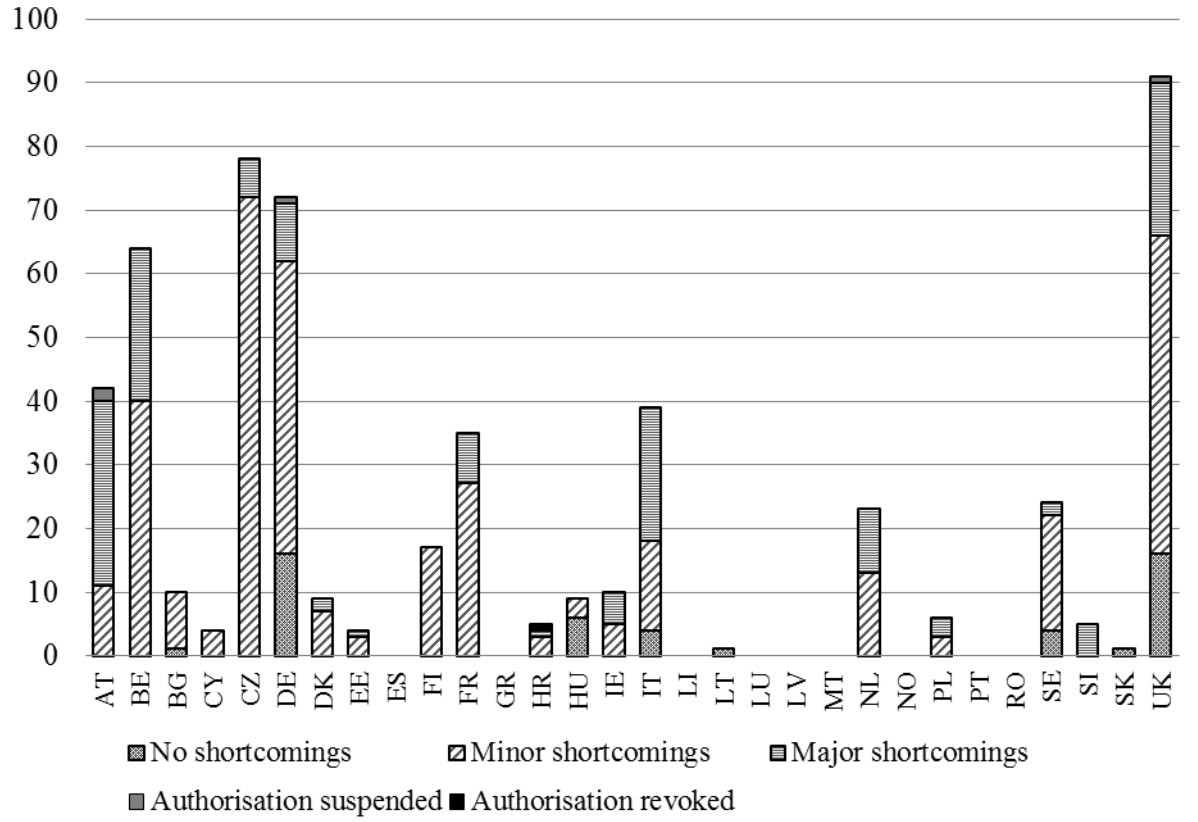



*Fig. 21b. Outcome of the 2011 inspections of authorised tissue establishments for non-reproductive tissues and cells*

For the ART sector, 338 inspections were carried out in 2011 in 23 Member States as well as in Liechtenstein and Norway (Figure 22a). These included:

- 305 routine inspections;

- 8 inspections following the communication of a serious adverse reaction (SAR) or event (SAE) and;

- 25 other inspections (e.g. following major organisational changes).

The outcome of these inspections was as follows: in 63 cases no shortcomings were noted, minor or major shortcomings were identified in 243 cases and 131 cases respectively, whereas in six cases inspections were followed by either suspension (three cases) or revocation of authorisation and closure of the tissue establishments (three cases) (Figure 22b).

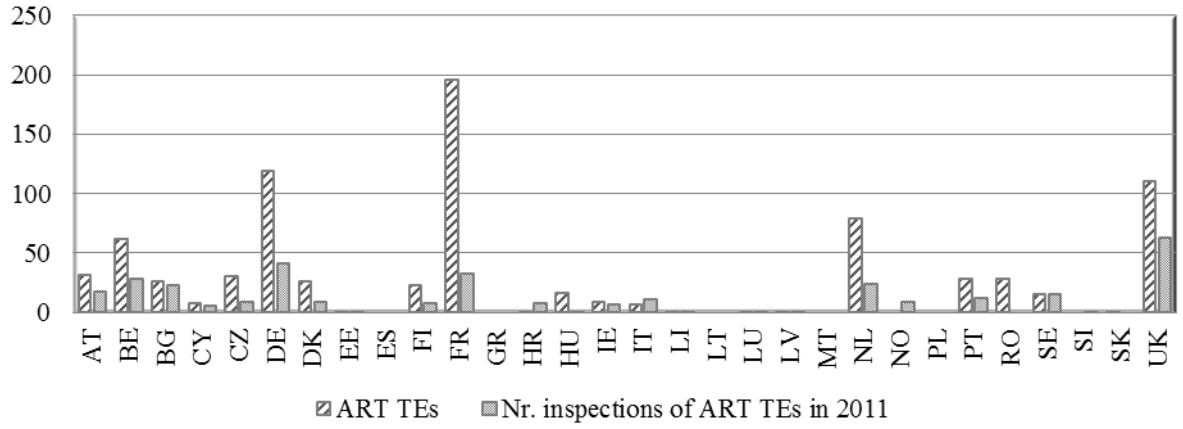



*Fig. 22a. Number of authorised ART establishments and the number of inspections carried out in 2011*

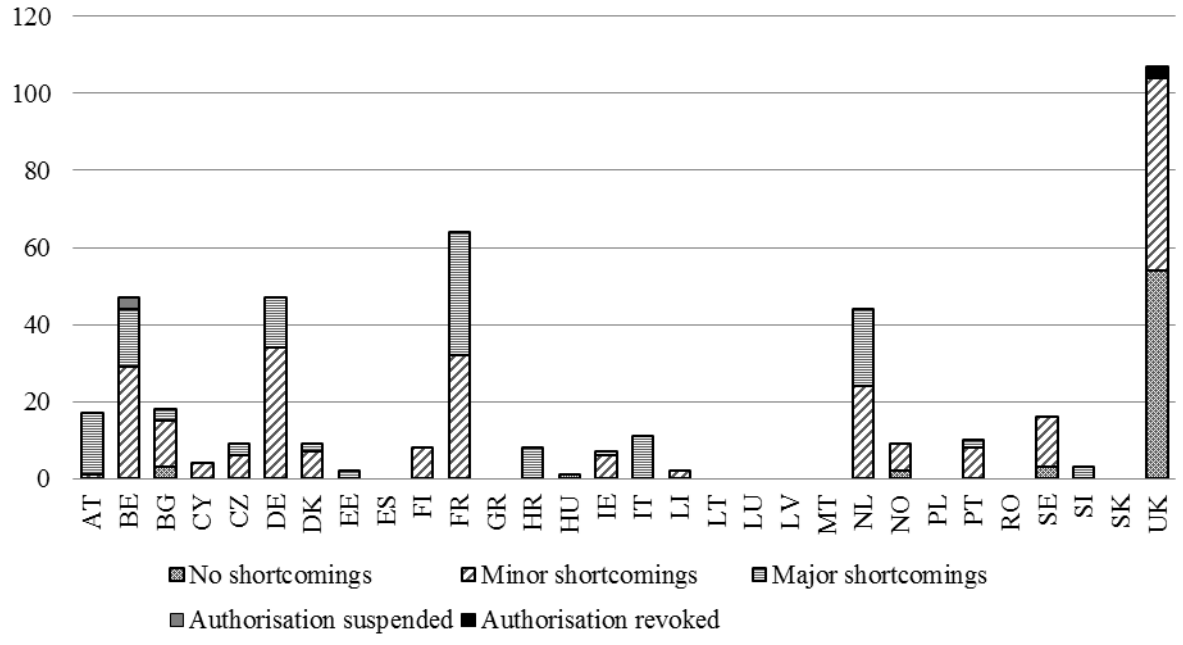



*Fig. 22b. Outcome of the 2011 inspections of authorised ART establishments*

Besides the abovementioned inspections, in 2011 inspections of procurement organisations outside the tissue establishments took place in 13 Member States (AT, BE, BG, CZ, DE, DK, FI, LU, MT, PL, PT, RO, SI) and Liechtenstein.

Additionally, inspections of third parties were performed by 12 Member States (BE, BG, CZ, DE, FR, HR, IT, MT, NL, PL, RO, SI). Most of the Member States indicated a variety of reasons for which third party inspections were not performed (e.g. no legal obligation, lack of inspection capacity, few or no third party agreements, third parties are limited to testing laboratories which are licensed and inspected by other authorities, tissue establishments have to audit the third parties and the audit report is reviewed during routine inspections).

Concerning the implementation of Article 7(2), 23 Member States confirmed respecting the required time interval between two inspections (two years). Moreover, Hungary informed that tissue establishments are inspected every year. Sweden indicated that all tissue establishments were authorised in 2010, and inspected for the first time in 2010 and 2011; thereafter the time interval between inspections has not exceeded two years. Four Member States (DK, HR, IT (only for the HPC and ART establishments) and NL) reported difficulties to fulfil this requirement mainly due to staffing problems within the national inspectorates.

In response to the requirement of Article 7(5) of Directive 2004/23/EC, in August 2010, the Commission published the Operational manual for competent authorities on inspection of tissue and cell procurement and tissue establishments – Guidelines for inspection (Commission Decision 2010/453/EU[4]). The Manual was translated in all the official languages[5]. Even though the Manual is not legally binding, 22 Member States (AT, BE, BG, CY, CZ, DK, EE, ES, FI, HR, HU, IE, IT, LU, LV, MT, NL, PL, PT, RO, SI, SK), and Liechtenstein and Norway reported using this Manual at national level. DE reported that according to the national legislation, the manual is not mandatory, but it is recommended as a guideline. Four Member States (DE, LT, SE, UK) reported that national guidelines were developed and are currently used at national level.

Twenty-five Member States (AT, BE, BG, CY, CZ, DE, DK, EE, ES, FI, FR, HR, HU, IE, IT, LT, LV, MT, NL, PL, PT, RO, SI SK, UK), and Liechtenstein and Norway, sent their inspectors to the training courses organised by the EU-funded projects EUSTITE[6] and SOHO V&S[7] and rated their usefulness and efficacy from good (three countries), to very good (ten countries) and essential (14 countries).

Regarding inspections of procurement sites in third countries from where tissue and cell preparations were imported into the EU, only Germany and France indicated organising such inspections. Germany reported that the inspection in the third country was a requirement pursuant to section 72b of the German Medicinal Products Act, whereas France specified that, in some cases, the national competent authority was asked to verify the accuracy of the data provided by the exporting procurement centre to the French tissue establishments.

As laid down in Article 7(6) and in agreement with the national competent authorities in three Member States (Bulgaria, Czech Republic, and Spain), joint inspections with other Member

4 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:213:0048:0050:EN:PDF

5 http://ec.europa.eu/health/blood_tissues_organs/docs/manual_en.pdf

6 http://ec.europa.eu/eahc/projects/database.html?prjno=2005204

7 http://ec.europa.eu/eahc/projects/database.html?prjno=20091110

States' competent authorities were organised. Bulgaria reported that a joint inspection was performed with the French competent authorities. Spain reported that the inspectors of the HTA inspected the Transplant Service Foundation (Spain) in relation to distribution of skin to the United Kingdom. Additionally, the United Kingdom reported a case where a Regulation Manager observed an inspection in Germany in 2012 following allegations made against a German tissue establishment about procurement without consent.

In line with the provisions in Article 7(7) of Directive 2004/23/EC, four Member States (CZ, FR, NL, UK) requested or organised inspections of a tissue establishment located in another EU country, in collaboration with the competent authority(ies) from that Member State. The Czech Republic indicated that the purpose of the inspection was to exchange information and regulatory approaches, whereas for France's and Netherlands' competent authorities the objective was to substantiate the data provided by the tissue supplier in that Member State.

Most of the Member States and Norway indicated an interest in developing joint inspections. Lack of resources and personnel are seen as the main obstacles for the five countries (CY, DK, FI, LU and LI) who declared having no interest in organising such inspections.

*Comments*

The analysis of the replies concerning inspections of tissue establishments indicates a good implementation of the Directives' requirements. If in most cases minor or major shortcomings were recorded, only a few suspensions and revocations of authorisations were reported, showing that tissue establishments are striving to comply with the EU quality and safety requirements. Besides suggesting a high degree of compliance, which would be welcomed, the small number of suspensions/revocations may also indicate under-enforcement (e.g. in countries which have never reported any shortcomings). No data on the number of tissue establishments that voluntarily ceased operations or were forced to cease operations for other reasons (e.g. economic) were provided.

Concerning the time interval between inspections, several Member States underlined the difficulty of performing inspections every two years. It was also suggested that instead of a fixed time interval, a risk-based approach may be equally valuable. The development of a risk assessment tool to prioritise inspections based on factors like the size of establishment, range of activity, experience of designated individuals responsible for oversight of the licence and compliance history was reported by some Member States.

The heterogeneous practices reported (desk-based vs. on-site inspections, routine vs. non-routine inspections), the discrepancies in the number of inspectors and their training/expertise, or the impossibility to provide the number of staff in charge of inspections in the regional competent authorities may explain why an agreement on the mutual acceptance of inspections was not yet reached. Even though most of the Member States reported using the non-binding "Operational manual for competent authorities on inspection of tissue and cell procurement and tissue establishments" published by the Commission in 2010, it was suggested that the current practices in the Member States should be further analysed and addressed, so that shortcomings identified during inspections in different Member States (e.g. classification of minor, major and critical deficiencies) result in similar consequences for the inspected establishment (e.g. indications for a revocation or suspension for similar deficiencies).

Concerning joint inspections, their outcome was in general satisfying and in particular allowed bringing expertise where this might be missing within their own Member State.

### *2.2.4 Traceability*

Member States must ensure that all tissue and cells procured, processed, stored or distributed on their territory can be traced from the donor to the recipient and vice versa. Additionally, Member States are required to implement a donor identification system which assigns a unique code to each donation and to each of the products associated with it (Article 8 of Directive 2004/23/EC and Article 9 and 10 of Directive 2006/86/EC).

Twenty-three Member States (BE, BG, CY, CZ, DE, DK, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SI, SK, UK) reported that a donor identification system was implemented in their countries. In most Member States, the unique code for each donation is assigned by the tissue establishment (BE, BG, CY, CZ, DK, EE, FI, FR, HR, HU, IE, LT, LU, LV, PL, PT), while in others by the procurement centre (DE, MT, SI, UK).

Other approaches were also notified:

- Portugal reported that the donation identification system in the ART sector underwent changes since the last reporting exercise. Since the 1st of January 2013, the unique code for each donation has been allocated centrally by the ART competent authority (Conselho Nacional de Procriação Medicamente Assistida);
- Slovenia and Portugal (for the ART sector) specified that a national database was put in place, providing for an automatic allocation of donation numbers;
- Norway indicated that the donor identification is based on the national unique personal number identification system.

Two Member States, Austria and Spain, as well as Liechtenstein, indicated having difficulties in implementing the provisions related to the donor identification system. Romania notified that the unique national donor identification system is under construction. Austria reported that the Federal Ministry of Health deferred the implementation of ISBT128 due to difficulties encountered during implementation, whereas in Spain and Liechtenstein, the requirements of Article 8 have been partially implemented (Art. 8.1), awaiting final guidance from the Commission regarding the implementation of the Single European Code.

Article 8 also requires tissue establishments to keep the data ensuring full traceability for a minimum of 30 years. This requirement is fulfilled by all the Member States which reported to the Commission. In 25 Member States (AT, BE, BG, CY, CZ, DE, DK, EE, ES, FI, FR, HR, HU, IE, IT, LT, LU, MT, NL, PL, PT, RO, SE, SK, UK-HTA) and Norway it is mandatory to retain both paper and electronic records. For the ART sector, the UK (HFEA) indicated that records can be electronic or paper records. In Latvia, Slovenia and Liechtenstein this requirement is fulfilled only by keeping paper records.

Member States have different approaches for ensuring the implementation of the provisions in Article 9 of Directive 86/2006/EC (e.g. data storage for 30 years). Most of the Member States (AT, BE, BG, CY, DE, DK, EE, FI, FR, IE, IT, LU, LV, MT, NL, PL, PT, SE, UK) and Liechtenstein and Norway reported verifying this requirement during routine inspections. In the United Kingdom, this requirement is also checked at the initial licence application stage. Austria, Croatia and the Czech Republic ask the tissue establishments to include appropriate procedures in their SOP. Spain specified that this requirement was not implemented in the ART sector.

*Comments*

The survey showed that a donor identification system was implemented by most Member States, with the unique code for each donation being assigned predominantly by the tissue establishments. It has to be underlined that countries which reported difficulties in implementing the donation identification system were either developing a central allocation system or were waiting for the adoption of the implementing legislation introducing a Single European Code for tissues and cells. Moreover, most of the Member States reported that detailed coding requirements and a harmonised implementation of the Single European Code for tissues and cells is desirable and actively supported the development by the Commission of the new coding requirements, adopted in 2015[8]. Regarding data storage, almost all Member States and EEA countries comply with the 30 years rule, by requesting both paper and electronic records and by verifying this requirement during routine inspections.

### *2.2.5 Import/export of human tissues and cells*

Under Article 9(1) of Directive 2004/23/EC, Member States must take all necessary measures to ensure that all imports of tissues and cells from third countries are undertaken by tissue establishments accredited, designated, authorised, licensed for the purpose of those activities and that imported tissues and cells can be traced from the donor to the recipient and vice versa. In 2008, only 11 Member States reported having clearly identified tissue establishments authorised to import tissues and cells.

The current survey revealed that 16 Member States (AT, BE, BG, CY, CZ, DE, DK, EE, FI, FR, HR, PT, RO, SE, SI, UK), as well as Norway, have a register of tissue establishments that are explicitly authorised to perform import/export of tissues and cells from third countries and provided data on their number. According to the data provided by these countries for 2011, 297 tissue establishments were authorised to import and 306 were authorised to export tissues and cells from/to third countries. Compared to the previous report (2008 data) when 16 Members States reported importing tissues and/or cells, the current survey shows that more countries (22) were importing tissues and/or cells in 2011 (Figure 23).

[8] Commission Directive (EU) 2015/565 of 8 April 2015 amending Directive 2006/86/EC as regards certain technical requirements for the coding of human tissues and cells, OJ L 93, 9.4.2015, p. 43–55

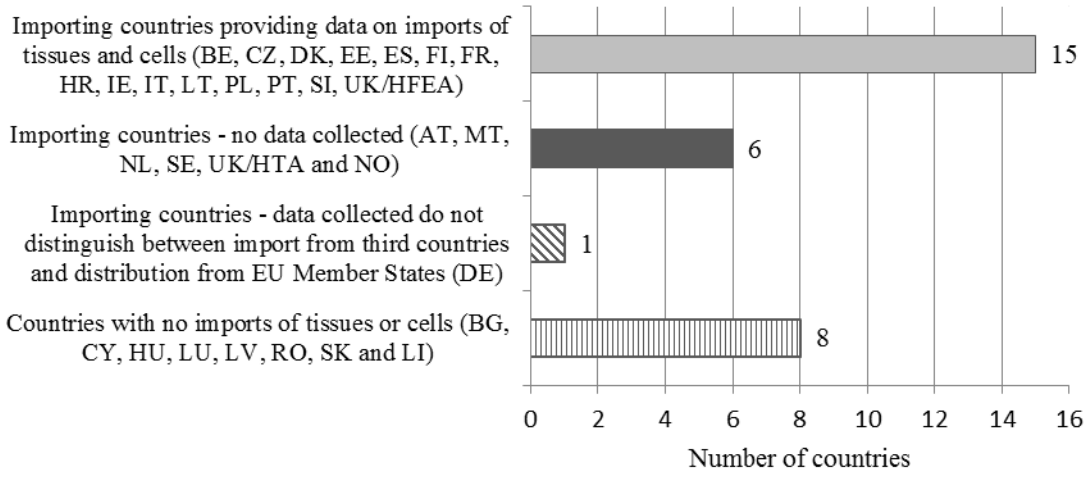



*Fig. 23. Countries importing human tissues and cells for human application (2011 data)*

Twenty-two countries indicated that imports from third countries were carried out in 2011, but only 15 provided data on the type and volume of the imported tissues and cells (Figures 24 and 25). Only nine Member States also collect data on the source of imports (BE, CZ, EE, ES, FI, HR, IT, SI, UK/HFEA). According to the reported data, most of the imports were from USA, Australia, Canada, Israel, and Switzerland. Other countries mentioned were China/Hong Kong, Taiwan, Russia, Uruguay and Bosnia Herzegovina. Six Member States acknowledged importing tissues and cells, but could not provide data on the amount and type of tissues or cells imported, and one Member State (Germany) is collecting data without distinguishing between tissues and cells imported from third countries and those distributed from other EU Member States. Seven Member States (BG, CY, HU, LU, LV, RO, SK) and Liechtenstein reported that no imports of tissues and cells were carried out in 2011.

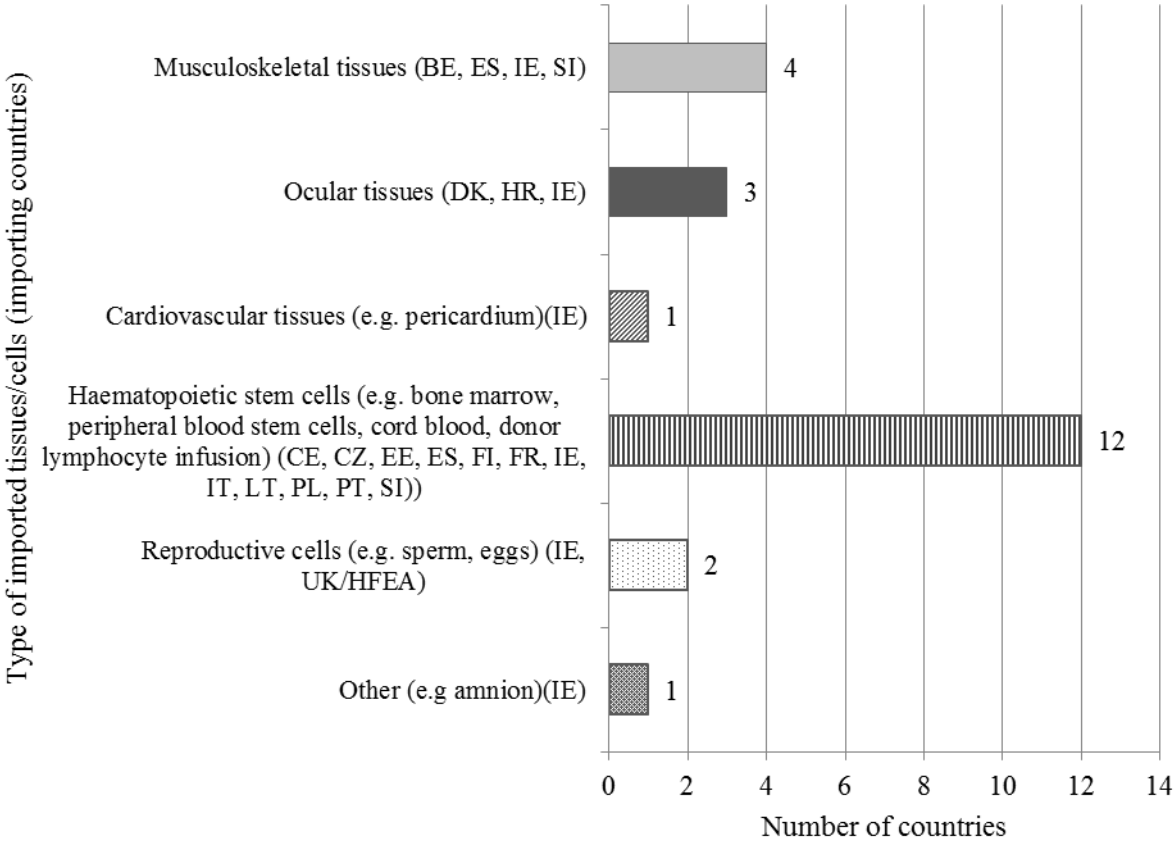



*Fig. 24. Type of tissues and cells imported (data reported for 2011 by 15 countries)*

Additionally, Germany reported that according to section 8d of the German Transplantation Act (TPG), all tissues entering Germany (both from third countries and EU Member States) must be notified to the Paul Ehrlich Institute, irrespective of their source (e.g. an EU Member State or a third country). In 2011, 45,073 units of tissues and cells entered Germany: 550 ocular tissue (cornea), 2,550 cardiovascular tissues (heart valves, vessels, and pericardium), 41, 648 musculoskeletal tissues (bone, cartilage, soft tissues), 325 reproductive cells (sperm), as well as 3,436,004 $cm^2$ of skin.

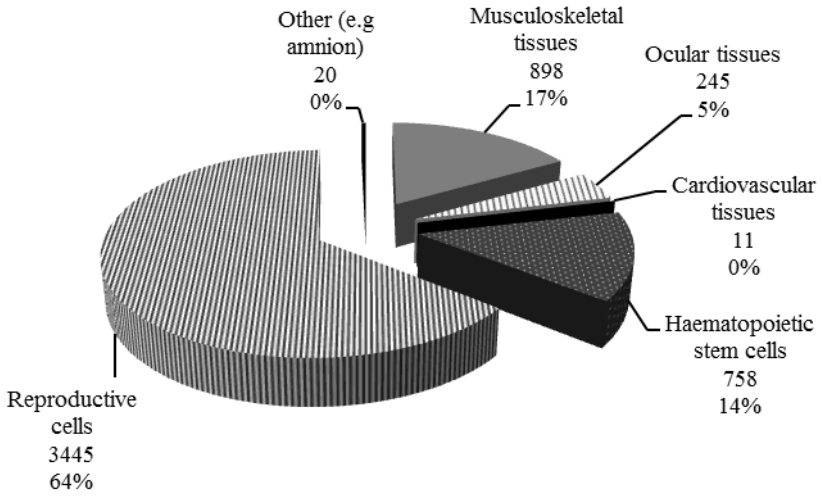



*Fig. 25. Volume of tissues and cells imported (units of tissues or cells; 2011 data)*

Due to the heterogeneous approach in recording data for the import of human tissues and cells it is still difficult to quantify the amount of imports into the Union.

Under Article 9(2), Member States must also take all necessary measures to ensure that all **exports of tissues and cells to third countries** are undertaken by tissue establishments accredited, designated, authorised or licensed for that purpose. Eighteen Member States (AT, BE, DE, DK, EE, ES, FI, FR, HR, IE, IT, MT, NL, PL, PT, SE, SI, UK) and Norway have a register of tissue establishments authorised to export tissues and cells to third countries.

Fourteen Member States (AT, BG, CZ, EE, FI, HR, HU, LT, LU, LV, MT, RO, SI, SK) and Liechtenstein and Norway reported that no exports of tissues and cells occurred in 2011 (Figure 26).

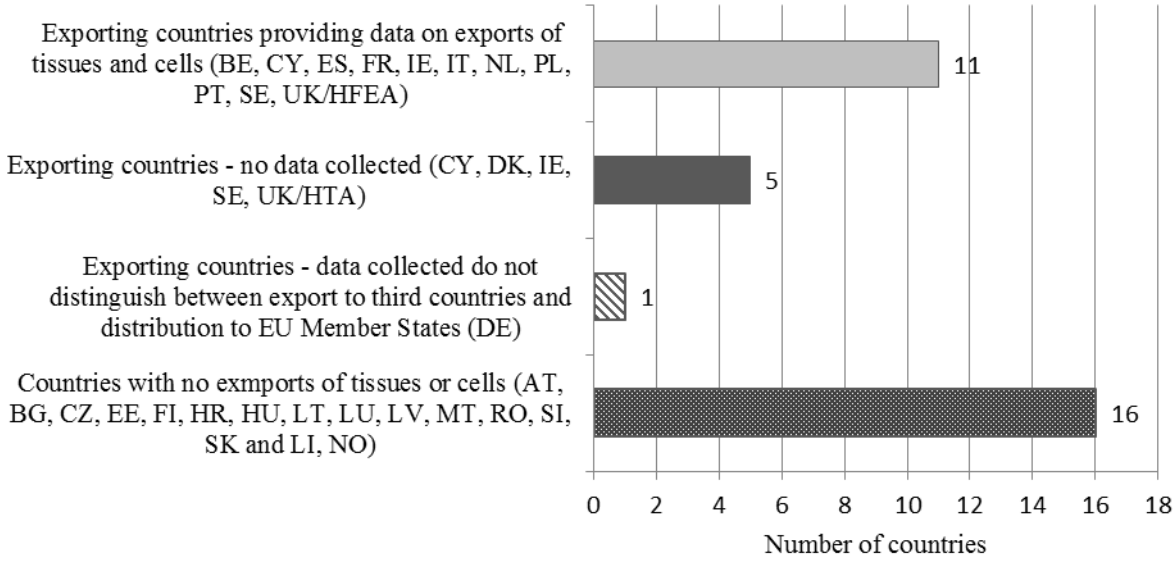



*Fig. 26. Tissue and cell exporting countries (2011 data)*

Overall 12,152 units of tissues and cells were reported as exported to third countries. Of the 11 countries exporting human tissue and/or cells in 2011, four specified that information on the country of destination is not collected by the national competent authority (CY, IE, SE, UK/HTA). The exporting countries, as well as the type and volume (in units) of tissues and cells exported, are shown in Figures 27 and 28.

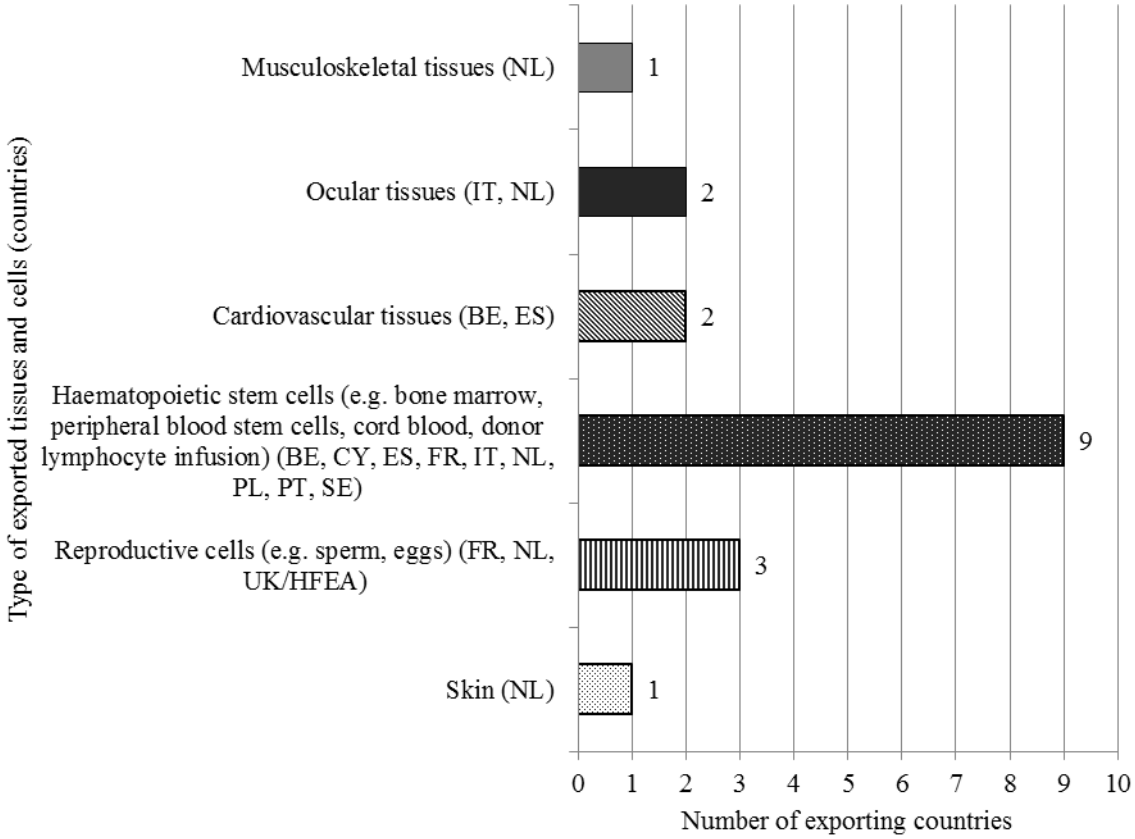



*Fig. 27. Exporting countries - type of tissues and cells (data reported for 2011 by 11 countries)*

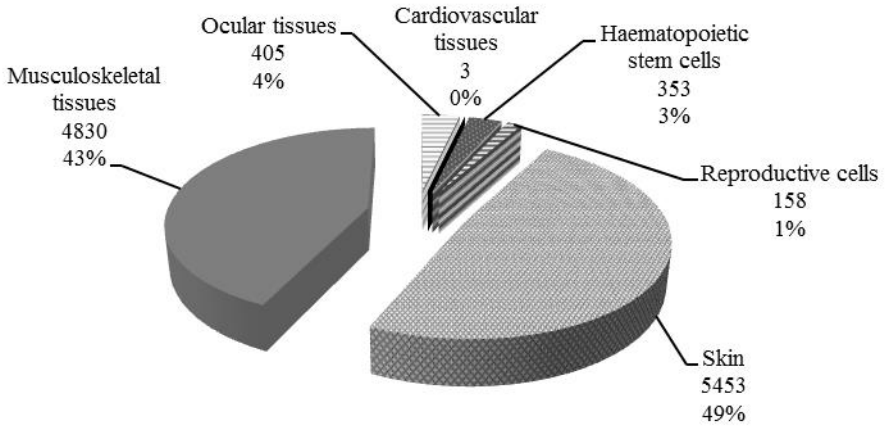



*Fig. 28. Volume of tissues and cells exported (units of tissues or cells; 2011 data)*

Similarly to the data reported for imports, Germany specified that according to section 8d of the German Transplantation Act (TPG) there is no distinction between export to third countries and distribution to EU Member States, therefore all tissues and cells leaving Germany are reported to the Paul Ehrlich Institute on an annual basis. In 2011, 148,285 units were reported as sent to healthcare facilities outside Germany, as following: 188 ocular tissue (cornea, limbal cells), 2,131 cardiovascular tissues (pericardium), 144,373 musculoskeletal tissues (bone, cartilage, soft tissues), 130 other (amniotic membrane), 1,463 reproductive cells (sperm). Additionally, 2,825,092 $cm^2$ of skin was also sent outside Germany.

The competent authority or authorities may also authorise the import or export of tissues and cells in case of an emergency (Art 9.3b). Nine Member States (CY, DE, DK, HR, MT, NL, RO, SI, UK) and Norway, indicated that direct distribution of tissues and cells to a specific recipient was authorised in 2011 for haematopoietic stem cells and ocular tissues.

Concerning the relation with self-sufficiency, the Member States approaches are different for import and export activities:

- For exporting tissues and/or cells:
    - BG, DK, ES, HR, IT, PL, PT, RO, SK reported that export of tissues and cells is authorised only after checking if local and/or national needs are fulfilled;
    - Bulgaria and Latvia indicated that exportation is authorised based on estimations performed on an annual basis;
    - BE, CZ, DK, EE, HU, IT, PL, SE, SI, UK indicated that exportation of tissues and/or cells is authorised irrespective of national needs.
- For importing tissues and/or cells:
    - BG, DK, ES, HR, IE, IT, RO, and Norway reported that imports are authorised only after checking that local/national needs are not fulfilled;
    - BG, IE, PL, PT, SE and Norway specified that imports of tissues/cells are authorised based on estimations showing that there is chronic deficiency of those tissues/cells.

Some Member States (Italy, Poland) acknowledged having a strict approach regarding tissues and cells coming from other EU Member States, which are treated like those imported from third countries. The United Kingdom informed that the Human Tissue Authority (HTA) provides specific online guidance for tissue establishments on import and export.

*Comments*

These data show that it would be useful for competent authorities to collect more comprehensive data on imports and exports of human tissues and cells through the tissue establishments' compulsory annual reports in accordance with Article 10(1), however, at this stage the reporting format is not harmonised.

The data provided, even though incomplete and sometimes ill-defined, confirm that more and more human tissues and cells - such as skin, bones, ocular tissues, heart valves, and haematopoietic stem cells - are imported from third countries or are exported for the benefit of patients outside the European Union. It has to be noted that it is difficult to draw conclusions

regarding the volume of imports and exports of human tissues and cells due the absence of a harmonised framework for data collection in the Member States. It should be underlined that some level of harmonisation exists for such data due to the Eurocet[9] project. However the fact that some countries do not distinguish between distribution within the European Union and import/export from/to third countries may be considered an important hurdle against data collection and analysis. In some countries the differences between the legal framework under which the tissue and cell legislation was transposed (e.g. transplantation vs. medicinal products legislation) may also contribute to the different datasets collected at national level.

Furthermore, mostly due to their more stringent quality and safety requirements, some countries treat tissues and cells distributed by EU Member States and those imported from third countries in the same way. It is expected that the recently adopted legal requirements regarding the procedures for verifying the equivalent standards of quality and safety of imported tissues and cells[10] will streamline the tissue and cells imports, and the collection of related data, guaranteeing the appropriate level of safety and quality across the Union.

### *2.2.6. Register of tissue establishments and reporting obligations*

Under Article 10(1) of Directive 2004/23/EC, tissue establishments must keep a record of their activities and submit an annual report to the competent authority or authorities, which should be publicly available.

Twenty Member States (AT, BE, BG, DE, EE, ES, FI, HR, HU, IE, IT, LT, MT, PL, PT, RO, SE, SI, SK, UK) and Liechtenstein and Norway, have created an annual report model on the activities of tissue establishments that makes the reporting of the yearly activities by tissue establishments easier.

All the reporting Member States receive annual reports from their tissue establishments corresponding to activities in the previous year(s). An overview of the number of tissue establishments providing data to the national competent authorities is presented in Figure 29.

[9] European Registry for Organs, Tissues and Cells, http://www.eurocet.org/

[10] Commission Directive (EU) 2015/566 of 8 April 2015 implementing Directive 2004/23/EC as regards the procedures for verifying the equivalent standards of quality and safety of imported tissues and cells Text with EEA relevance. OJ L 93, 9.4.2015, p. 56–68

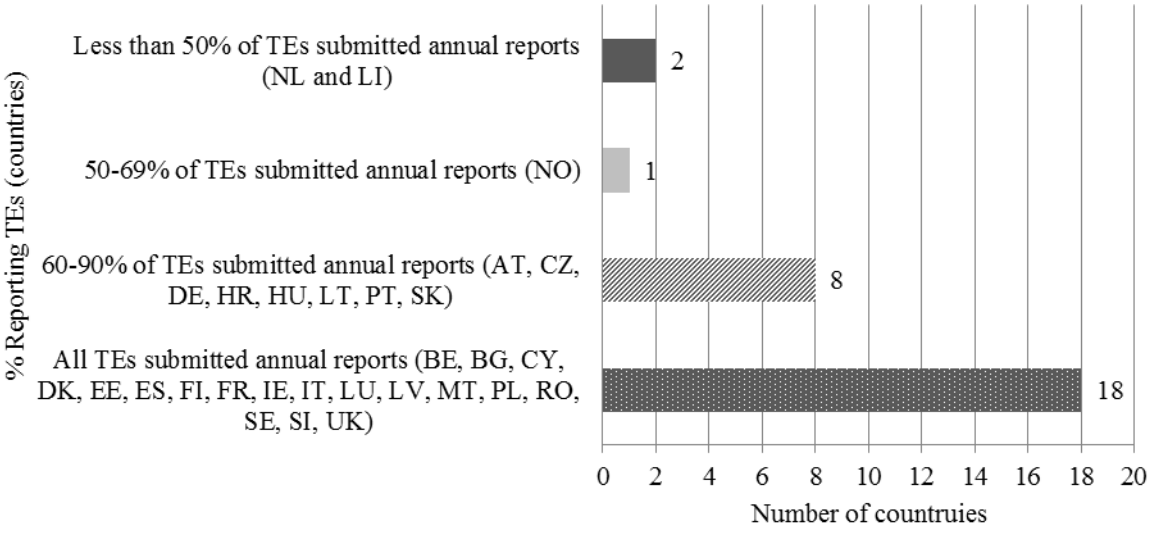



*Fig. 29. Annual reporting by the tissue establishments (2011 data)*

It should be emphasised that the annual reports submitted by the tissue establishments are essential in providing a suitable indication of the activities carried out in the field as well as reference data for assessing the needs and risks in the tissue and cell transplantation field.

Only nine Member States (BE, BG, CZ, ES, IT, MT, PL, RO, SE) and Norway, had made the tissue establishments' reports publicly available in 2012. For the Member States which did not make the tissue establishments' reports available, the main reasons were that at the moment of submitting their replies to the implementation survey, legal provisions in their national legislation were absent (inappropriate transposition of Art. 10(1)) or there was an insufficient capacity at competent authority level.

Under Article 10(2) of Directive 2004/23/EC, the competent authorities are responsible for maintaining a publicly accessible register of tissue establishments specifying the activities for which they have been accredited/designated/authorised/licensed. Twenty-five Member States and Norway indicated that they have a public register available (AT, BE, BG, CY, CZ, DE, DK, EE, ES, FI, FR, HR, HU, IE, IT, LT, LV, MT, NL, PL, PT, RO, SE, SI, UK). In most cases the annual reports and the register are accessible through the competent authorities' web pages (Table IV). Liechtenstein reported that there are no legal requirements in their national legislation concerning the publicly accessible register of tissue establishments. Luxembourg informed that the information is given on demand. In Slovakia, this register is under preparation.

| Country | Link to the national register of tissue establishments |
|---|---|
| AT | http://www.basg.gv.at/arzneimittel/gewebe/register-29-gsg/ |
| BE | www.fagg-afmps.be |
| BG | http://www.bgtransplant.bg/iat/transplantation.php?target_f |
| CY | www.moh.gov.cy |
| CZ | www.sukl.cz/Rewievs and Lists/List of subjects from human tissues, cells and blood branch/List of holders of licence according the law on human TC |
| DE | http://www.pei.de/DE/infos/meldepflichtige/meldung-gewebe-8d-transplantationsgesetz/berichte-pei/berichte-meldung-8d-transplantationsgesetz-tpg-node.html |
| DK | http://laegemiddelstyrelsen.dk/da/service-menu/produktomraader/vaev-og-celler/register-over-godkendte-vaevscentre |
| EE | http://www.ravimiamet.ee/en/list-licensed-handlers-cells-tissues-and-organs-tissue-establishments |
| ES | https://reports.ont.es/Autorizaciones.aspx<br>For ART http://www.cnrha.msssi.gob.es/registros/centros/home.htm |
| FI | http://www.fimea.fi/download/23600_FI_Lista_Suomessa_toimivista_kudoslaitoksista_10-7-2013.pdf |
| FR | http://ansm.sante.fr/var/ansm_site/storage/original/application/b9b896c06d8367834865273951775d4b.pdf ; http : //www.agence.biomedecine.fr/Autorisation-des-centres ; http : //www.agence.biomedecine.fr/Les-etablissements-autorises.73 |
| HR | Non-reproductive tissues and cells:<br>http://www.zdravlje.hr/ministarstvo/zdravstvene_ustanove_u_republici_hrvatskoj/ustanove_s_odobrenjem_za_obavljanje_djelatnosti_uzimanja_pohranjivanja_i_presadivanja_tkiva_i_stanica<br>ART:<br>http://www.zdravlje.hr/ministarstvo/zdravstvene_ustanove_u_republici_hrvatskoj/ustanove_s_odobrenjem_za_obavljanje_djelatnosti_medicinski_pomognute_oplodnje |
| HU | https://www.antsz.hu/bal_menu/igazgatas/sejt_es_szovetbank_nyt.html |
| IE | http://www.imb.ie/EN/Blood-Tissues--Cells/Blood--Tissue-Establishments-.aspx?page=1&name=&orderby=name&orderascending=True&type=3&sitestatus=1&withdrawdate= |
| IT | http://www.trapianti.salute.gov.it/cnt/cntHomeSezione.jsp?id=10&area=cnt-tessuti&menu=menuPrincipale |
| LI | No register |
| LT | www.transplantacija.lt |
| LU | No register. Information available on demand. |
| LV | http://www.zva.gov.lv/doc_upl/audu-sunu-20130726.pdf |
| MT | https://ehealth.gov.mt/HealthPortal/public_health/healthcare_serv_standards/tissues_cells_organs.aspx |
| NL | http://www.farmatec.nl/doc/pdf/Internetoverzicht%20Wvkl-erkenningen%20en%20-vergunningen%20afgegeven%20vanaf%201%20juni%202007_18122.pdf |
| NO | http://www.helsedirektoratet.no/kvalitet-planlegging/bio-genteknologi/celler-og-vev/Sider/default.aspx |
| PL | http://www.kcbtik.pl/?Banki_Tkanek |
| PT | http://www.dgs.pt/ms/8/default.aspx?pl=&id=5521&acess=0 (DGS); CNPMA: http://www.cnpma.org.pt/centros_lista.aspx |
| RO | www.transplant.ro |
| SE | http://www.ivo.se/Tillstand-och-register/register/vavnadsinrattningar/Sidor/default.aspx |
| SI | http://www.slovenija-transplant.si/index.php?id=presajanje-tkiv |
| SK | No register. Under preparation. |
| UK | http://www.hta.gov.uk/_db/_documents/Licensing_Reports_-_HA_201307021659.pdf<br>http://guide.hfea.gov.uk/guide/AllClinics.aspx?x=A |

*Table IV. Publicly accessible national registers of tissue establishments (2011 data)*

Under Article 10(3) of Directive 2004/23/EC, Member States and the Commission should establish a network linking the national tissue establishment registers. Until now this network was ensured through Eurocet[7], which is a registry of national tissue establishments and activity reports managed by the Italian Competent Authority. Twenty-three Member States acknowledged that they also report data to Eurocet on a voluntary basis (AT, BE, BG, CY, CZ, DE, ES, FI, FR, HR, HU, IT, LT, LU, LV, MT, PL, PT, RO, SE, SI, SK UK). Three Member States (Denmark, Ireland, and Netherlands) and EEA countries do not usually report their data to Eurocet. In this respect, the Danish competent authority specified that data request for clinical information on tissues/cells is not part of their activities. Ireland informed that their competent authority (the Irish Medicines Board at the time) is not legally required to submit data regarding tissues and cells activity to the Eurocet registry and Netherlands declared that no raw data is readily accessible to the competent authority.

*Comments*

Overall, the Member States and the EEA countries comply with the requirements in Article 10 of Directive 2004/23/EC. National registers of tissues establishments are made available through the competent authorities' web pages and also via the Eurocet page. However, the tissue establishments' reports are not publicly available in all the reporting countries, mainly due to an insufficient transposition of this provision into the national legislation which resulted in several pre-infringement procedures through the EU Pilot platform. If the issue of making the annual reports provided by the tissue establishments public can be dealt with only at national level, the new legal provisions for the application of the Single European Code shall also satisfy the requirement in Art 10(3), by establishing the EU Tissue Establishment Compendium including all the tissues establishments with their contact details and the status of their accreditation/designation/authorised or licence. By updating the data in this Compendium, the tissues and cells competent authorities demonstrate full transparency and provide support to healthcare professionals searching for a tissue or cell provider within the Union. Moreover, the inclusion in the EU Tissue Establishment Compendium will reinforce the credentials of the EU tissue establishments in front of their partners and customers around the world.

### *2.2.7. Notification of serious adverse events and reactions*

Under Article 11(1) of Directive 2004/23/EC, Member States must ensure that there is a system in place to report, investigate, register and transmit information about serious adverse events[11] and reactions[12] which may influence the quality and safety of tissues and cells and which may be attributed to the procurement, testing, processing, storage and distribution of tissues and cells. Serious adverse reactions observed during or after clinical application which

[11] According to Article 3(m) of Directive 2004/23/EC, 'Serious adverse event' means any untoward occurrence associated with the procurement, testing, processing, storage and distribution of tissues and cells that might lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions for patients or which might result in, or prolong, hospitalisation or morbidity.

[12] According to Article 3(n) of Directive 2004/23/EC, 'Serious adverse reaction' means an unintended response, including a communicable disease, in the donor or in the recipient associated with the procurement or human application of tissues and cells that is fatal, life-threatening, disabling, incapacitating or which results in, or prolongs, hospitalisation or morbidity.

may be linked to the quality and safety of tissues and cells should be also reported. The procedures for notifying serious adverse events and reactions were adopted in Commission Directive 2006/86/EC.

| | |
|---|---|
| AT | Austrian Medicines and Medical Devices Agency (AGES) |
| BE | Federal Agency for Medicines and Health Products (FAMHP) |
| BG | Executive Agency for Transplantation (IAT) |
| CY | Ministry of Health |
| CZ | State Institute for Drug Control (Pharmacovigilance Department) |
| DE | Paul Ehrlich Institute (PEI) |
| DK | Danish Health and Medicines Authority |
| EE | State Agency of Medicines |
| ES | National Transplant Organisation (ONT), the competent authorities of the autonomous regions and the National Group of Biovigilance. |
| FI | Finnish Medicines Agency (Fimea) |
| FR | Agence de la Biomedicine (ABM) |
| HR | Ministry of Health |
| HU | National Public Health and Medical Officer Service - Office of the Chief Medical Officer (NPHMOS-OCMO) |
| IE | Irish Medicines Board (IMB) - Tissue & Cell Vigilance |
| IT | National Transplant Centre (CNT) |
| LI | Amt für Gesundheit |
| LT | National Transplant Bureau under the Ministry of Health |
| LU | Direction de la Santé |
| LV | State Agency of Medicines - Senior expert of Pharmaceutical Activities Compliance Evaluation Department |
| MT | The Directorate for Health Care Standards of the Superintendence of Public Health |
| NL | Health Care Inspectorate (IGZ) |
| NO | Norwegian Directorate of Health |
| PL | National Centre for Tissue and Cell Banking (for tissue establishments), Poltransplant and National Centre for Tissue and Cell Banking (for procurement and transplantation). |
| PT | Instituto Português do Sangue e da Transplantação (for non-reproductive tissues and cells) and Conselho Nacional de Procriação Medicamente Assistida (CNPMA - for the ART sector) |
| RO | Ministry of Health – the State Sanitary Inspectorate |
| SE | Health and Social Care Inspectorate |
| SI | Agency of Medicinal Products and Medical Devices of the Republic of Slovenia |
| UK | HTA (for non-reproductive tissues and cells) and HFEA (for the ART sector) |

*Table V. Organisations responsible for tissue and cell vigilance (2011 data)*

All reporting Member States except for Slovakia have a national vigilance system in place. In most Member States vigilance falls under the responsibility of the main national competent authority, but in several Member States this is either delegated to the regional competent

authorities (DE, ES) or specific bodies (NL - Health Care Inspectorate). An overview of the organisations responsible for tissue and cell vigilance in the reporting EU and EEA countries is included in Table V.

Only in 15 Member States (AT, BE, CZ, DE, DK, ES, FI, FR, HU, IE, LT, MT, NL, PT, SI) and Liechtenstein and Norway, were dedicated vigilance officers appointed. In the other countries, this role is assigned to the tissues and cells inspectors. Additionally in the United Kingdom, for the ART sector the HFEA appointed a dedicated vigilance officer, whereas HTA reported having a dedicated team of Regulation Managers in place who assess SAREs from establishments. A Regulation Officer acts as the administrator and data manager for the team and the reporting system is monitored by the team on a 24-hour basis, and any reports received are responded to within 24 hours.

Regarding the compliance of tissue establishments in reporting SAR and SAE to the national competent authorities, the percentage of the tissue establishments complying with this requirement (expressed as % from the total number of authorised tissue establishments at national level) is shown in Figure 30. The relatively large group of establishments that do not report SARE data is a point that requires further attention.

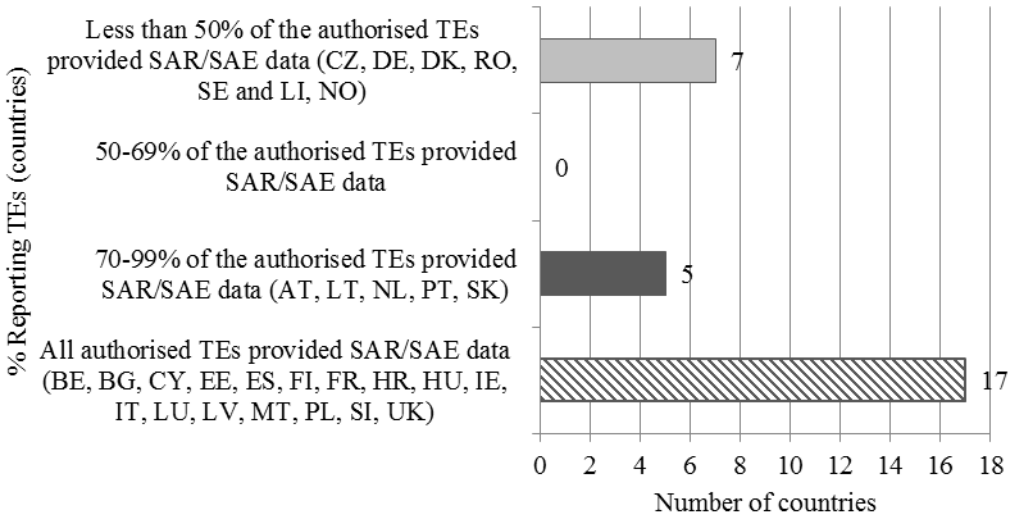



*Fig. 30. SAR/SAE reporting to the national competent authorities (2011 data)*

In addition, Italy informed that tissue establishments are required to report SAR/SAE as they occur and the competent authority compiles the annual report. However the tissue establishments must provide detailed information to transplant centres on how and when to report SAR/SAE and this is reviewed during routine inspection. A similar approach was reported by the United Kingdom competent authorities (HTA and HFEA), where tissue establishments have to report SAR/SAEs within 24 hours of their discovery, and not via an annual report.

Most of the Member States (AT, BE, BG, CY, CZ, DE, DK, ES, FR, HR, HU, IE, LT, LV, MT, PL, PT, RO, SE, SI, UK-ART sector) and Liechtenstein and Norway confirmed having in place a mandatory procedure for SAR/SAE reporting by the transplantation centres to the

distributing tissue establishments, this also being a requirement in their national legislation. Members States not having such a procedure in place have different approaches:

- In Estonia and Slovakia, reporting of SAR/SAE by the transplantation centres is obligatory by law;
- In Finland, Italy and Netherlands, when distributing tissues and/or cells, the tissue establishments are responsible for providing full instructions for reporting to the transplantation centres;
- In the United Kingdom, for non-reproductive tissues and cells and reproductive tissues, the SAREs reporting requirement is outlined in HTA standards. Establishments licensed by the HTA are required to have end-user agreements in place with transplantation centres, which include the requirement to report SAREs, and incident reporting is promoted and also monitored on inspection.

Regarding recalls, all countries require their tissue establishments to have a recall procedure. Only four Member States (DK, EE, FR and UK) reported that recalls were issued by tissue establishments in their country for 2011.

In accordance with Article 7(1) of Directive 2006/86/EC, Member States must submit to the Commission an annual report on the serious adverse reactions and events notified to the competent authority. Most of the Member States acknowledged using at national level the template (based on the Annexes of Directive 2006/86/EC). In seven Member States (BE, DE, FR, NL, PT, SI, UK) and Norway, a template and guidelines developed at national level are used.

Twenty-two Member States (AT, BE, BG, EE, ES, FI, FR, HR, HU, IE, IT, LT, LU, MT, NL, PL, PT, RO, SE, SI, SK, UK) and Norway confirmed giving feedback to the tissue establishments regarding SAR/SAE recorded at national level.

Nineteen Member States (BE, BG, EE, ES, FI, FR, HR, HU, IE, LT, LU, MT, PL, PT, RO, SE, SI, SK, UK) and Norway reported giving feedback to the tissue establishments regarding SAR/SAE recorded at EU level.

As regards communication of rapid alerts, 22 Member States (AT, BE, CY, DE, EE, ES, FI, FR, HR, HU, IE, LT, LU, LV, MT, NL, PL, PT, SE, SI, SK, UK) and Liechtenstein and Norway reported that a system/procedure is in place at national level for notifying tissue establishments and procurement sites in case of a national rapid alert or of a rapid alert issued via the EU RATC platform. Five Member States reported not having such a system/formal procedure:

- Bulgaria informed that the system is under construction and communication is done by email;
- The Czech Republic reported using the already established system for pharmaceuticals or medical devices;
- Denmark reported that the national system is effective in notifying the tissue establishments which thereafter are responsible for contacting the POs;
- Italy declared that no written procedure was formalised and rapid alerts are communicated by email on a case-by-case basis;

- Romania informed that a national procedure was under development, but the Ministry of Health is responsible for communicating the alerts issued via the EU RATC platform to the National Transplant Agency and the sanitary inspectors.

Moreover, 21 Member States (AT, BE, CY, CZ, DE, DK, ES, FI, FR, HR, HU, IE, LT, MT, NL, PL, PT, RO, SE, SI, UK) circulate the alerts received via the tissues and cells national vigilance system, when relevant, to other national vigilance/alert systems (haemovigilance, pharmacovigilance, medical devices).

Concerning training courses for the personnel in charge of vigilance at national/local level, 22 Member States (AT, BG, CY, DE, DK, EE, ES, FI, FR, HR, HU, IE, IT, LT, LV, MT, NL, PL, PT, RO, SI, UK) and Norway welcomed the organisation of specific courses at EU level. The training course organised by the SoHO V&S project was ranked as good (one Member State), very good (11 Member States) and excellent (ten Member States). Only five Member States (BE, CZ, LU, SE, SK) and Liechtenstein did not send their staff to these courses, mostly because of lack of time or turnover of personnel.

*Comments*

The importance of SARE reporting is confirmed by the interest of the Member States in collaborating with the Commission to improve the current reporting system (e.g. refine the SARE reporting templates for improving collection of data in the ART sector) and to expand communication with other countries and other sectors (e.g. foster cooperation with relevant third countries with regard to SAR/SAE reporting, establishment of an interface for SARE reporting to other product areas, such as medical devices used throughout the donation-clinical application chain. Nevertheless, the aim of the annual reporting to the Commission is to identify the most frequent causes of SAR/SAE allowing for the development of appropriate corrective measures, which will ultimately make the medical application of human tissues and cells safer. In this context, because many errors are not always reported voluntarily or are discovered at a later stage and not reported in a timely manner, the corrective measures may not be made in a timely manner. Additionally, the "root causes" of these SARE/SAE should be correctly identified, analysed and reported with enough level of detail in order to allow for a complete description of the practices/factors which may lead to systematic errors. Moreover, underreporting and accurate data collection remain two objectives which need to be addressed at all levels, from clinical practitioners and tissue establishment staff to competent authorities.

Something that has to be emphasised is the support of the Member States' authorities in the development of the Rapid Alerts for Tissues and Cells (RATC) launched by the Commission in February 2013[13], which allows national health authorities to exchange, in a timely manner, urgent information in case of alerts (including SAR/SAE) relating to human tissues or cells transferred between Member States. The first annual summary report of the RATC platform[14] published in August 2014 showed an increase in the number of the alerts initiated by the national vigilance contact points, the platform providing wider possibilities of communication and information dissemination with the choice of contacting single or groups of national competent authorities.

[13] http://ec.europa.eu/dgs/health_consumer/dyna/enews/enews.cfm?al_id=1340
[14] http://ec.europa.eu/health/blood_tissues_organs/docs/ratc_report_2013_en.pdf

## 2.3 Donor selection and evaluation

Directives 2004/23/EC and 2006/17/EC contain a number of requirements regarding donor selection and evaluation. They relate to (1) principles governing tissue and cell donation, (2) consent, data protection and confidentiality the authorisation of tissue establishments, (3) donor selection and evaluation and procurement of tissues/cells, (4) testing of tissue and cell donors.

### *2.3.1. Principles governing tissue and cell donation (Art. 12)*

Under Article 12(1) of Directive 2004/23/EC, Member States must endeavour to ensure voluntary unpaid donations of tissues and cells. Donors may receive compensation strictly limited to making good the related inconveniences. In such cases, Member States must define the conditions under which compensation may be granted. Member States must regularly submit reports on these measures to the Commission. On the basis of these reports the Commission will inform the European Parliament and the Council of any necessary measures it intends to take.

The results of the 2014 survey performed by the Commission on the implementation of the principle of VUD for tissues and cells in the Union are included in the Commission Staff Working Document on the implementation of the principle of voluntary and unpaid donation for human tissues and cells, accompanying the Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on the implementation of Directives 2004/23/EC, 2006/17/EC and 2006/86/EC setting standards of quality and safety for human tissues and cells.

In a nutshell, the latest survey shows that, overall, Member States comply with Article 12, with most responding countries reporting that the principle of VUD is mandatory at national level. However, its concrete application varies across the Union, with considerable heterogeneity as regards practices vis-à-vis tissue and cell donors.

### *2.3.2. Consent, data protection and confidentiality*

Under Article 13(1) of Directive 2004/23/EC, the procurement of human tissues and cells shall be authorised only after all mandatory national consent or authorisation requirements have been met.

Regarding the consent system for living donation of tissues and cells, with the exception of Liechtenstein, all the other reporting countries have an opt-in system (explicit consent) (Figure 31).

Concerning the consent system for deceased donation of tissues and cells, an overview of the replies is shown in Figure 32.

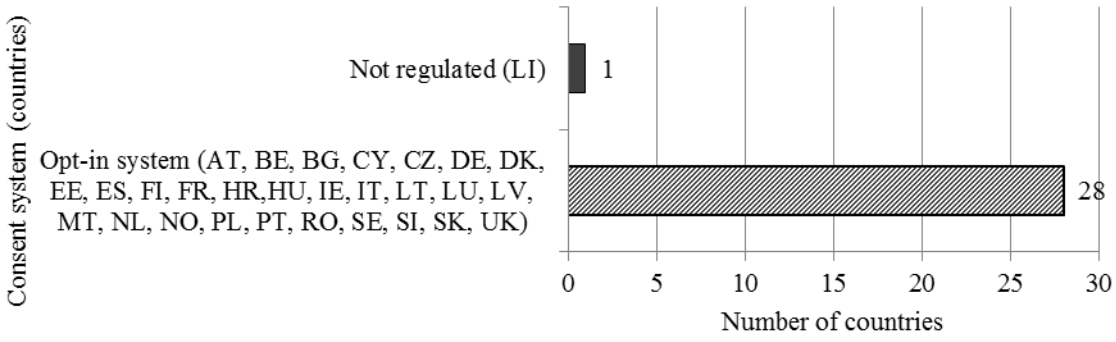



*Fig. 31. The consent systems for living donation of tissues and cells*

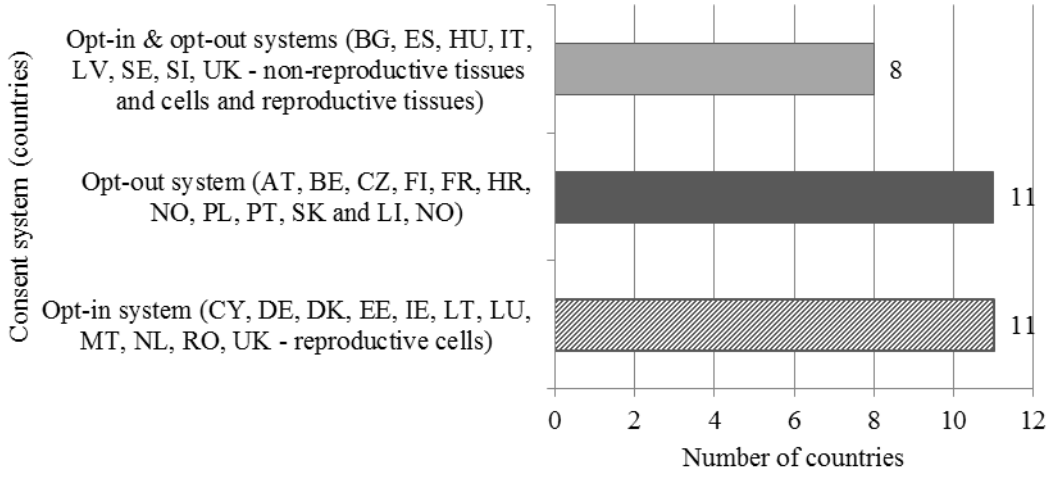



*Fig. 32. The consent systems for deceased donation of tissues and cells*

Whereas, the consent system for living and deceased donation is different in 17 countries (AT, BE, BG, CZ, FI, FR, HR, HU, IT, LV, PL, PT, SE, SI, SK, UK and Norway), only three Member States (Denmark, Luxembourg and Spain) have different consent systems for deceased tissue and organ donation.

Irrespective of the consent system, in case of deceased donations, there are various options for who is allowed to authorise tissue donation (Figure 33).

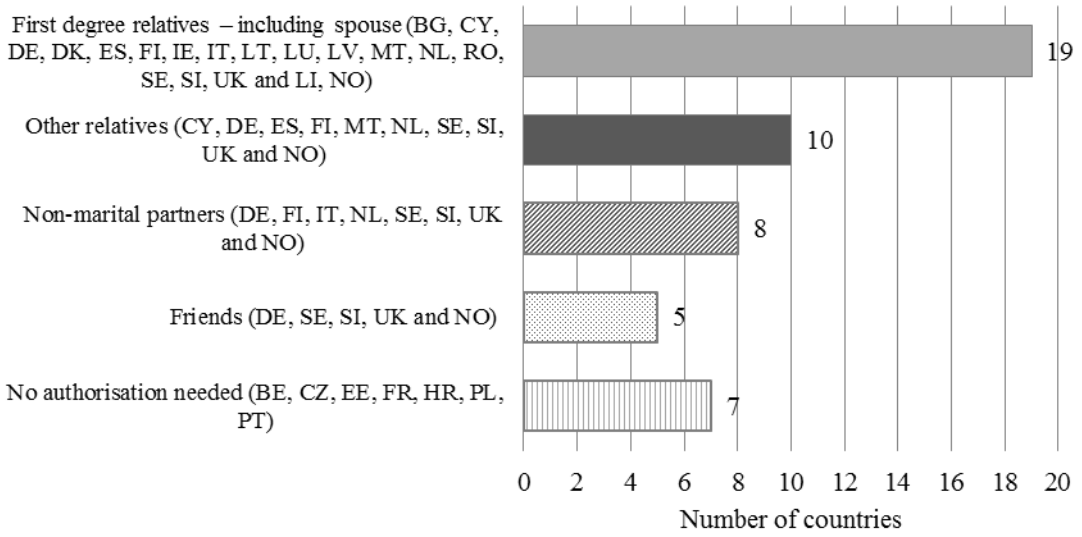



*Fig. 33. Persons allowed authorising deceased donation of tissues and cells*

Several Member States provided additional clarifications. In Netherlands, in case of a donor child aged 12 or below the consent is given by the legal guardian. The United Kingdom specified that in England, Wales and Northern Ireland a person in life or a person's "nominated representative" can give consent, but there is no mention of "nominated representatives" under the Human Tissue Act in Scotland.

In all reporting Member States and EEA countries, the consent is verified during inspections by various means, from analysis of documentation and interviews with personnel to interviews with living donors or relatives of deceased donors (Figure 34).

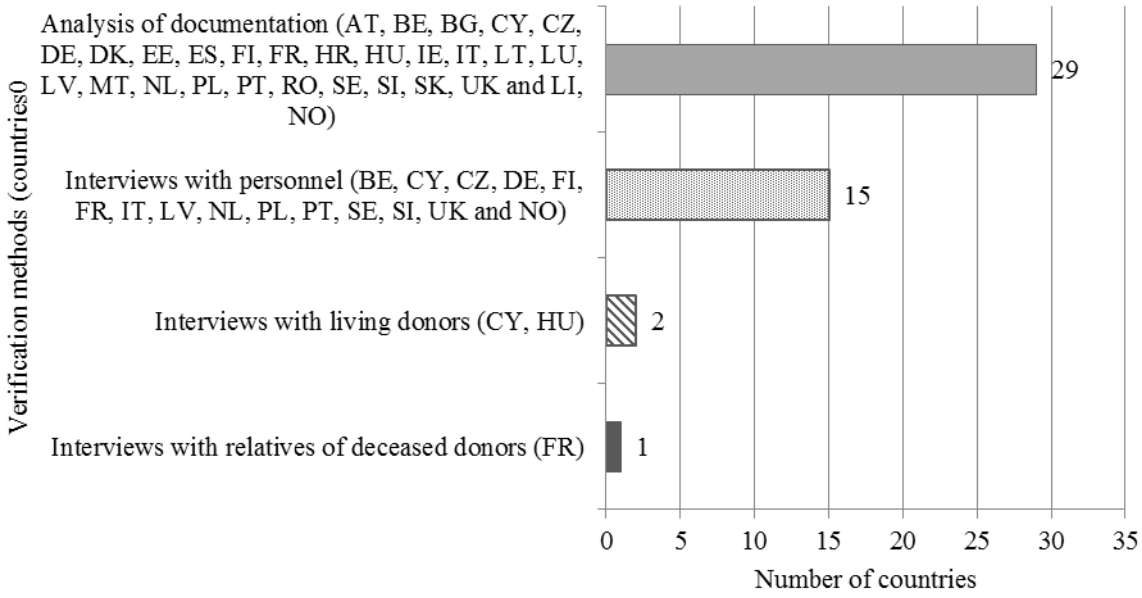



*Fig. 34. Verification of donors consent during inspections (2011 data)*

Article 13(2) of Directive 2004/23/EC requests the Member States take all the necessary measures to ensure that donors and their relatives, as well as any persons granting authorisation on behalf of the donors are provided with the appropriate information. All reporting countries, except Ireland and Slovakia, stated that only trained personnel are allowed to provide such information. In Ireland, the requirement of Art 13(2), the information provided to donors and their families is also verified during inspections together with the donor files. Additionally, in some Member States (BG, DE, ES, LT, PL, SE, SK, UK), the information for donors is standardised at national or regional level. Germany specified that general information for donors is available due to national public awareness activities and is also provided by medical associations. For ART donors, in Spain the information is controlled at regional level and in the United Kingdom it is assessed during the initial application for tissue establishment licence.

Concerning national measures taken to ensure that both donors and recipients remain unidentifiable as required by Art.14(1) of Directive 2004/23/EC, several approaches were reported. Many Member States (CZ, DE, EE, ES, FI, FR, HR, HU, IE, LT, LV, RO) and Norway stated that anonymity is ensured by the application of the data protection national legislation. In addition, anonymity is ensured by implementing the unique donor identification number (coding system) for both donor and recipient (AT, BE, BG, CY, IT, LU, MT, PL, SE, SI, UK-HTA and LI). Additional methods were: control measures decided by tissue establishments (Denmark); verification by the competent authority of the access to information and of the procedures put in place by the tissue establishment to ensure the confidentiality (Portugal); providing third parties only with the tissue code (Slovakia).

Member States and EEA countries also reported on the measures taken to ensure that the identity of the recipient is not disclosed to the donor and vice versa required under Article 14(3) of Directive 2004/23/EC. Besides applying the national requirements on data protection (CY, DE, EE, ES, FR, HU, IE, LT, LV, NL, RO, SI), introducing the unique donor identification number (AT, FI, HR, IT, LU, MT, PL, SE, SK and LI, NO) is another method widely used for ensuring data confidentiality. Other approaches were reported: restricted access to the donor data (Bulgaria); requirements included in the tissue establishments' SOP and inspected by the competent authority before granting a licence (Czech Republic); appropriate procedures put in place by both tissue establishments and organisations responsible for human application (Denmark); validation by the competent authority of the procedures; validation by the competent authority of the procedures established at tissue establishment level (Portugal); with the exception of directed donations, information regarding the donor identity is not included in the recipient file and vice-versa (United Kingdom).

With regard to disclosure of donor data in case of gamete donation, the approaches taken by the reporting Member States and EEA countries are summarised in Figure 35. The special circumstances in which some countries (generally prohibiting the disclosure of gamete donor data) would allow disclosure include:

- Children reaching 14 years old (Austria);
- When the egg donor is a relative of the woman who wishes to undergo artificial insemination (Estonia);
- In case of a child born with a congenital disease (Spain);

- Children conceived through IVF procedures (Norway);
- When donors express consent to disclose his/her data and only when the children born following ART procedures with donated gametes turn 18; other cases following a court decision (Portugal);
- At the request of authorities (e.g. police, coroner office)(Romania);
- Only to the child at adult age, but not to his/her parents)(Sweden);
- To the medical staff only for medical reasons (Slovenia).

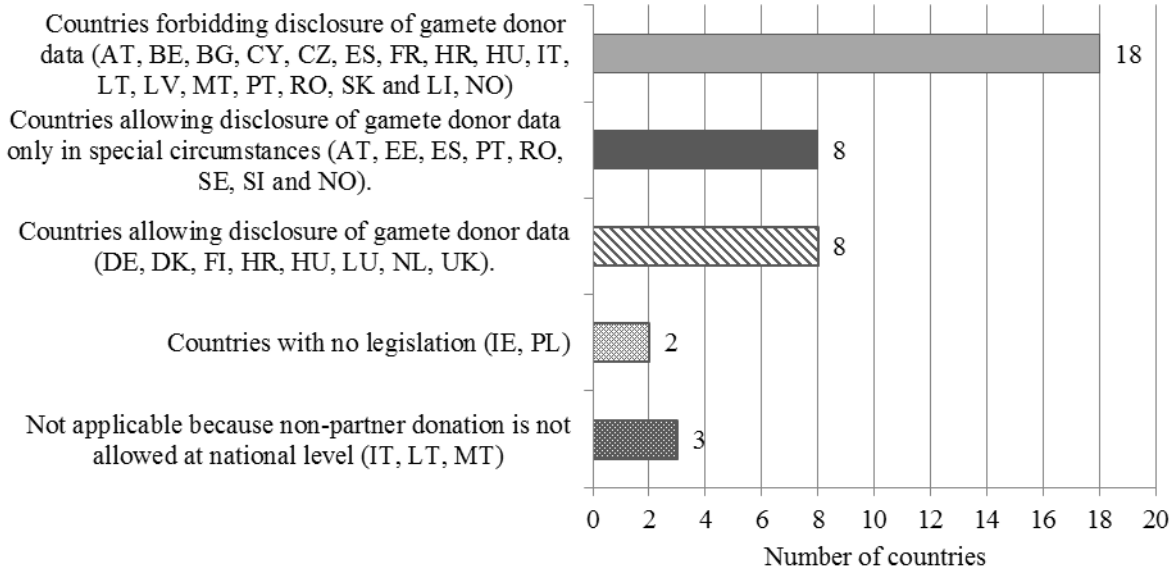



*Fig. 35. Disclosure of gamete donor data (2011 data)*

*Comments*

Overall, the survey showed that regardless of the consent system, all responding countries put measures in place for verifying donors' consent. On the other hand, only in a few Member States is this checked by interviewing the living donors or the relatives of the deceased donors. In addition only trained personnel are allowed to provide appropriate information to donors, but only in a few countries has this information been standardised at national level. Concerning donor anonymity, most countries rely on the EU and national data protection legislation, but also on coding. In this context, the new requirements on the application of the Single European Code for tissues and cells may be considered an additional tool for ensuring that donor data are not disclosed to the recipient.

### *2.3.3. Donor selection and evaluation. Procurement of tissues and cells*

Under Article 15 of Directive 2004/23/EC, donor evaluation and selection by the tissue establishments should be carried out in accordance with the provisions laid down in Annex I (donors of non-reproductive tissues and cells) and III (donors of reproductive tissues and cells) of Directive 2006/17/EC.

Compliance with these requirements is verified by inspections of tissue establishments, procurement sites, and ART establishments by audit documentation, standardised questionnaires at national levels and/or regular evaluation of medical personnel (Figure 36 and 37).

Furthermore, three Member States (Belgium, Germany, Italy) reported having more stringent criteria for donor selection:

- Belgium reported having one additional selection criterion - “persons that have undergone documented or undocumented neurosurgery";
- Germany informed that the exclusion criteria are adapted to the donor of a specific tissue;
- Italy reported that additional tests are required - NAT testing for HIV, HBV and HCV of HSC donors; toxoplasma IgM for amniotic membrane donors is mandatory; CMV IgM for heart valve, vessels and amniotic membrane; CMV for skin; CMV, toxoplasma and EBV testing for HPC unrelated donors; serum archive for all donors.

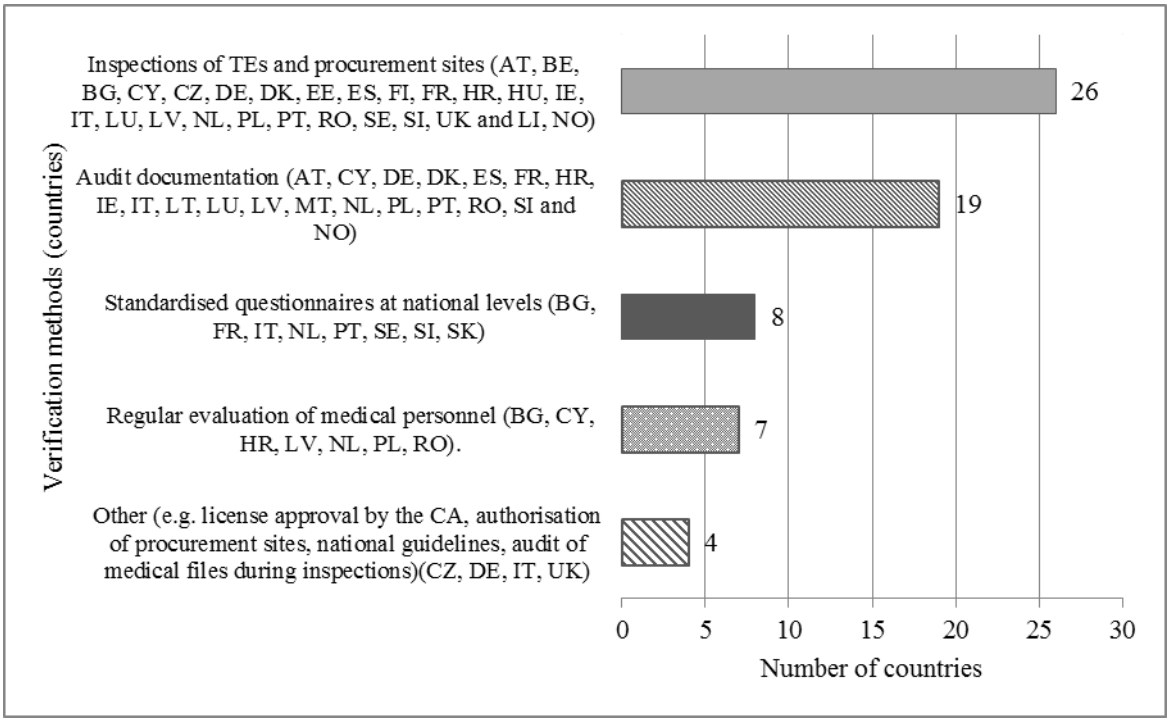



*Fig. 36. Verifying the compliance of tissue establishments and procurement sites with the requirements of Annexes I and III of the Directive 2006/17/EC (2011 data)*

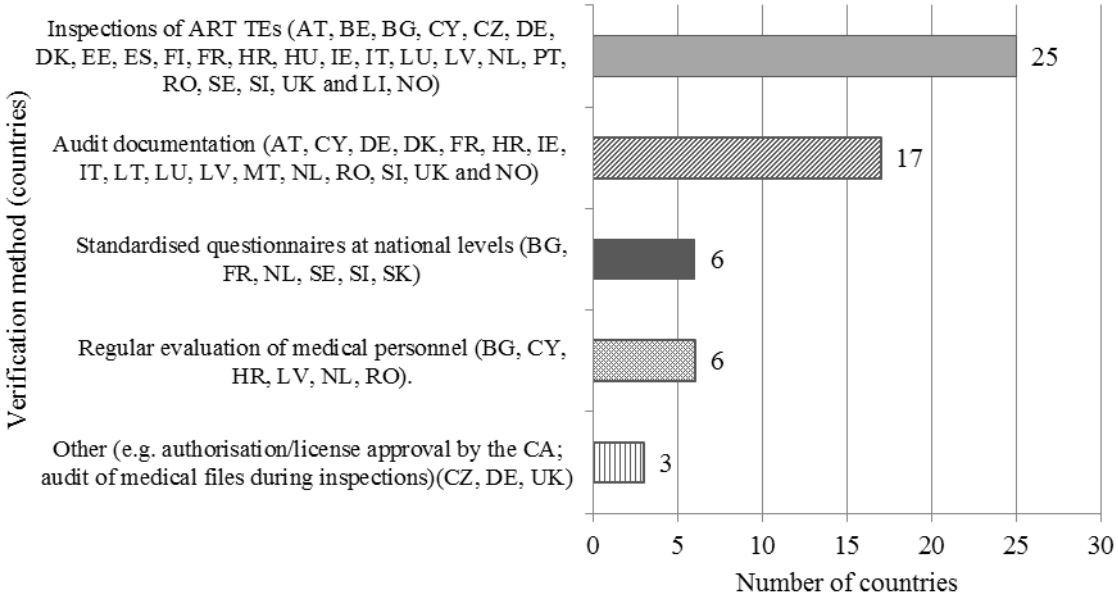



*Fig. 37. Verifying the compliance of ART establishments with the requirements of Annex II of the Directive 2006/17/EC (2011 data)*

A general concern that is expressed regularly by the competent authorities is the absence of regulation focused on the protection of the living donor.

In most Member States, the evaluation of deceased donors of tissues and cells relies on the medical records of the donor, the interview with the donor's family or a person who knew the donor well and the autopsy report. In approximately half of the reporting countries an interview with the treating physician or with the general practitioner is also required (Figure 38). One country (Liechtenstein) reported having only living donors.

Moreover, other practices were also reported:

- Belgium reported that a physical examination of the body is also required;
- In Germany, a post mortem physical examination as well as the results of the laboratory tests required according to Annex II of Directive 2004/23/EC;
- Liechtenstein reported that there are only living donors, for cord blood cells;
- Slovakia informed that other examinations might be done in case they are needed;
- The United Kingdom reported that there are no mandatory sources and tissue establishments may use several sources to evaluate a donor.

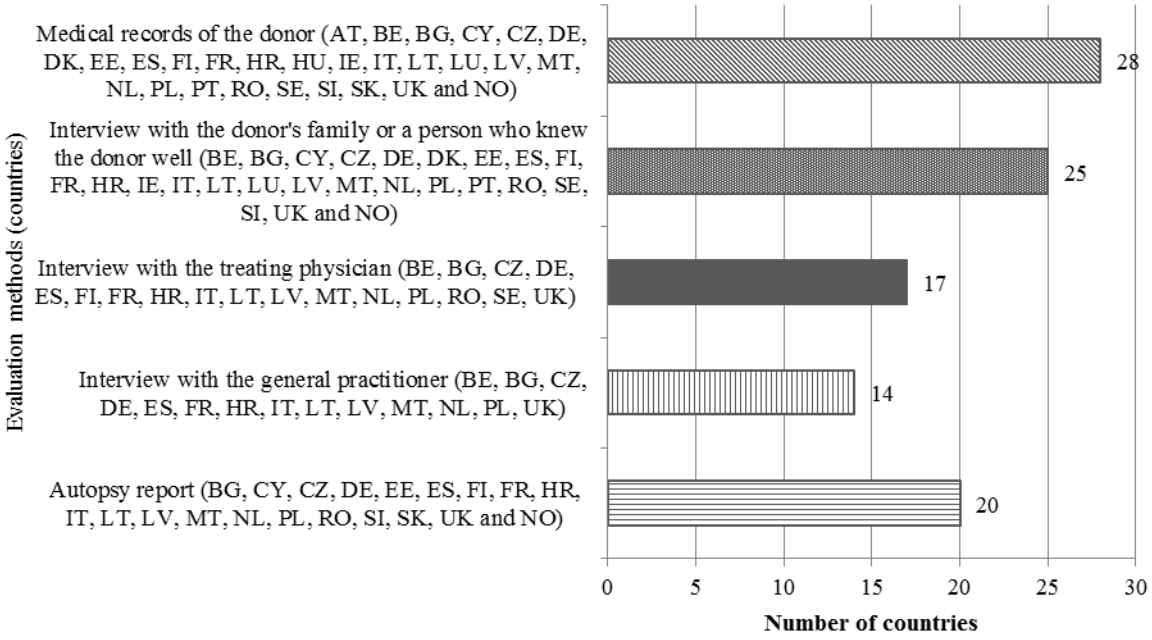



*Fig. 38 Evaluation of deceased donors of human tissues and cells (2011 data)*

Concerning the selection of donors of reproductive cells, four Member States indicated having more stringent criteria than those listed in Annex III to Directive 2006/17/EC:

- Belgium - Testing for Treponema pallidum;
- Czech Republic - HIV p 24 laboratory testing (NAT testing is not acceptable);
- Portugal - age of the donor (maximum age for oocyte donors is 35 and for sperm is 45. For ovocyte donation only three ovocyte pick-ups cycles per donor are allowed. For sperm donation, a donor can be used for the birth of eight living children);
- United Kingdom – age of donors. HFEA also specified that posthumous use of gametes or embryos created using gametes from a donor who has since deceased may only be used if the gamete provider has been screened in accordance with the requirements set out in the EU Directives.

No Member State declared having more stringent criteria for autologous donation than those listed in Annex I to Directive 2006/17/EC. Furthermore, no Member States request more information on the donation of tissues/cells than the mandatory one as laid down in the Annex to Directive 2004/23/EC.

In most of the Member States compliance with the requirements for tissues and cells procurement, packaging and transport is verified by the competent authorities when performing inspections. Auditing of tissue establishments and centres of human application, as well as inspections of the centres of human application have been reported by several countries as additional measures for verifying compliance with the EU procurement, packaging and transport requirements (Figure 39). Other Member States also reported requesting written SOPs and approval licence (Czech Republic), authorisation of procurement

establishments pursuant to sec. 20b of the German Medicinal Products Act (Germany), more requirements for specific tissues and cells (Italy), related information in the Tissue Establishment Dossier that is requested prior to inspections (Malta), correct procedures in place at the initial application assessment stage, and follow up during two-yearly inspections (United Kingdom).

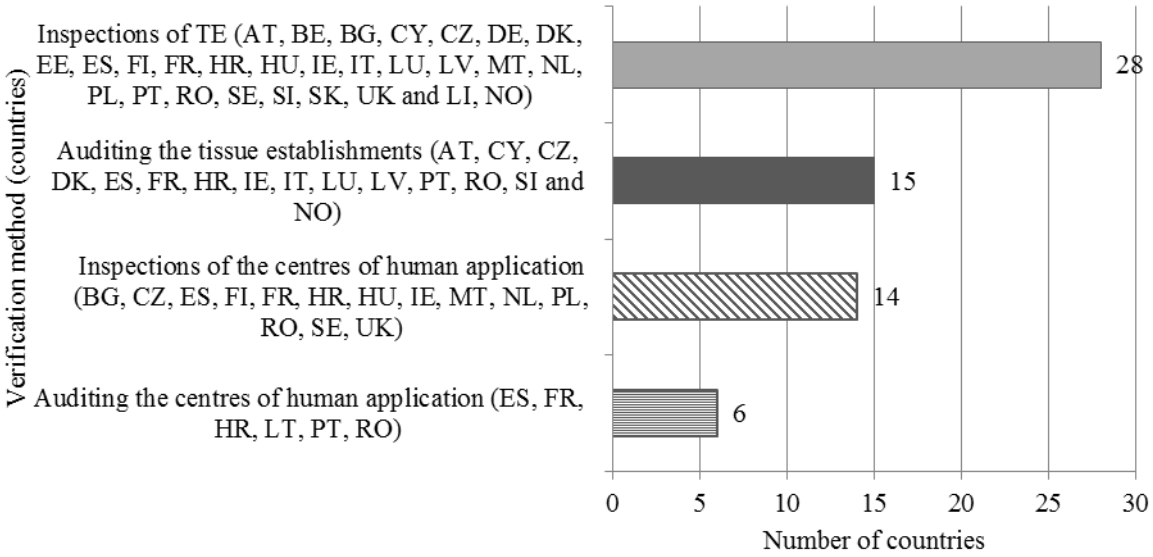



*Fig. 39. Verification of compliance with the EU requirements for procurement, packaging in Directive 2006/17/EC (2011 data)*

*Comments*

In summary, the survey showed that inspections are the most important verification method used by the Member States' competent authorities when verifying the compliance of tissue establishments with the EU donor evaluation and selection requirements. Nevertheless it has to be underlined that a few countries rely only on the medical records of the donor and/or the autopsy report without interviewing the donor's family or his/her treating physician/general practitioner, which may raise concerns. In relation to the selection of gamete donors, only two Member States (Portugal, United Kingdom) reported that the donor's age was included among the selection criteria for oocyte donors. The use of selection criteria should be transparent and subject to continuous evaluation in order to minimise safety risks.

Several Member States have called for an enhanced harmonisation of the criteria for donor selection and evaluation, stressing the importance of using a standardised donor evaluation procedure (e.g. consultation of all relevant sources for the medical and behavioural history of deceased donors).

### *2.3.4 Donor testing*

Under Article 4 of Directive 2006/17/EC, the national competent authorities must ensure that donors of tissues and cells, except donors of reproductive cells, undergo the biological tests set out in point 1 of Annex II. Also, Article 4(2) of Directive 2006/17/EC requires the

competent authorities to ensure that donors of reproductive cells undergo the biological tests set out in points 1, 2 and 3 of Annex III.

An overview of the donor testing in all the reporting countries is shown in Figure 40 (for donors of non-reproductive tissues and cells) and Figure 41 (for donors of reproductive tissues and cells).

| **Tests for donors of NON-reproductive tissues and cells/country** | AT | BE | BG | CY | CZ | DE | DK | EE | ES | FI | FR | HR | HU | IE | IT | LI | LT | LU | LV | MT | NL | NO | PL | PT | RO | SE | SI | SK | UK |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Anti-HIV 1 Ab | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| Anti-HIV 2 Ab | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| HIV Ag | | | | | Y | | | | Y | Y | Y | | | | | | Y | | | | | | | | Y | Y | Y | | |
| NAT HIV 1 | Y | Y | | | | | Y | Y | Y | Y | Y | Y | | | | | | | | | | | | Y | | | | | |
| HBs Ag | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| Anti HBc Ab | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| NAT HBV | Y | Y | | | | | | | Y | Y | Y | Y | | | | | Y | | | | | | | Y | | | | | |
| Anti HCV-Ab | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | y | Y |
| NAT HCV | Y | Y | | | | | Y | Y | Y | Y | Y | Y | | | | | Y | | | | | | | Y | | | | | |
| Treponema Pallidum | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| HTLV-1 | | | | | | | | | Y | | Y | | | | | | Y | | | | | Y | | Y | Y | | | | Y |
| NAT HTLV-1 | | | | | | | | | Y | | Y | | | | | | | | | | | | | | | | | | |

*Fig. 40. Testing of donors non-reproductive tissues and cells (2011 data)*

| **Tests for donors of reproductive tissues and cells/country** | AT | BE | BG | CY | CZ | DE | DK | EE | ES | FI | FR | HR | HU | IE | IT | LI | LT | LU | LV | MT | NL | NO | PL | PT | RO | SE | SI | SK | UK |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Anti-HIV 1 Ab | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| Anti-HIV 2 Ab | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| HIV Ag | | | | | Y | | | | Y | Y | Y | Y | | | | | | | | | | | | | Y | Y | Y | | |
| NAT HIV 1 | Y | Y | | | | | | Y | Y | Y | | | | | | | | | | | | | | | | | | | |
| HBs Ag | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| Anti HBc Ab | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| NAT HBV | Y | Y | | | | | | | Y | Y | | | | | | | | | | | | | | | | | | | |
| Anti HCV Ab | | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | | Y | Y | Y | Y | Y | | Y | Y | Y | Y | Y | Y |
| NAT HCV | Y | Y | | | | | | Y | Y | Y | | | | | | | | | | | | | | | | | | | |
| NAT Chlamydia | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | | | | | | | Y | | Y | Y | | Y | | | | | |
| Treponema Pallidum | Y | Y | Y | y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| HTLV-1 | | | | | | | | | Y | | | | | | | | | Y | | | | Y | | Y | Y | Y | | | Y |
| NAT HTLV1 | | | | | | | | | Y | | | | | | | | | | | | | | | | Y | | | | |

*Fig. 41. Testing of donors of reproductive tissues and cells (2011 data)*

The survey confirms that all reporting countries comply with the mandatory testing requirements laid down in Annex I to Directive 2006/17/EC. The other testing requirements such as testing of HTLV-1 antibody for donors living in or originating in high-prevalence areas or with sexual partners origination from those areas, as well as additional testing depending on the donors' travel and exposure history and the characteristics of the tissue and cell donated (e.g. CMV, EBV, Toxoplasma gondii, malaria, West Nile virus, Dengue fever, Chikungunya, Trypanosoma cruzi) are also performed.

One practical concern for the implementation of such requirements is however the lack of a common view on high-prevalence areas for these diseases. The Commission has therefore asked ECDC to elaborate assessments and maps for use by the Member States' competent authorities and tissue establishments across the Union.

Compared to the 2008 data, many countries introduced more stringent testing requirements of donors of non-reproductive tissues and cells (Fig 38), as following:

- NAT HIV: AT, BE, DK, ES, FI, FR, HR, PT;
- NAT HBV: AT, BE, ES, FI, FR, HR, LT;
- NAT HCV: AT, BE, DK, ES, FI, FR, HR, LT, PT.

Regarding testing donors of reproductive cells, most of the reporting countries comply with the requirements in Annex III to Directive 2006/17/EC, with some exceptions. Two Member States (Lithuania, Poland[15]) did not comply entirely because of inappropriate transposition of the Directives for the ART sector. Additionally, nine Member States (HU, IE, IT, LU, MT, RO, SE, SI, SK) and Liechtenstein do not perform NAT for Chlamydia as requested in Annex III to Directive 2006/17/EC.

Three Member States (Austria, Belgium and Finland) declared that more stringent requirements were introduced for donors of reproductive cells (e.g. mandatory NAT testing for HIV, HBV and HCV).

Concerning NAT testing, several countries specified that this type of testing is mandatory only in specific circumstances:

- Austria: only for deceased donations and living autologous donations;
- Croatia: only for non-reproductive tissues and cells;
- Denmark: for deceased donors;
- Estonia: for donors of reproductive and non-reproductive tissues and cells NAT HIV 1 and NAT HCV tests are required only if Anti-HIV 1 and Anti HCV-Ab are not performed;
- Finland: for donors of non-reproductive tissues and cells;
- France: for non-reproductive tissues and cells, and only NAT HIV for egg donation (immediately before the collection of the eggs as a second determination of the viral status of the donor) ;
- Germany: for deceased donors (exceptions for cornea and skin), in addition to serological testing;
- Lithuania: only for HBV and HCV;
- Portugal: only for non-reproductive tissues and cells.

Countries in which NAT testing is not obligatory by law, have different approaches toward introducing this type of testing:

- Denmark intends to make NAT testing for HIV, HBV and HCV mandatory for egg donors;
- Estonia, Ireland and Romania encourage the use of NAT testing, but the cost-benefit has to be taken into account;
- In Hungary the NAT technique is performed, but it is not compulsory by law;
- In Latvia NAT is performed routinely for HIV, HBV and HCV, but is not mandatory by law;
- In Cyprus the technique is performed for donors of reproductive cells, if cells are issued without retesting of donors after 180 days;
- In Poland NAT testing is used only for verification of questionable serological results;

[15] In 2015 Poland has adopted new legislation for the ART sector and is in process of implementing it.

- Four Member States (IE, MT, NL, SE) and Norway declared having no plans to make NAT testing mandatory (mainly because epidemiological data and the cost-benefit analysis do not motivate such a decision);
- Slovenia reported that no discussion/decision was taken at national level regarding this issue;
- In the United Kingdom the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) has recommended NAT testing, in particular product testing rather than donor serum testing. Mandatory NAT testing is supported by HTA particularly in case of a treatment involving donation from multiple donors and where the donations are not stored and therefore cannot be retested at 180 days.

Seven Member States (AT, DE, FI, HR, IE, IT, SI) and Norway expressed concerns regarding the accuracy of tests for cadaveric donors, mainly because of the limited number of manufacturers and the absence of validated CE-marked kits. Therefore, in some countries (e.g. Germany) the competent authorities recommend validating the assay systems before use on cadaveric samples.

Nine Member States (CY, ES, HR, HU, IE, IT, LV, PT, SE) reported requesting international accreditation for testing laboratories (e.g. ISO, EFI). In Romania the accreditation is not mandatory, but nevertheless it is frequently used.

*Comments*

The data reported show that most of the EU and EEA countries comply with the testing requirements stipulated in Directives 2004/23/EC and 2006/17/EC. Several countries have introduced more stringent testing requirements such as NAT testing for HBV, HCV and HIV for either or both donors of non-reproductive and reproductive tissue and cells, whereas in most Member States and EEA countries the use of this type of testing is not motivated by the cost-benefit analysis and/or the epidemiological context.

Additional tests required by Member States are usually justified for local reasons, like e.g. the increased prevalence of a certain infectious disease. These criteria may however also create barriers for exchanging tissues and cells between Member States. Members States should therefore have at least mutual transparent view on the tests implemented in each of the Member States.

Several of the testing requirements have been subject to discussion in the bi-annual competent authorities meetings and their relevance/value and use/feasibility should be continuously assessed in order to keep the tests aligned with the changes in the underlying risks that they need to help address.

An agreement at EU level on the compulsory use of NAT screening in certain circumstances based on new scientific data on its efficacy and cost-effectiveness may decrease even further the viral transmission risk.

It should also be kept in mind that the application of (some) tests can have a major impact on the local availability of tissues and cells.

It was noted in the discussions of the competent authority meetings that while the theoretical value of testing can be high, the effective value depends largely on the implementation and validation of these tests. Testing can therefore not be considered as the single pillar for safety of tissues and cells but is to be combined with deferral criteria and, where applicable,

inactivation techniques. It is only the combined implementation of all pillars that can minimise safety risks.

## 2.4 Quality and safety of tissues and cells

Directives 2004/23/EC and 2006/86/EC contain a number of provisions concerning quality and safety of tissues and cells intended for human application. They refer to (1) quality management, responsible person and personnel, (2) tissue and cell reception, processing, storage, labelling and packaging, (3) distribution of tissues and cells for human application, (4) relations between tissue establishments and third parties and (5) penalties applicable to in case of infringement of the national tissues and cells legislation.

### *2.4.1 Quality management, responsible person, personnel*

Under Article 16 of Directive 2004/23/EC, Member States must take all the necessary measures to ensure that all tissue establishments put in place and keep up to date a **quality system**, including a minimum of documentation, which must also be available for inspection by the competent authorities.

The compliance of tissue establishments with the requirements of this Article is verified by the national competent authorities when authorising and inspecting the tissue establishments and by performing internal or external audits (Figure 42).

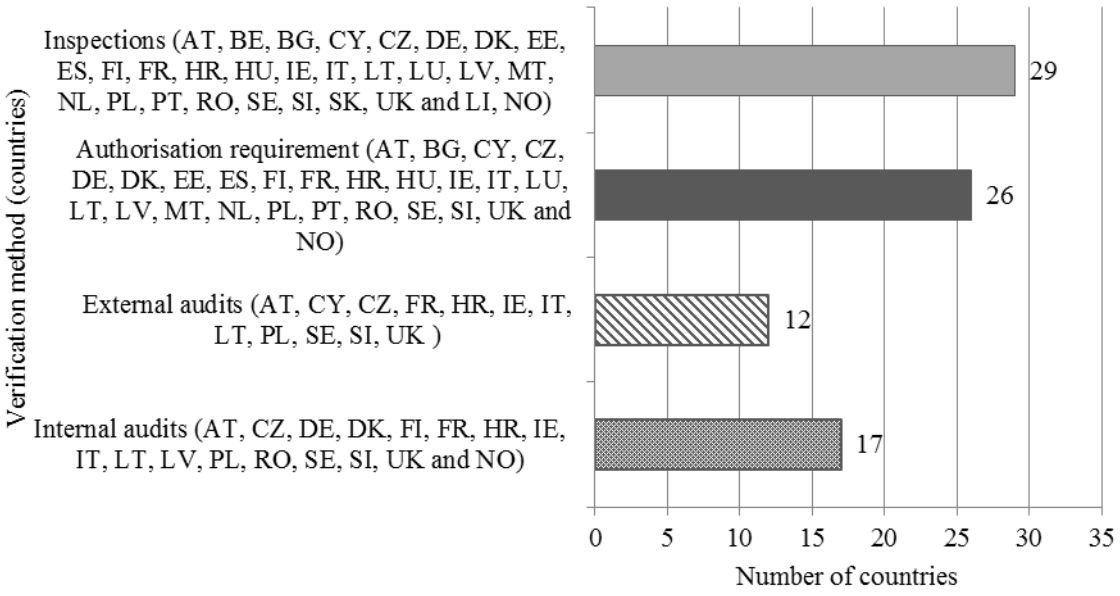



*Fig. 42. Verification of compliance with the requirements of Art 16 (quality management) of Directive 2004/23/EC (2011 data)*

Article 17 of Directive 2004/23/EC requires every tissue establishment to designate a responsible person with appropriate qualifications, who should fulfil the tasks laid down in this Article. The verification methods employed by the competent authorities for ensuring the fulfilment of this legal obligation are presented in Figure 43.

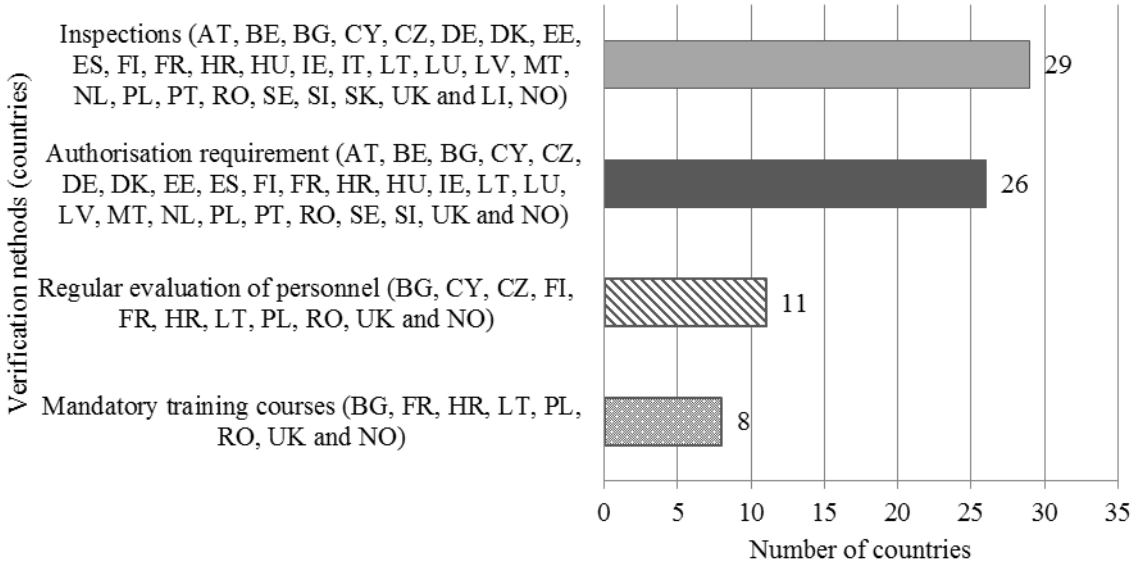



*Fig. 43. Verification of compliance with the requirements of Art 17 (responsible person) of Directive 2004/23/EC (2011 data)*

Besides the abovementioned methods, Sweden reported that in case of a change of the responsible person, an application together with the CV of the new responsible person must be approved by the competent authority.

Likewise, Article 18 of Directive 2004/23/EC entails that tissue establishment personnel directly involved in all the activities, from procurement to distribution of human tissues and cells, should be properly qualified and should be provided with suitable training. A summary of the verification methods used by the competent authorities for ensuring appropriate training of the tissue establishments' personnel is shown in Figure 44.

Some Member States reported additional procedures:

- Italy specified providing a non-mandatory training for the personnel directly involved in the activity of tissue establishments;
- Malta informed that during inspections, the team of inspectors asks for the documentation concerning the training of the personnel directly involved in the activities of tissue establishments;
- Sweden reported that during the inspections interviews with the personnel directly involved in the activities of tissue establishments are conducted and that the possibility of participation to additional/advanced training courses is discussed.

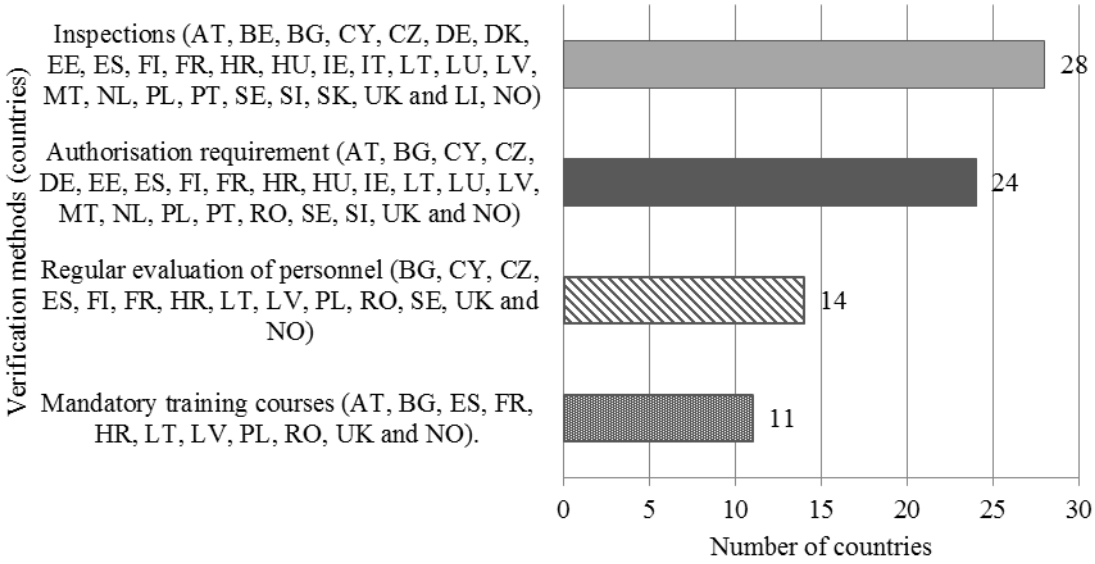



*Fig. 44. Verification of compliance with the requirements of Art 18 (personnel) of Directive 2004/23/EC (2011 data)*

Twenty Member States (BE, BG, CY, DE, DK, EE, ES, FR, HR, HU, IE, IT, LV, MT, PL, PT, SE, SI, SK, UK) and Norway reported that they have national/regional/local training programmes for the personnel of tissue establishments. Other Member States reported that their personnel is trained in other EU countries (AT, CZ, FI, LT, LV, NL, RO and Liechtenstein) or in non-EU countries (Czech Republic, Netherlands, Romania). In addition, Poland mentioned that each tissue establishment designates a quality manager.

*Comments*

As all steps from tissue and cell donation until their distribution for medical application relies on staff professionalism, all personnel should be appropriately qualified and should benefit from appropriate training. The present survey confirmed that Member States are trying to ensure an appropriate level of training for the tissue establishments' personnel, and the compliance with the EU training requirements is systematically checked during inspections and also before granting an authorisation/accreditation/licence to the tissue establishments. It has to be underscored that additional support on training of tissue establishments' personnel was given through EU-funded projects such as European Quality System for Tissue Banking (EQSTB)[16] and European Good Tissue Practices (EuroGTPs)[17]. The good practices on quality management, responsible persons and personnel developed by the EU-funded initiatives were also included by the Council of Europe in a dedicated Guide to the quality and safety of tissues and cells.

[16] http://ec.europa.eu/chafea/projects/database.html?prjno=2003209
[17] http://eurogtps.com/HOME/tabid/38/Default.aspx

### *2.4.2. Tissue and cell reception, processing, storage, labelling and packaging*

The measures taken by the Member States and EEA countries for ensuring that tissue establishments fulfil the requirements in Article 19 (Tissue and cell reception) of Directive 2004/23/EC and in Annex IV to Directive 2006/17/EC, are presented in Figure 45.

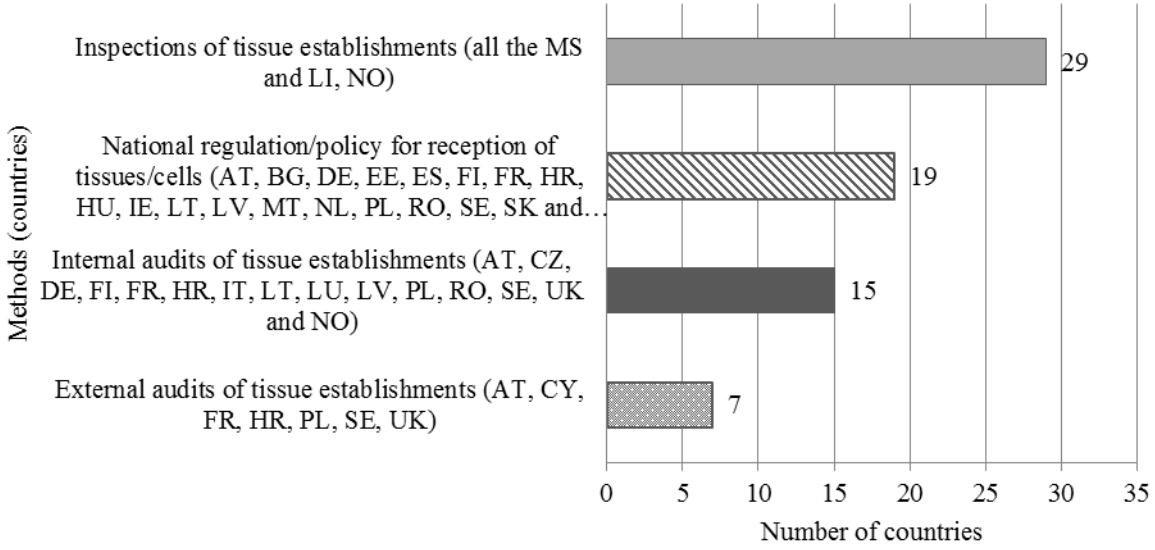



*Fig. 45. Verification of compliance with the requirements of Art 19 (tissue and cell reception) of Directive 2004/23/EC (2011 data)*

Article 20 of Directive 2004/23/EC obliges tissue establishments to include in their standard operating procedures all processes that affect quality and safety thus ensuring that they are carried out under controlled conditions. Detailed requirements concerning tissue and cell processing are laid down in Annex II to Directive 2006/86/EC. An overview of the verification methods used by the competent authorities for ensuring that these requirements are met is shown in Figure 46.

Article 21 of Directive 2004/23/EC, as well as Annex II to Directive 2006/86/EC lay down the obligations of tissue establishments related to the tissues and cell storage conditions. An outline of the control measures used by the competent authorities for ensuring that these requirements are fulfilled is presented in Figure 47.

Article 22 of Directive 2004/23/EC together with Annex II to Directive 2006/86/EC stipulate the tissue establishments' obligations related to labelling, documentation and packaging of human tissues and cells. A synopsis of the control measures applied by the competent authorities for ensuring that these requirements are fulfilled is presented in Figure 48.

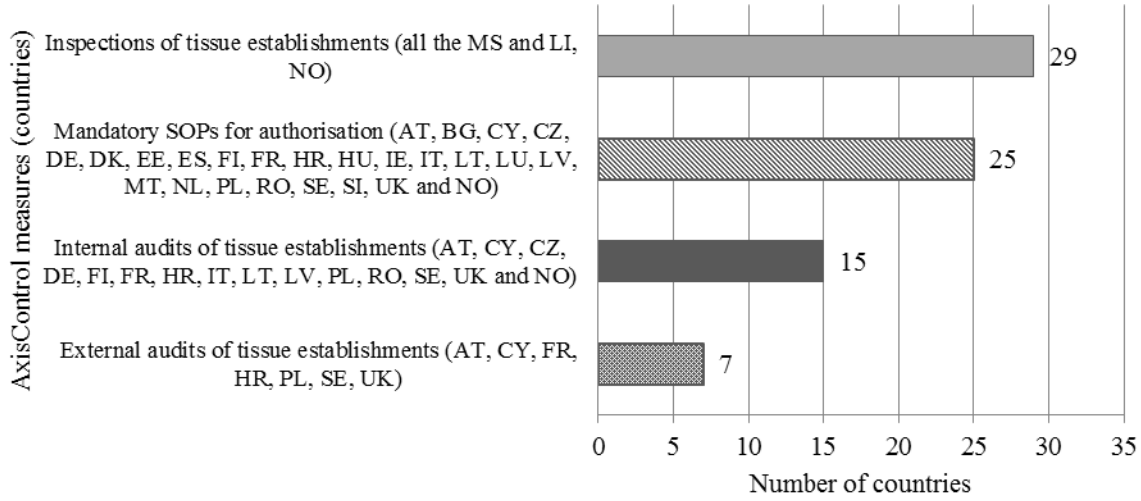



*Fig. 46. Verification of compliance with the requirements of Art 20 (tissue and cell processing) of Directive 2004/23/EC (2011 data)*

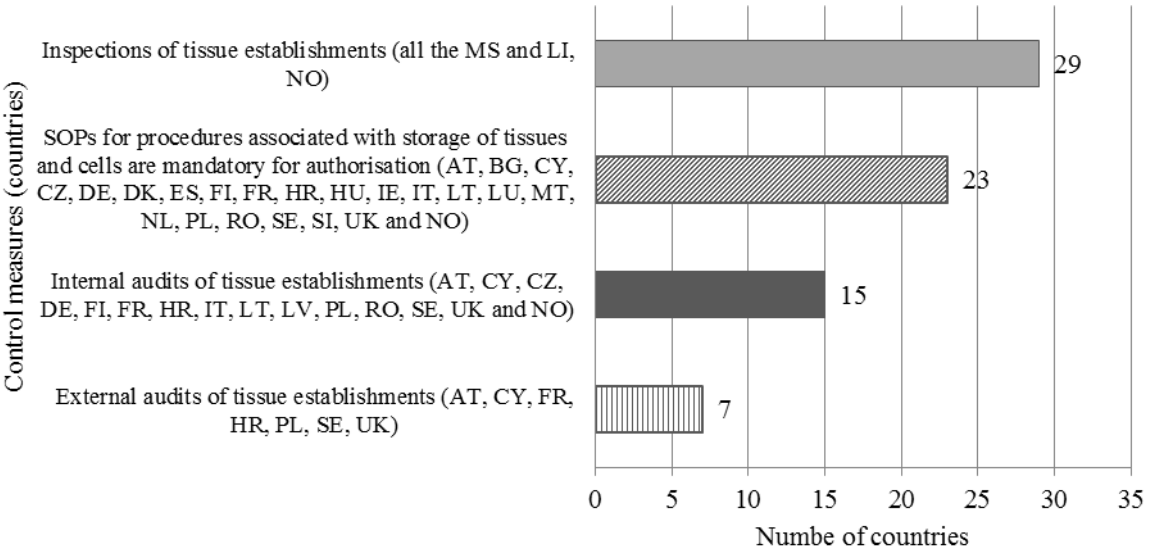



*Fig. 47. Verification of compliance with the requirements of Art 21 (storage of tissues and cells) of Directive 2004/23/EC (2011 data)*

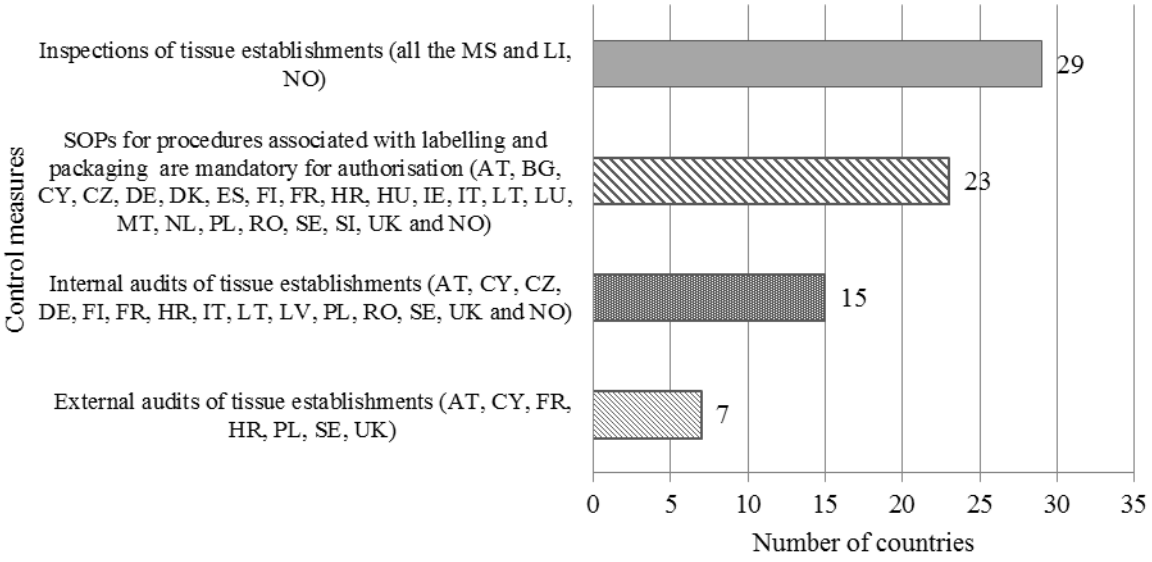



*Fig. 48. Verification of compliance with the requirements of Art 22 (labelling, documentation and packaging) of Directive 2004/23/EC (2011 data)*

Due to their importance, Germany suggested that requirements for microbiological testing of the source materials as well as of the final tissue product should be included in case of a potential revision of the legislation. It was underlined that microbiological testing for bacteria and fungi must be performed on the starting or incoming tissue itself, where possible.

Additionally, Poland added that external audits are not obligatory, but some of the tissue establishments applied for and received ISO accreditation. The JACIE accreditation programme of procurement and transplantation centres as well as tissue establishments in the field of HSC started in 2013.

*Comments*

The importance of inspections is highlighted again in the context of compliance with the reception, processing, storage, labelling and packaging requirements. It is the most frequent approach to control their implementation. Mandatory SOPs are also required during the authorisation/accreditation/designation or licensing process in most of the responding countries.

### *2.4.3. Distribution of tissues and cells for human application (Intra-community exchange)*

Most of the Member States and EEA countries reported having cross-border exchanges of human tissues and cells distributed (either distributing or receiving to/from another Member State/EEA country or both).

Eleven Member States (AT, BE, DE, DK, FR, HR, IT, LT, NL, PT, SE) and Norway declared having more stringent safety and quality requirements than the minimum ones required by the EU tissues and cells Directives. Of these, some (BE, DK, SE and Norway) expect that the responsible person of the tissue establishment located in the other Member State/EEA will ensure the compliance with the more stringent requirements before releasing the products. If

needed, the competent authority from the receiving country is informing about the more stringent requirements the tissue establishment intending to distribute tissues and/or cells on their territory.

Different or additional requirements by Member States might be well justified for local reasons, e.g. to address the increased prevalence of a certain disease. Members States should however have a mutually transparent view and understanding on the requirements implemented in each of the Member States.

Article 23 of Directive 2004/23/EC requires tissue establishments to ensure the quality of tissues and cells during distribution. For most of the Member States, national competent authorities ensure that tissue establishments fulfil the requirements of this Article when granting authorisations, by inspections, audit or control of documentation (Figure 49).

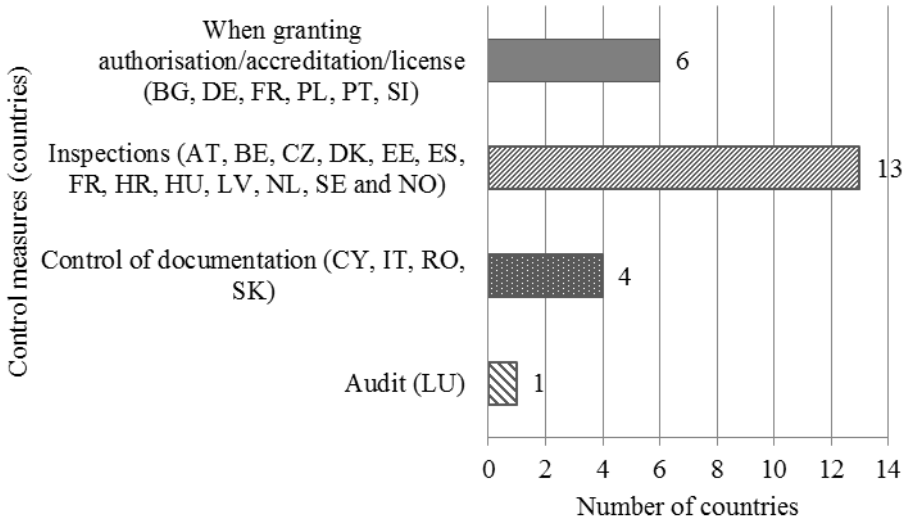



*Fig. 49. Verification of compliance with the requirements of Art 23 (distribution) of the Directive 2004/23/EC (2011 data)*

In most of the reporting countries direct distribution of tissues and cells from another EU Member State/EEA country to organisations responsible for human application (e.g. hospitals/clinics) on their territory is allowed. Four Member States (CZ, HR, PT and UK but only for gametes) and Liechtenstein reported that direct distribution is not allowed. An outline of the answers provide to this question is shown in Figure 50.

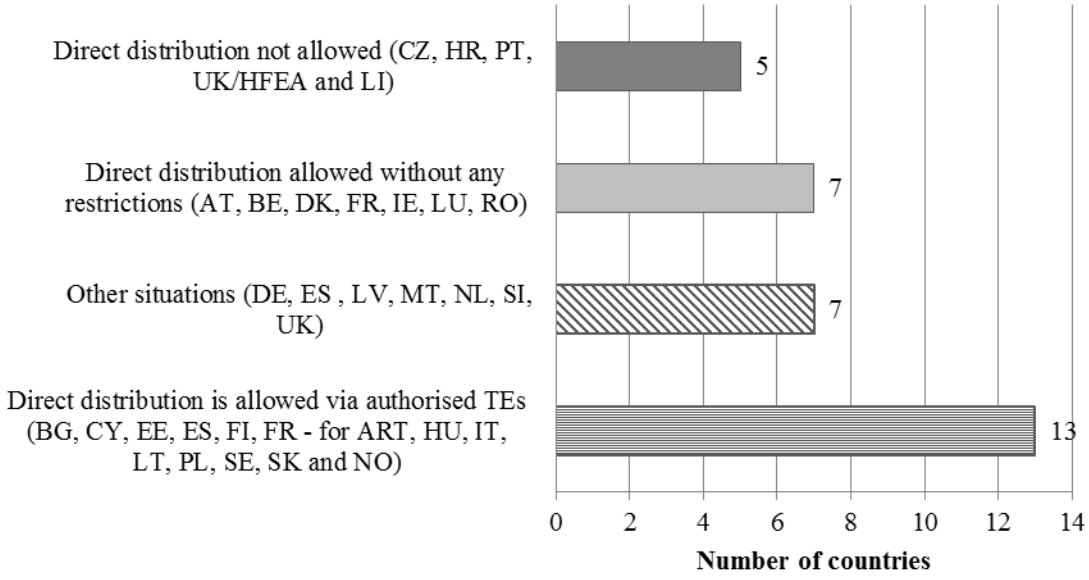



Fig. 50. Direct distribution of tissues and cells (2011 data)

The other situations reported are detailed below:

- Germany specified that before the first placing on the market, a certificate issued by the Paul-Ehrlich Institute is required (section 21a sub-section 9 AMG); the certificate shows that the products to be distributed in Germany have equivalent quality standards with the ones already on the market. In the case of non-equivalence, a "full marketing authorisation" (authorisation for tissue preparations regarding Section 21a AMG) must be obtained;
- Latvia informed that there are no legal provisions regarding distribution to Latvian hospitals from tissue establishments in another Member State;
- Malta indicated that direct distribution to hospitals/clinics through brokers is possible only after notification of the competent authority who authorises the entry if the relevant documentation shows equivalence of standards;
- In the Netherlands, restrictions apply only for unprocessed tissues, which is done only via an authorised tissue establishment;
- In Slovenia distribution to hospitals/clinics is allowed, but with special authorisation issued for each case;
- Spain indicated that only the distribution of products derived of human tissues such as demineralised bone matrix (DBM) and lyophilized products may be distributed directly to hospitals/clinics;
- In the United Kingdom, direct distribution is allowed to end users, without requiring a licence, provided tissues and cells will not be stored for longer than 48 hours.

Concerning direct distribution of specific tissues and cells to a recipient (Article 6 of Directive 2006/17/EC), five Member States (FR, LT, MT, SI, SK) reported having authorised such procedures in 2011 for haematopoietic stem cells (France, Lithuania), musculoskeletal tissues (Lithuania, Malta) as well as gametes and embryos (FR).

Only 18 Member States (BE, BG, DE, EE, ES, FI, FR, HR, IE, IT, LT, NL, PT, RO, SE, SI, SK, UK) reported that data related to the cross-border exchange between their country and another Member State/EEA country are collected at national level. However, the data collected varies from one country to another, with some Member States providing data on the number and type of tissues distributed as well the country of destination/origin (BE, BG, DE, EE, FI, HR, IE, IT, LT, PL, PT), other only data on the number and type of tissues distributed (Netherlands, Spain, Sweden) or just the total number distributed within the EU (United Kingdom). Additionally, Germany collects data on tissues and cells entering and leaving their territory with no distinction between import/export from/to third countries and distribution within the EU.

Overall, for 2011, 18 countries reported that 59,375 units of human tissues and cells were distributed to other EU and EEA countries:

- 41,271 units were distributed by United Kingdom. Data per tissue type were not reported;
- 16,461 units were distributed by 13 Member States (BE, BG, EE, ES, FI, IE, IT, LT, NL, PL, PT, SE, UK/HFEA) (Figure 51);
- 1,643 units of replacement tissues (musculoskeletal, ocular tissues and cardiovascular tissues) were distributed by France. It was specified that distribution of haematopoietic stem cells units was reported to EBMT. Distribution of cryopreserved sperm to one Member State (Spain) for patients who travel abroad for egg donation was also was reported.

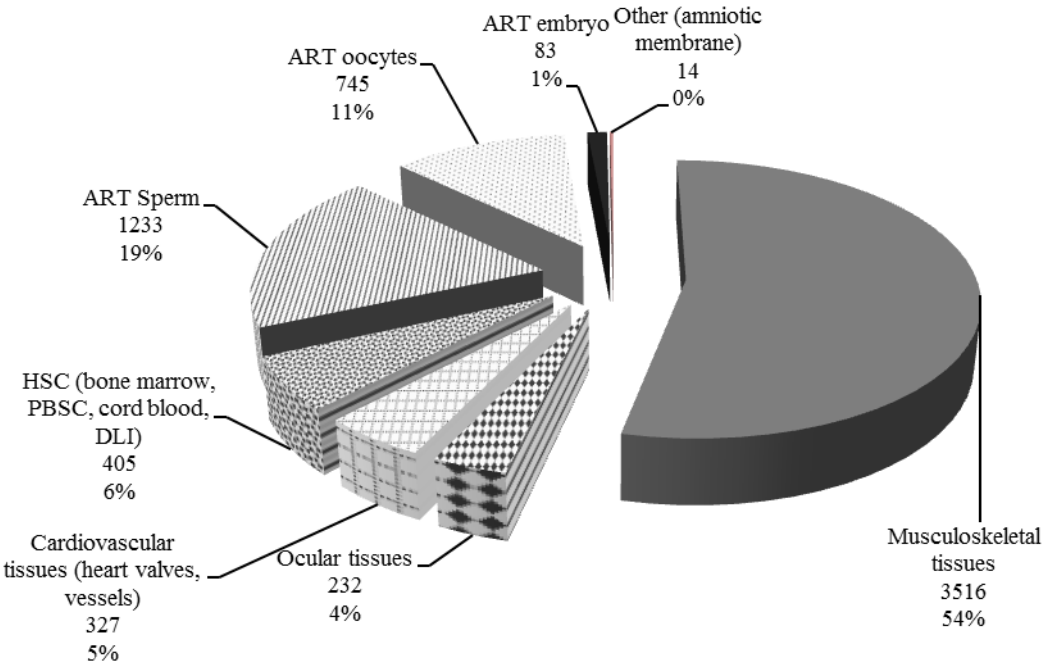



*Fig. 51. Volume of tissues and cells distributed for clinical application to another Member State or EEA country (units of tissues or cells – absolute and relative values; 2011 data)*

The number above does not include cord blood units, cord blood segments and teeth for autologous use transported for storage in another Member State (e.g. as reported by Slovenia).

One Member State (Romania) collects data on distribution of tissues and cells but reported that no such products were distributed in 2011. Slovakia informed that data collection started only in December 2012, so 2011 data is not available.

Information on tissues and cells received from other EU Member States and EEA countries was also asked. For 2011 it was reported that 255,346 units of human tissues and cells were received from other EU and EEA countries:

- 238, 244 units were received by the United Kingdom;
- 4,480 units of replacement tissues (musculoskeletal, ocular tissues and cardiovascular tissues) were reported by France. Data per tissue type were not reported;
- 12,622 units were reported by 13 Member States (BE, BG, EE, ES, FI, IE, IT, LT, NL, PL, PT, SE, UK/HFEA) (Figure 52).

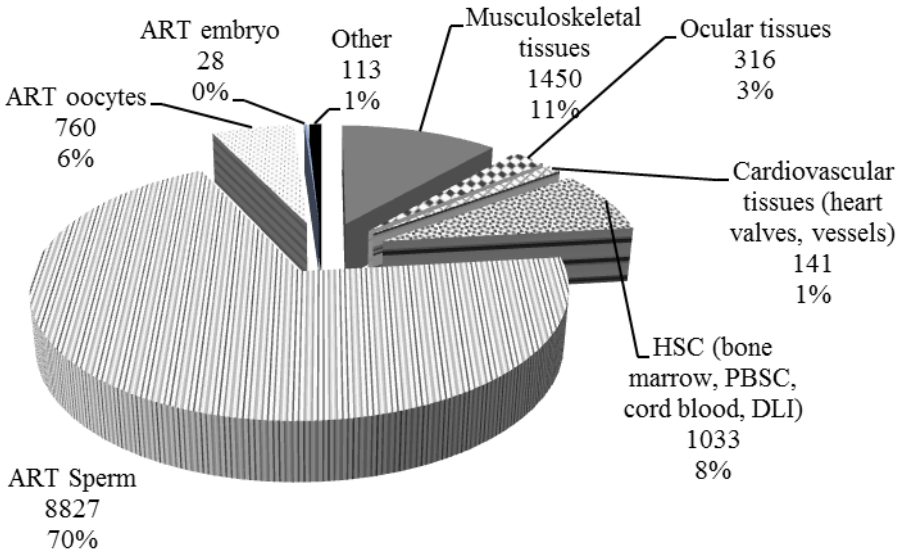



*Fig. 52. Volume of tissues and cells received for clinical application from another EU Member State or EEA country (units of tissues or cells – absolute and relative values; 2011 data)*

Four Member States (HR, PL, RO, SK) informed that no tissues and cells were received from other EU or EEA countries in 2011.

Slovenia and Slovakia did not provide details on the type of tissues and cells for which the authorisation was granted.

In addition, only nine Member States (AT, DE, DK, ES, IE, IT, MT, NL, UK for non-reproductive tissues and cells) and Liechtenstein and Norway reported allowing **brokerage** companies for either distribution in EU and/or import/export of tissues and cells. The legal framework for the brokerage companies varies, as follows:

- Authorisation by the national competent authority is required (Austria, Malta);
- No specific legal provisions, but the competent authority informs the brokerage company on the principles of tissues and cells legislation and periodically monitors their activities (Denmark);

- National legislation in place for “brokering of medicinal products” (sec. 4 para. 22a German Medicinal Products Act), but no experience in implementing these regulations with regard to “classical tissues” (Germany);
- Possibility to operate under a third party agreement with a public, authorised tissue establishment (e.g. currently occurring for processed bone products) (Italy);
- Legislation in place, according to which a broker is a legal entity allowed to make financial and logistic arrangements between seller and buyer without handling the tissues (handling the tissues is only allowed to authorised tissue establishments) (Netherlands);
- Authorisations for brokerage are provided by the regional authorities (Spain);
- Brokers are considered intermediaries obtaining tissue for end-users, however most of them are licensed as they are engaged in an intermediate storage step. The competent authority's role is to authorise and monitor them through inspection. Currently only one broker is licensed for distribution and import/export, without storage (United Kingdom).

Three Member States (Austria, Germany, Ireland) as well as Liechtenstein and Norway specified that even though brokers are allowed, they are not actively supplying healthcare professionals and other types of establishments.

In the six Member States which indicated that brokers actively supply health professionals in their country (DK, ES, IT, MT, NL, UK), brokers are located either on their territory (DK, ES, IT, MT, UK) or in another country (ES, IE, IT, NL). Spain also specified that the verification of compliance with the safety and quality requirements is performed through analysis of the documentation provided by the broker.

*Comments*

As demonstrated by the Member States' replies, there are important cross-border movements of human tissues and cells within the EU and EEA countries. This may be considered the result of the quality and safety standards laid down in Directive 2004/23/EC and its implementing Directives, which have created the framework for facilitating transnational movements within the Union. However, it has to be underlined that like for import and export, data collected by the Member States probably serve different purposes and use various methodologies, so it is very difficult to draw a clear conclusion on the volume of tissues exchanged and the importance of EU distribution compared to import/export in this sector. Additionally the more stringent requirements introduced by some Member States, as well as the different legal framework under which the EU tissues and cells legislation was transposed (e.g. transplantation vs. medicinal products) may hamper to some extent the flow of tissues and cells within the Union.

### *2.4.4 Relations between tissue establishments and third parties*

Article 24 of Directive 2004/23/EC lays down the requirements between tissue establishments and third parties, which include the situations when a written third party agreement is mandatory and the obligations of the tissue establishments when selecting the third parties, as well as their obligation to keep a complete lists of these agreements and to provide copies of the agreements upon request from competent authorities.

Only two Member States (Hungary, Luxembourg) reported that third party agreements are not included in their national legislation. From the countries allowing third parties agreements, only four Member States (CY, FI, RO, SK) and Liechtenstein reported that no third party agreements were notified to the national competent authorities.

Concerning the responsibilities entrusted to third parties, Member States reported that written agreements with third parties have been concluded for several activities within the donation-distribution chain (Figure 53).

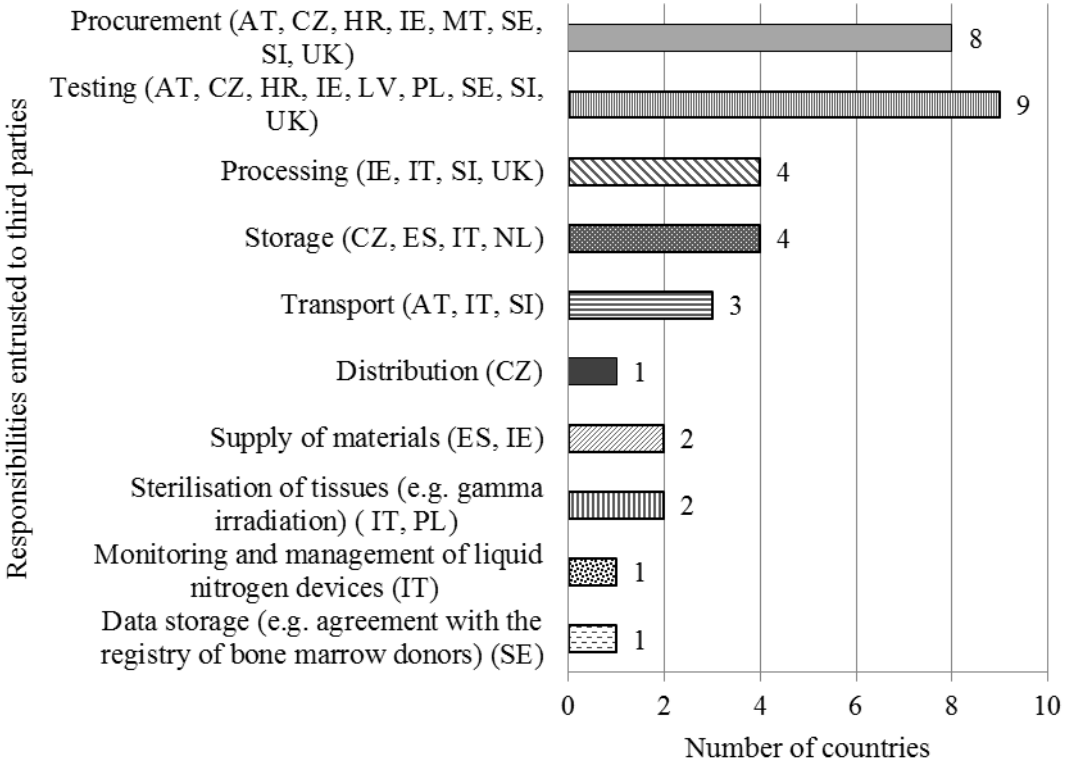



*Fig. 53. Tissue establishments' written agreements with third parties (2011 data)*

Seven Member States (BE, BG, DE, EE, FR, LT, PT) and Norway reported only the circumstances and did not provide detailed data on activities for which third parties agreements can be concluded.

Member States and EEA countries reported that third party agreements are checked (Art 6.2) by the competent authority(ies) mainly by inspection (AT, BE, BG, CZ, DE, DK, EE, ES, FR, HR, IE, IT, LV, NL, PL, PT, SE, UK and NO), by evaluating the contractual agreements (Denmark, Latvia, Malta), but also when granting authorisations/accreditations /designations or licences (BG, CZ, DE, EE, ES, FR, IE, NL, PL, PT, SE, SI, UK and NO).

The competent authority for non-reproductive tissues and cells in United Kingdom (HTA) specified having powers to enter and inspect third party premises, powers to direct a licensed establishment to put in place a third party agreement with a supplier of goods or services where it considers this necessary. The HTA equally has powers to direct an individual licensed establishment not to use a named supplier of either goods or services. Under extreme

circumstances the HTA may give details of suppliers from whom no licensed establishment may receive goods or services.

In Italy, third parties that carry our critical steps such as processing or storage of tissues or cells on behalf of tissue establishments must have direct authorisations from the Ministry of Health, which are issued by the national competent authority (*Centro Nazionale Trapianti*) on the basis of inspections. In Sweden, a new third party agreement is considered a major change in the authorisation of a tissue establishment and it requires the approval of the competent authority (by document review).

*Comments*

The fact that third parties may be involved in all the steps of the chain from donation and procurement until distribution shows the importance that needs to be given to the written agreements established by the tissue establishments and their verification by the national competent authorities. In this respect, it should be highlighted that Directive (EU) 2015/566 as regards the procedures for verifying the equivalent standards of quality and safety of imported tissues and cells[18] provides for the harmonisation of the minimum requirements in terms of contents of written agreements between importing tissue establishments and their third country suppliers.

### *2.4.5. Penalties*

Under Article 6(4) of Directive 2004/23/EC, the competent authority or authorities may revoke or suspend the accreditation/designation/authorisation/licence of a tissue establishment if it is found to no longer comply with the requirements of the Directives.

Twenty-two Member States (AT, BE, BG, CY, CZ, DE, EE, ES, FI, FR, IE, IT, LU, LV, MT, NL, PL, PT, RO, SE, SI, UK) and Liechtenstein and Norway indicated that penalties for infringements of the national provisions pursuant to Directive 2004/23/EC were defined. Five Member States (AT, CZ, DE, NL, UK) indicated that such penalties were already imposed, but only two Member States reported imposing penalties in 2011 (Germany – one fine; United Kingdom/HTA – 11 penalties). The United Kingdom reported that the majority of penalties were imposed following inspections where shortfalls against regulatory requirements had been identified; penalties imposed included conditions or directions on seven licences, suspensions of specific licensable activities on three licences and one revocation, but none were followed by criminal sanctions.

*Comments*

The penalties foreseen in national legislation, their criteria for implementation and their effective implementation can differ significantly between Member States. In order to ensure mutual trust between Member States, in particular for cross-border movements, some Member States suggested further collaboration and coordination, potentially in a dedicated EU initiative related to inspections and authorisations.

[18] Commission Directive (EU) 2015/566 of 8 April 2015 implementing Directive 2004/23/EC as regards the procedures for verifying the equivalent standards of quality and safety of imported tissues and cells Text with EEA relevance. OJ L 93, 9.4.2015, p. 56–68

## Annex 1: Individual country responses to the survey on the implementation of the EU Tissues and Cells Directives conducted in 2012 and based on 2011 information

Note: In a number of cases clarification requests were sent to Member States to verify the information included in their submission. It is important to note that while the original replies of Member States are shown below, the text, tables and figures reflect the updated information provided by Member States during a verification process. Where there are discrepancies, the text, tables and figures in the document itself contain the correct information.

### *A.1.1. Survey response Austria*

| **1. Public information** | |
|---|---|
| 1.1. Name of National Competent Authority (NCA) 1: | Federal Office for Safety in Health Care (BASG) / AGES Austrian Agency for Health and Food Safety |
| 1.1.2. Address of NCA 1: | Traisengasse 5 A-1200 Vienna Austria |
| 1.1.3. Telephone (central access point): | +43505550 |
| 1.1.4. E-mail (central access point): | inspektionen@ages.at |
| 1.1.5. Website: | www.basg.gv.at |
| 1.1.6. The NCA is responsible for? (more than 1 answer possible) | Non-reproductive tissues and cells<br>Reproductive tissues and cells<br>Blood and blood components<br>Pharmaceuticals<br>Medical devices |
| 1.1.7. What are the role/tasks of the NCA? (more than 1 answer possible) | Accreditation, authorisation, licensing of TEs<br>Inspection<br>Vigilance |
| 1.2. National Competent Authority 2? | No |
| 1.5. Please give a short description of the legal status and organisation of the National Competent Authority(ies) (e.g. departments, staffing, number of senior and junior inspectors, staff working on EU affairs and legal matters, vigilance officers, budget, independence from government etc.). | Federal Office for Safety in Health Care (BASG) and AGES The Federal Office for the Safetyin Health Care (BASG) / AGES was set up in January 2006 and is responsible for marketing authorisation of medicinal products in Austria and assessment of medicinal products and medical devices which are already on the market regarding efficacy, adverse reactions, production, shipment and storage. Fully owned by the Republic of Austria, BASG / AGES acts on behalf of the Republic as represented by the Federal Ministry of Health (BMG). The Federal Office for Safety in Health Care (BASG) is responsible for carrying out public services undertakings. BASG is directly subordinate to the Federal Ministry of Health (BMG). It consists of three members, which are appointed by the Federal Minister of Health. One of these members was delegated by the BMG, another by AGES; the third member is the head of BASG / AGES. AGES is thus connected closely to the BASG; it is represented by two members in the Federal Office and provides it with services, staff and facilities. The employees of BASG / AGES are responsible for carrying out public services undertakings and act on behalf of the Federal Office. The written decisions issued by the BASG are not subject to reversal change by the administration, thus making it the first and final authority. The instituts of the Austrian Medicines and Medical Devices Agency: Institute Pharmakovigilance (Head: Dr. Bettina Schade) Institute OMCL (Head: Dr. Gerhard Beck) Institut Marketing Authorisation & Lifecycle Management (Head: Dr. Christa Wirthumer-Hoche) Institute Inspections, Medical Devices & Haemovigilance (Head: DDr. Alexander Hönel) Head of the Austrian Medicines and Medical Devices Agency: Ao. Univ.-Prof. Dr. Marcus Muellner |

| | |
|---|---|
| | The tasks concerning tissues and cells are mainly located at the Instituts Inspections, Medical Decives & Haemovigilance at the department Pharma and there at the group Blood & Tissues Inspections & Vigilance. The group Blood & Tissues Inspections & Vigilance consists of a team of inspetors (4), a vigilace team (3), and the head of the group. |
| 1.6. In case of MS with federal or decentralised systems, please indicate the roles/tasks of the Regional Competent Authority(ies). (more than 1 answer possible) | Not applicable |
| 1.7. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies) for tissues and cells: | Not applicable |
| **2. Procurement (Article 5 Directive 2004/23/EC)** | |
| 2.1. Do you authorise the "conditions of procurement"? | Yes |
| 2.1.1. How do you authorise the "conditions of procurement"? (more than 1 answer possible) | By inspecting some procurement centres<br>By inspecting the documentation associated with procurement that is available in the tissue establishment working with procurement centres |
| 2.1.2. How many such authorisations were granted in 2011 (01/01-31/12/2011)? | 35 |
| 2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011). | 32 |
| 2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011). | 15 |
| 2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues were carried out in 2011 (01/01-31/12/2011). | 36 |
| 2.2.4. Please provide the number of procurement centers in which procurement of tissues/cells for ATMP manufacturing were carried out in 2011 (01/01-31/12/2011). | 9 |
| 2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC and its implementing Directive 2006/17/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) ? (more than 1 answer possible) | Inspections of the site/centre |
| 2.4. Are you also responsible for the accreditation, designation, authorisation or licensing of laboratories performing donor testing? | No |
| 2.4.2. Which National Authority is in charge of this activity? | missing implementation in national law |
| 2.5. How do you ensure, as CA for T&C, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art. 5(2))? (more than 1 answer possible) | Analysis of the mandatory documentation requested from the tissue establishment |
| 2.6. Please provide data on qualified laboratories accredited, authorised or licensed in your country (e.g. number, year of accreditation/authorisation/license, which donor tests are performed etc.). | missing implementation in national law |
| 2.7. Do you have any additional comments on procurement? | - |
| **3. Testing (Art 4 Annexes I, II and III of Directive 2006/17/EC)** | |
| 3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>NAT HIV 1<br>HBs AG<br>Anti HBc<br>NAT HBV<br>Anti HCV-Ab<br>NAT HCV |

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| | Treponema Pallidum |
| 3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>NAT HIV 1<br>HBs AG<br>Anti HBc<br>NAT HBV<br>NAT HCV<br>NAT Chlamydia<br>Treponema Pallidum |
| 3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to encourage its use? Please specify why or why not (e.g. number of additional cases detected, cost-benefit etc.). | only for autologous donations NAT testing is not mandatory reproductive autologous: NAT testing not mandatory reproductive allogeneic: NAT testing mandatory deceased: NAT testing mandatory living autologous: NAT testing not mandatory living allogeneic: NAT testing mandatory |
| 3.4. Do you have concerns on accuracy of the available tests and test procedures for deceased donors? | Yes |
| 3.4.1. Please specify why: | because there are no CE-marked kits for the testing of blood of dec |
| 3.5. Are any other laboratory tests required for donors of non-reproductive tissues and cells in your Member State? | No |
| 3.6. Are any other laboratory tests required for donors of reproductive tissues and cells in your Member State? | No |
| 3.7. Do you request/use international accreditation systems for testing laboratories? | No |
| 3.8. Do you have any additional comments on testing? | - |
| **4. Accreditation, designation, authorisation or licensing of tissue establishments (Article 6, Directive 2004/23/EC)** | |
| 4.1. Do you have a system of designation, authorisation, accreditation or licensing for all types of tissue establishments under your responsability? | Yes |
| 4.2. Is inspection a prerequisite for the designation, authorisation, accreditation or licensing of tissue establishments? | Yes |
| 4.2.1. How many inspections were performed in 2011 for authorising/accrediting/licensing/designating TEs? | 57 |
| 4.3. Are preparation processes authorised? | Yes |
| 4.3.1. How are they authorised? (more than 1 answer possible) | During inspections organised for this purpose |
| 4.4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were suspended in 2011? | 2 |
| 4.5. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011? | 0 |
| 4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)? | No |
| **4bis. Overview of tissue/cells establishments authorised by the NCA** | |
| 4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible): | Musculo-skeletal tissue establishments<br>Cord blood tissue establishments<br>ART tissue establishments<br>Multi-tissue establishments |
| 4.7.2. How many musculo-skeletal tissue establishments? | 1 |
| 4.7.6. How many cord blood tissue establishments? | 1 |
| 4.7.7. How many ART tissue establishments? | 7 |
| 4.7.8. How many multi-tissue establishments? | 1 |
| 4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible): | Skin tissue establishments<br>Musculo-skeletal tissue establishments<br>Cardiovascular tissue establishments<br>HSC tissue establishments<br>Cord blood tissue establishments<br>ART tissue establishments<br>Multi-tissue establishments |
| 4.8.1. How many skin tissue establishments? | 1 |

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| 4.8.2. How many musculo-skeletal tissue establishments? | 16 |
| 4.8.4. How many cardiovascular tissue establishments? | 1 |
| 4.8.5. How many HSC tissue establishments? | 3 |
| 4.8.6. How many cord blood tissue establishments? | 2 |
| 4.8.7. How many ART tissue establishments? | 4 |
| 4.8.8. How many multi-tissue establishments? | 2 |
| 4.9. Tissue establishments first time authorised between 01/01/2011 and 31/12/2011 (more than 1 answer possible): | Musculo-skeletal tissue establishments<br>HSC tissue establishments<br>Cord blood tissue establishments<br>ART tissue establishments<br>Multi-tissue establishments |
| 4.9.2. How many musculo-skeletal tissue establishments? | 9 |
| 4.9.5. How many HSC tissue establishments? | 1 |
| 4.9.6. How many cord blood tissue establishments? | 2 |
| 4.9.7. How many ART tissue establishments? | 22 |
| 4.9.8 How many multi-tissue establishments? | 5 |
| 4.10. All tissue establishments authorised by 31/12/2011 (more than 1 answer possible): | Musculo-skeletal tissue establishments<br>Ocular tissue establishments<br>HSC tissue establishments<br>Cord blood tissue establishments<br>ART tissue establishments<br>Multi-tissue establishments<br>Other tissue establishments |
| 4.10.2.1. How many public musculo-skeletal tissue establishments? | 10 |
| 4.10.2.2. How many private musculo-skeletal tissue establishments? | 6 |
| 4.10.3.1. How many public ocular tissue establishments? | 1 |
| 4.10.3.2. How many private ocular tissue establishments? | 0 |
| 4.10.5.1. How many public HSC tissue establishments? | 6 |
| 4.10.5.2. How many private HSC tissue establishments? | 0 |
| 4.10.6.1. How many public cord blood tissue establishments? | 0 |
| 4.10.6.2. How many private cord blood tissue establishments? | 3 |
| 4.10.7.1. How many public ART tissue establishments? | 14 |
| 4.10.7.2. How many private ART tissue establishments? | 18 |
| 4.10.8.1. How many public multi-tissue establishments? | 14 |
| 4.10.8.2. How many private multi-tissue establishments? | 3 |
| 4.10.9.1. Please specify the type of 'other' public tissues/cells establishements and how many. | none |
| 4.10.9.2. Please specify the type of 'other' private tissues/cells establishements and how many. | Tumor tissue (Glioblastoma multiforme) 1TE Subcutaneous adipose tissue 1TE |
| 4.11. How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Art. 6(5) during 2011? Please provide number(s) per type tissues/cells. | 0 |
| **4ter. Sanctions** | |
| 4.16. Have penalties for infringements of the national provisions pursuant to the Directive been defined (Article 27)? | Yes |
| 4.16.1. Have penalties already been imposed? | Yes |
| 4.16.1.1. How many penalties have been imposed in 2011 (from 01/01/2011-31/12/2011)? | 0 |
| 4.16.1.2. What were the reasons for imposing the penalties? Please describe. | - |
| 4.16.1.3. What kind of penalties were imposed? Please describe (e.g. suspension of authorisation, criminal penalty etc.) | - |
| 4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing? | A legally necessary certificate for tissue establishments, issued after each inspection, would be desireable in order to display the current status of authorization (comparable to a GMP-Certificate in the pharmaceutical area). |
| **5. Inspections (Article 7, Directive 2004/23/EC)** | |
| 5.1. Is a system in place for organising inspections and control measures of tissue establishments? | Yes |
| 5.1.1. If yes, please specify the CA/Department of the CA in charge | Austrian Agency for Health and Food Safety (AGES), Institute |

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| of inspections. | Inspections, Medical Devices & Haemovigilance |
| 5.1.2. If yes, please specify staffing (how many inspectors). | 4 |
| 5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible) | Yes |
| 5.2.1. If yes, please specify. (more than 1 answer possible) | Blood<br>Pharmaceuticals<br>Advanced therapies |
| 5.3. How many routine inspections of tissue establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011)? | 40 |
| 5.3.1. How many inspections of tissues establishments for non-reproductive tissues/cells were conductedin 2011 (from 1/1/2011 to 31/12/2011) following serious adverse events or reactions, or suspicion thereof ? | 0 |
| 5.3.2. How many other type of inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | 2 (enforcement inspections) |
| 5.3.3. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | 0 |
| 5.3.4 Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where minor shortcomings were noted? | 11 |
| 5.3.5. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where major shortcomings were noted? | 29 |
| 5.3.6. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by suspension of authorisation? | 2 |
| 5.3.7. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by closure? | 0 |
| 5.3.8. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of other inspections carried out? Please specify. | 2, Due to major changes in the TE additional inspections were performerd. |
| 5.4. How many routine inspections were conducted in ART establishments (from 1/1/2011 to 31/12/2011)? | 18 |
| 5.4.1. How many inspections were conducted in ART establishments following serious adverse events or reactions, or suspicion thereof (from 1/1/2011 to 31/12/2011)? | 0 |
| 5.4.2. How many other type of inspections were conducted on ART establishments (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | 0 |
| 5.4.3. Outcome of inspections of ART tissue establishments carried out in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | 0 |
| 5.4.4. What was the number of inspections carried out in ART establishments where minor shortcomings were noted? | 1 |
| 5.4.5. What was the number of inspections carried out in ART establishments where major shortcomings were noted? | 16 |
| 5.4.6. What was the number of inspections carried out in ART establishments followed by suspension of authorisation? | 0 |
| 5.4.7. What was the number of inspections carried out in ART | 0 |

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| establishments followed by closure of respective establishements? | |
| 5.4.8. What was the number of other inspections of ART establishments? Please specify. | 2, Due to major changes in the TE additional inspections were performerd. |
| 5.5. Which type of routine inspections do you conduct? (more than 1 answer possible) | General system-oriented inspections<br>Thematic inspections<br>Desk based reviews |
| 5.6. How do you decide which type of routine inspection to conduct? | Desk based reviews are conducted if only minor changes in the TE took place. For routine inspections or for first inspections of a TE general system-oriented inspections are conducted. However there can be also a focus on special topics. Thematic inspections are triggered where major shortcomings are not solved or following SAE or SAR. |
| 5.7. Until 2011, did you implement the requirement concerning the time interval between two inspections (Art. 7.3.)? | Yes |
| 5.8. How many TEs were inspected at least twice between 2008-2011 (01/01/2008-31/12/2011)? | 7 |
| 5.9. Did you perform/conduct inspections of procurement sites outside tissue establishments? | Yes |
| 5.9.1. If yes, how many? | 28 |
| 5.10. Did you carry out inspections of third parties? | No |
| 5.10.2. If no, why not? | lack of inspection capacity |
| 5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)? | Yes |
| 5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)? | Yes |
| 5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses ;on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)? | 4 |
| 5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))? | No |
| 5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))? | No |
| 5.15. Did you organise any inspections of procurement centres or tissue establishments in third countries from which tissues and/or cells were imported in your country (as recorded by 31/12/2011)? | No |
| 5.16. Have you asked another MS, or have you been requested by any other MS, on the results and control measures of your inspections, as part of an enquiry/investigation? | No |
| 5.17. Would you be interested in developing joint inspections? Joint inspections should be understood as inspections of tissue establishments conducted jointly by two or more Member States' Competent Authorities on their territory or in third countries. | Yes |
| 5.18. Do you have any additional comments on inspections? | more harmonisation and exchange of information on EU level in regard of inspections would be helpful (e.g. establishing a tissue & cells inspectors workin group) |
| **6. Import/export (Article 9 Directive 2004/23/EC)** | |
| 6.1. Do you have a register of authorised tissue establishments that are explicitly authorised to perform import/export of tissues and celles from/to third countries? | Yes |
| 6.2. Please specify the number of tissue establishments authorised to import tissues and cells from third countries (recorded by 31/12/2011). | 2 |
| 6.3. Please specify the number of tissue establishments authorised to export tissues and cells from third countries (recorded by 31/12/2011). | not recorded |

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| 6.4. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of skin from third countries. | Inspections at the importing establishments take place, the product is released by the Austrian establishment, SOPs and contracts are inspected to ensure the equivalent standards, the Austrian company has to perform audits at the site they are importing from |
| 6.5. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of musculo-skeletal (bone, tendons, fascia etc.) tissues from third countries. | Inspections at the importing establishments take place, the product is released by the Austrian establishment, SOPs and contracts are inspected to ensure the equivalent standards, the Austrian company has to perform audits at the site they are importing from |
| 6.6. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of ophtalmic (cornea, sclera, etc ) tissues from third countries. | Inspections at the importing establishments take place, the product is released by the Austrian establishment, SOPs and contracts are inspected to ensure the equivalent standards, the Austrian company has to perform audits at the site they are importing from |
| 6.7. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cardio vascular tissues from third countries. | Inspections at the importing establishments take place, the product is released by the Austrian establishment, SOPs and contracts are inspected to ensure the equivalent standards, the Austrian company has to perform audits at the site they are importing from |
| 6.8. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) (other than cord blood) from third countries. | Inspections at the importing establishments take place, the product is released by the Austrian establishment, SOPs and contracts are inspected to ensure the equivalent standards, the Austrian company has to perform audits at the site they are importing from |
| 6.9. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cord blood from third countries. | Inspections at the importing establishments take place, the product is released by the Austrian establishment, SOPs and contracts are inspected to ensure the equivalent standards, the Austrian company has to perform audits at the site they are importing from |
| 6.10. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of reproductive cells (sperm, egg cells) from third countries. | Inspections at the importing establishments take place, the product is released by the Austrian establishment, SOPs and contracts are inspected to ensure the equivalent standards, the Austrian company has to perform audits at the site they are importing from |
| 6.11. Did you import tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | Yes |
| 6.11.1. If yes, please provide the data concerning the number/volume of imported tissues and cells by country of origin. | no data available, notification not required by national law |
| 6.12. Did you export tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | No |
| 6.13. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on imports/exports of tissues/cells between your country and other third countries? | No |
| 6.14. What is the relation between import/export of tissues and cells and self-sufficiency? (more than 1 answer possible) | F. Other |
| Please specify 'other': | only import is authorised - no estimations are performed |
| 6.15. Did you authorise direct imports of tissues/cells to hospitals/clinics in your country? | No |
| 6.16. Do you have any additional comments on import/export? | - |
| **7. Distribution/intra community exchanges (Article 23 Directive 2004/23/EC)** | |
| 7.1. Do you have intra-community exchanges of tissues and cells? | Yes |
| 7.1.1. If yes, how do you address the possible more stringent quality and safety measures established by other Member States? Please specify. | The different, more stringent national laws of all member states can not be known. Product which are brought to other member states must fulfill the Austrian Cell and Tissue Safety Act. |
| 7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States? | Yes |
| 7.1.2.1. How do you address this difference for tissues and cells coming from a MS with minimum quality requirements? Please specify. | If the tissues or cells have been released by a responsible person in the EU, the products can be used in Austria. |
| 7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify. | During inspections records, SOPs are reviewed. |
| 7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible). | Yes, no restrictions apply |
| 7.4. Have you authorised direct distribution to the recipient of specific tissues and cells (Art. 6, Directive 2006/17/EC)? | No |

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| 7.5. Do you collect data regarding the cross-border exchange of tissue/cells between your country and other EU MS? | No |
| 7.6. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on cross-border exchanges of tissues/cells between your country and other EU MS? | No |
| 7.7. Do you allow brokerage companies for either distribution in EU and/or import/export of tissues/cells? In this context, a brokerage company means a body that arranges transactions between a supplier (tissue establishment/company selling tissues or cells) and a buyer (a tissue establishment/a hospital or clinic/an individual) without undertaking activities of processing, preservation or storage. | Yes |
| 7.7.1. Please describe the legal requirements and your role (if any) as a Competent Authority, in their authorisation/monitoring or inspection. | For import/export of tissue and cells an authorisation by the CA is required. For the arrangement of transactions within the EU no authorisation is required. |
| 7.8. Are brokers actively supplying health professionals/establishments in your country? | No |
| 7.9. Do you have any additional comments on distribution? | - |
| **8. Register of tissue establishments and reporting obligations (Article 10, Directive 2004/23/EC)** | |
| 8.1. Do you have an annual report model/template on the activities of tissue establishments in your Member State? (Article 10(1)). If yes, please upload the template. | Yes |
| 8.2. How many tissue establishments submitted annual reports of their activities during 2011. Please provide an estimation. (1 answer possible) | 60-99% |
| 8.3. Are these reports publicly available? (Article 10(1)) | No |
| 8.4. Do you publish a national annual report of the consolidated activities of all tissue establishments in your country? | No |
| 8.4.2. If no, why not? | Data for 2009 were published, due to no national legislations there was no further publishing since then. Legislation was changed recently. The data of 2012 will be published. |
| 8.5. Is there a publicly accessible register of authorised tissue establishements in place? (Article 10(2)) | Yes |
| 8.5.1. If yes, please provide us with the link to the register's web site. | http://www.basg.gv.at/arzneimittel/gewebe/register-29-gsg/ |
| 8.6. Do you provide data regarding tissues and cells activities to the EUROCET registry (non-mandatory reporting)? | Yes |
| 8.6.1. If yes, what data are provided to EUROCET? Please specify. | update of register of TEs and their tasks was provided to EUROCET in July 2013 |
| 8.7. Do you have any additional comments on reporting? | - |
| **9. Traceability (Article 8, Directive 2004/23/EC; and Directive 2006/86/EC)** | |
| 9.1. Was the donor identification system (Art. 8(2)) implemented in your country? | No |
| 9.1.1. If no, why not? | The Federal Ministry of Health deferred the implementation of ISBT128 on 16.12.2008 due to difficuties in the practical implementation in the area of tissues and cells. |
| 9.2. Who assigns the unique code for each donation? (only 1 answer possible) | Other |
| Please specify 'other'. | TE or procurement center |
| 9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible) | Both paper records and electronic forms |
| 9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify. | Needs to be specified in SOPs. Checking examples during routine inspections. |
| 9.5. Do you have any additional comments on traceability? | - |
| **10. Notification of serious adverse events and reactions (Article 11 Directive 2004/23, Article 6 Directive 2006/76)** | |
| 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))? | Yes |
| 10.1.1. If yes, which CA/institution is responsible? | AGES (our CA) |
| 10.1.2. If yes, please provide a short description of its organisation. | see 1.5 |
| 10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use the SAR/E (to the CA (2006/76 art 6.4)) templates developed to the Annual reporting ot the EC also at national level? | Yes |

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| 10.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level? | Yes |
| 10.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all TEs? | Yes |
| 10.5. How many tissue establishments provided in 2011 the SAR/SAE data as requested (please provide the % from the total number of TEs authorised in your country). | 70-99% |
| 10.6. Do you have a mandatory procedure for the transplantation centres when reporting SAR/SAE to the TEs which distributed the tissues/cells (Art 11.2)? | Yes |
| 10.6.1. If yes, please provide a brief description. | it is regulated by national law |
| 10.7. Do you give feedback to the TEs regarding SAR/SAE recorded at national level? | Yes |
| 10.7.1. Please specify. | each TE receives a confirmation of the notification after submitting |
| 10.8. Do you give feedback to the TEs regarding SAR/SAE recorded at EU level? | No |
| 10.8.2. Please specify why not. | currently there is no summary report of the Commission available |
| 10.9. Do you require your TEs to have a recall procedure? | Yes |
| 10.10. How many recalls related to safety and quality of tissues/cells were issued in your country in 2011? Please specify the number and which tissues were recalled and why (e.g. missing consent, quality defects etc). | there were no recalls in 2011 |
| 10.11. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites in case of a national rapid alert? | Yes |
| 10.11.1. If yes, please give a short description of the system/procedure. | all involved TE and procurement sites will be informed by email |
| 10.12. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites when a rapid alert is issued via the EU RATC platform? | Yes |
| 10.12.1. If yes, please give a short description of the system/procedure. | all involved TE and procurement sites will be informed by email |
| 10.13. Do you provide data regarding SAR/SAE to the EUROCET registry (non-mandatory reporting)? | No |
| 10.13.2. If no, please specify why not. | leck of capacity, not mandatory |
| 10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems? | Yes |
| 10.14.1. If yes, please specify which of the following systems are usually contacted. (more than 1 answer possible) | Haemovigilance<br>Pharmacovilance<br>Medical devices |
| 10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S? | Yes |
| 10.15.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (insufficient) - 2 (sufficient) 3 (good) - 4 (very good) to 5 (essential)? | 5 |
| 10.16. Do you have any additional comments on SARE reporting? | - |
| **11. Consent and personal data protection (Article 13 and 14, Directive 2004/23/EC)** | |
| 11.1. What consent system for living tissue/cell donation do you have in place within your Member State? | Explicit consent (opt-in) |
| 11.1.1. Please specify your choice of consent system for living tissue/cell donation. | Before procurement of tissues or cells the donor has to be informed about the procedure, any risks, testings etc. and has to give his consent with his signature. |
| 11.2. What consent system for deceased tissue/cell donation do you have in place within your Member State? | Presumed consent (opt-out) |
| 11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible) | Other |
| Please specify 'other'. | People who object to donation of tissues or organs after death can sign up in register. Medical personnel has to counsel this register |

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| | before any procurement of tissues or organs of deceased donors can take place. |
| 11.4. Is the consent system for deceased tissue donation the same as for organs? | Yes |
| 11.5. How is this consent verified during inspections? (more than 1 answer possible) | Analysis of documentation |
| 11.6. What measures are in place to ensure that donors/relatives/authorising persons on behalf of donors are provided with the appropriate information, as requested by Art. 13(2)? (more than 1 answer possible) | Only trained personnel is allowed to provide such information |
| 11.7. What measures are in place to ensure that both donors and recipients remain unidentifiable when access is given to third parties (Art. 14(1)). Please specify. | Usually donors are traceable by a unique donor identification number. |
| 11.8. Please specify what measures are in place to ensure that the identity of the receipient is not disclosed to the donor and vice versa. | Usually donors are traceable by a unique donor identification number. |
| 11.9. Does your national legislation allows disclosure of donor data in case of gametes donation? | No |
| 11.9.1. If no, please specify the circumstances and measures in place. | Parents will just get any necessary medical information or information regarding physical appearance of the sperm donor. However to the child the personal data of the sperm donor will be disclosed when he or she is 14 year old. |
| 11.10. Do you have any additional comments on consent and data protection? | - |
| **12. Selection, evaluation and procurement (Article 15 Directive 2004/23; Annexes I-IV Directive 2006/17)** | |
| 12.1. How do you ensure that all requirements related to the evaluation and selection of donors (except donors of reproductive cells) are respected in your country (Art. 15(1), Annex I Directive 2006/17/EC)? (more than 1 answer possible) | Inspections of TEs and procurement sites<br>Audit of documentation |
| 12.2. How do you ensure that all requirements related to the evaluation and selection of donors of reproductive cells are respected in your country (Art 15 (1), Annex III of Directive 2006/17/EC)? (more than 1 answer possible) | Inspections of ART centres<br>Audit documentation |
| 12.3. Do you have more stringent criteria for donor selection than those listed in Annex I of the Directive 2006/17/EC? | No |
| 12.4. What sources are required in your MS for the evaluation of a deceased donor of tissues/cells? (more than 1 answer possible) | Medical records of the donor |
| 12.5. Do you have more stringent criteria for selection of donors of reproductive cells than those listed in Annex III of the Directive 2006/17/EC? | No |
| 12.6. Do you have more stringent criteria for autologous donation than those listed in Annex I of the Directive 2006/17/EC? | No |
| 12.7. Do you require more information on the donation of tissues/cells than the mandatory one as laid down in the Annex of Directive 2004/23/EC (Art 15(3)? | No |
| 12.8. How do you ensure that all requirements regarding tissues and cells' procurement, packaging and transport are complied with by tissue establishments in your country (Art 15(1), Annex IV of Directive 2006/17/EC? (more than 1 answer possible)(For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)) | Inspection of tissue establishment<br>Audit of tissue establishment |
| 12.9. Do you have any additional comments on selection, evaluation and procurement? | - |
| **13. Quality management, responsible person, personnel (Article 16, 17, 18 Directive 2004/23/EC)** | |
| 13.1. How do you ensure that tissue establishments in your country have in place a quality system respecting the provisions of the | Authorisation requirement<br>Inspections |

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| Directive 2004/23/EC Art 16.1? (more than 1 answer possible). (For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)). | Internal audits<br>External audits |
| 13.2. How do you ensure that tissue establishments have a responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible) | Authorisation requirement<br>Inspections |
| 13.3. How do you ensure an appropriate training for the personnel directly involved in the activities of tissue establishments? (more than 1 answer possible) | Authorisation requirement<br>Inspections<br>Mandatory trainings |
| 13.4. Do you have national/regional/local training programmes for the personnel of tissue establishments? | No |
| 13.4.2. If no, in which country(ies) is your personnel trained? | EU countries |
| 13.4.2.1. Please specify EU-countries. | EATB training, a.s.o. |
| 13.5. Any additional comments on quality management, responsible person, personnel? | - |
| **14 Reception, processing, storage, labelling and packaging (Art 19-22 Directive 2004/23/EC)** | |
| 14.1. How do you ensure that tissue establishments in your country fulfill the requirments of the Art. 19 (Tissue and cell reception) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | National regulation/policy for reception of tissues/cells<br>Inspections of tissue establishments<br>Internal audits of tissue establishments<br>External audits of tissue establishments (e.g. ISO) |
| 14.2. How do you ensure that tissue establishments in your country fulfill the requirements of the Art. 20 (Tissue and cell processing) of Directive 2004/23/EC? (more than 1 answer possible) | SOPs for all processes affecting quality and safety are mandatory for authorisation<br>Inspections of tissue establishments<br>Internal audits of tissue establishments<br>External audits of tissue establishments (e.g. ISO) |
| 14.3. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 21 (tissue and cell storage conditions) of Directive 2004/23/EC? (more than 1 answer possible) | SOPs for procedures associated with storage of tissues and cells are mandatory for authorisation<br>Inspections of tissue establishments<br>Internal audits of tissue establishments<br>External audits of tissue establishments (e.g. ISO) |
| 14.4. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | SOPs for procedures associated with labelling and packaging are mandatory for authorisation<br>Inspections of tissue establishments<br>Internal audits of tissue establishments<br>External audits of tissue establishments(e.g. ISO) |
| 14.5. Any additional comments on reception, processing, storage, labelling and packaging? | - |
| **15. Third party agreements (Art. 24 Directive 2004/23/EC)** | |
| 15.1. Are third party agreements foreseen/allowed in your national legislation? | Yes |
| 15.1.1. If yes, have tissue establishments in your Member State notified third party agreements? | Yes |
| 15.1.1.1. Under which circumstances and for which responsibilities? | transport agreements, agreements with laboratories for laboratory testing, agreements with clinical teams (procurement) |
| 15.1.1.2. How are third party agreements controlled (Art 6.2) by the Competent Auhtority(ies) in your MS? Please specify. | during routine inspections |
| 15.2. Any additional comments on third party agreements? | - |
| **16. General comments - implementation** | |
| 16.1. Do you have at national level more stringent quality and safety requirements than those requested by the EU legislation in this field (e.g. restrictions concerning the donation/use of certain tissues/cells, mandatory unpaid donation etc.)? | Yes |
| 16.1.1. Please specify. | The donation fo egg cells or embryos is not allowed. Deceased donors have to be tested by NAT for HIV, HBV and HCV. Of all the blood samples of donors samples have to be stored at the TE for 30 years so that all laboratory tests can be repeated twice. |

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| 16.2. Has your Member State encountered any difficulties in implementing the requirements in the EU Tissues and Cells Directives? Please choose from the options below. | ART provisions |
| 16.2.1. For all selected options in question 16.2., please provide a short description. | difficulties regarding the requirements on the premisis (air grade, monitoring of air grade) |
| 16.3. In your opinion, in which of following Directives are there shortcomings (if any)? (more than 1 answer possible) | Directive 2006/17/EC<br>Directive 2006/86/EC |
| 16.3.2. How would you suggest to solve these issues in Directive 2006/17/EC? | In the case of donations of autologous living donors or partner donations where test results are positive (HIV 1, 2, Hepatitis B, C etc.) the tissues or cells should not only be stored separately (Annex I 2.1.1, Annex III 2.3) but there should also be facilities in place to ensure separate processing to eliminate the risk of cross-contamination and mix up. For deceased donors blood samples should be tested for HIV, Hepatits B and C genome by NAT. |
| 16.3.3. How would you suggest to solve these issues in Directive 2006/86/EC? | The paragraph "Annex I, D Facilities/Premises 4 (c)" should be explained and it should be clarified under which circumstances it applies. It should be defined which air quality for the environment is required if this paragraph is applicable. |

## *A.1.2. Survey response Belgium*

| **1. Public information** | |
|---|---|
| 1.1. Name of National Competent Authority (NCA) 1: | FAMHP: Federal Agency for Medicines and Health Products |
| 1.1.2. Address of NCA 1: | Eurostation building, place Victor Horta, 40/40 B – 1060 Brussels |
| 1.1.3. Telephone (central access point): | 00.32.2.524.80.00 |
| 1.1.4. E-mail (central access point): | welcome@afmps-fagg.be |
| 1.1.5. Website: | www.fagg-afmps.be |
| 1.1.6. The NCA is responsible for? (more than 1 answer possible) | Non-reproductive tissues and cells<br>Reproductive tissues and cells<br>Blood and blood components<br>Pharmaceuticals<br>Medical devices |
| 1.1.7. What are the role/tasks of the NCA? (more than 1 answer possible) | Accreditation, authorisation, licensing of TEs<br>Inspection<br>Vigilance |
| 1.2. National Competent Authority 2? | No |
| 1.5. Please give a short description of the legal status and organisation of the National Competent Authority(ies) (e.g. departments, staffing, number of senior and junior inspectors, staff working on EU affairs and legal matters, vigilance officers, budget, independence from government etc.). | The Federal Agency for Medicines and Health Products (FAMHP) (Law of 20/07/2006), a federal agency of public interest, is the competent authority in terms of quality, safety and efficacy of drugs and health Products. Our activities are divided into three branches (DG) also called "pillars". . PILLAR 1 "DG PRE authorization" manages all activities before the first authorization to market a drug or a health product . PILLAR 2 "DG POST authorization" manages all activities after the first authorization to market a drug or a health product . PILLAR 3 "DG inspection" ensures all inspection and control activities |
| 1.6. In case of MS with federal or decentralised systems, please indicate the roles/tasks of the Regional Competent Authority(ies). (more than 1 answer possible) | Not applicable |
| 1.7. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies) for tissues and cells: | / |
| **2. Procurement (Article 5 Directive 2004/23/EC)** | |
| 2.1. Do you authorise the "conditions of procurement"? | Yes |
| 2.1.1. How do you authorise the "conditions of procurement"? (more than 1 answer possible) | By inspecting the documentation associated with procurement that is available in the tissue establishment working with procurement centres |
| 2.1.2. How many such authorisations were granted in 2011 (01/01-31/12/2011)? | 27 TE's |
| 2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011). | 37 TE's |
| 2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011). | 23 TE's |
| 2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues were carried out in 2011 (01/01-31/12/2011). | 62 TE's |
| 2.2.4. Please provide the number of procurement centers in which procurement of tissues/cells for ATMP manufacturing were carried out in 2011 (01/01-31/12/2011). | 15 TE's |
| 2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC and its implementing Directive 2006/17/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) ? (more than 1 answer possible) | Analysis of the mandatory documentation |
| 2.4. Are you also responsible for the accreditation, designation, authorisation or licensing of laboratories performing donor testing? | No |

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| 2.4.2. Which National Authority is in charge of this activity? | Belgium: Scientific Institute for Public Health (WIV-ISP) |
| 2.5. How do you ensure, as CA for T&C, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art. 5(2))? (more than 1 answer possible) | Analysis of the mandatory documentation requested from the tissue establishment |
| 2.6. Please provide data on qualified laboratories accredited, authorised or licensed in your country (e.g. number, year of accreditation/authorisation/license, which donor tests are performed etc.). | The following data are available for each laboratory: Agreement number,Issue Date, Validity Date, Name Director, Type of service for which the agreement is valid, Agreement valid for 5 year maximum. |
| 2.7. Do you have any additional comments on procurement? | In Belgium, procurement is the responsibility of the TEs. There are no "procurement centers" in Belgium. “Procurement” is mentioned in the EU directive, but “procurement centers” are not mentioned nor defined in the EU Directive. Therefore, the term “procurement center” should not be used in this questionnaire. |
| **3. Testing (Art 4 Annexes I, II and III of Directive 2006/17/EC)** | |
| 3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>NAT HIV 1<br>HBs AG<br>Anti HBc<br>NAT HBV<br>Anti HCV-Ab<br>NAT HCV<br>Treponema Pallidum |
| 3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>NAT HIV 1<br>HBs AG<br>Anti HBc<br>NAT HBV<br>Anti HCV-Ab<br>NAT HCV<br>NAT Chlamydia<br>Treponema Pallidum |
| 3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to encourage its use? Please specify why or why not (e.g. number of additional cases detected, cost-benefit etc.). | NAT testing is mandatory. |
| 3.4. Do you have concerns on accuracy of the available tests and test procedures for deceased donors? | No |
| 3.5. Are any other laboratory tests required for donors of non-reproductive tissues and cells in your Member State? | No |
| 3.6. Are any other laboratory tests required for donors of reproductive tissues and cells in your Member State? | No |
| 3.7. Do you request/use international accreditation systems for testing laboratories? | No |
| 3.8. Do you have any additional comments on testing? | HTLV-1 and NAT HTLV-1 should be asked in the questionnaire, not HTLV-2. In Belgium, for living donors, NAT tests may be replaced by serology 6 months after collection/procurement of tissues or cells. |
| **4. Accreditation, designation, authorisation or licensing of tissue establishments (Article 6, Directive 2004/23/EC)** | |
| 4.1. Do you have a system of designation, authorisation, accreditation or licensing for all types of tissue establishments under your responsability? | Yes |
| 4.2. Is inspection a prerequisite for the designation, authorisation, accreditation or licensing of tissue establishments? | Yes |
| 4.2.1. How many inspections were performed in 2011 for authorising/accrediting/licensing/designating TEs? | 5 inspections as a prerequisite for the authorization of TEs |
| 4.3. Are preparation processes authorised? | Yes |
| 4.3.1. How are they authorised? (more than 1 answer possible) | During routine inspections |

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| | During inspections organised for this purpose<br>By review of a submitted application with supporting documentation |
| 4.4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were suspended in 2011? | 0 |
| 4.5. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011? | 0 |
| 4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)? | No |
| **4bis. Overview of tissue/cells establishments authorised by the NCA** | |
| 4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible): | Musculo-skeletal tissue establishments<br>HSC tissue establishments<br>ART tissue establishments<br>Other tissue establishments |
| 4.7.2. How many musculo-skeletal tissue establishments? | 1 |
| 4.7.5. How many HSC tissue establishments? | 1 |
| 4.7.7. How many ART tissue establishments? | 23 |
| 4.7.9. Please specify the type of tissues/cells and how many. | Cell Therapy 1 |
| 4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible): | ART tissue establishments |
| 4.8.7. How many ART tissue establishments? | 3 |
| 4.9. Tissue establishments first time authorised between 01/01/2011 and 31/12/2011 (more than 1 answer possible): | Musculo-skeletal tissue establishments<br>HSC tissue establishments<br>ART tissue establishments |
| 4.9.2. How many musculo-skeletal tissue establishments? | 1 |
| 4.9.5. How many HSC tissue establishments? | 1 |
| 4.9.7. How many ART tissue establishments? | 20 |
| 4.10. All tissue establishments authorised by 31/12/2011 (more than 1 answer possible): | Skin tissue establishments<br>Musculo-skeletal tissue establishments<br>Ocular tissue establishments<br>Cardiovascular tissue establishments<br>HSC tissue establishments<br>Cord blood tissue establishments<br>ART tissue establishments<br>Other tissue establishments |
| 4.10.1.1. How many public skin tissue establishments? | 3 |
| 4.10.1.2. How many private skin tissue establishments? | 0 |
| 4.10.2.1. How many public musculo-skeletal tissue establishments? | 15 |
| 4.10.2.2. How many private musculo-skeletal tissue establishments? | 0 |
| 4.10.3.1. How many public ocular tissue establishments? | 4 |
| 4.10.3.2. How many private ocular tissue establishments? | 0 |
| 4.10.4.1. How many public cardiovascular tissue establishments? | 6 |
| 4.10.4.2. How many private cardiovascular tissue establishments? | 0 |
| 4.10.5.1. How many public HSC tissue establishments? | 16 |
| 4.10.5.2. How many private HSC tissue establishments? | 0 |
| 4.10.6.1. How many public cord blood tissue establishments? | 7 |
| 4.10.6.2. How many private cord blood tissue establishments? | 1 |
| 4.10.7.1. How many public ART tissue establishments? | 62 |
| 4.10.7.2. How many private ART tissue establishments? | 0 |
| 4.10.9.1. Please specify the type of 'other' public tissues/cells establishements and how many. | Cell Therapy: 15 Keratinocytes: 3 Tympano-ossicular: 4 Amniotic membrane: 4 |
| 4.10.9.2. Please specify the type of 'other' private tissues/cells establishements and how many. | Cell Therapy: 3 |
| 4.11. How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Art. 6(5) during 2011? Please provide number(s) per type tissues/cells. | 0 |
| **4ter. Sanctions** | |
| 4.16. Have penalties for infringements of the national provisions pursuant to the Directive been defined (Article 27)? | Yes |

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| 4.16.1. Have penalties already been imposed? | No |
| 4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing? | In 2011: three new applications for an authorisation have not resulted in the granting of an authorization |
| **5. Inspections (Article 7, Directive 2004/23/EC)** | |
| 5.1. Is a system in place for organising inspections and control measures of tissue establishments? | Yes |
| 5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections. | Directorate General Inspection of FAMHP |
| 5.1.2. If yes, please specify staffing (how many inspectors). | 5 inspectors Tissues & Cells, Blood |
| 5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible) | Yes |
| 5.2.1. If yes, please specify. (more than 1 answer possible) | Blood |
| 5.3. How many routine inspections of tissue establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011)? | 40 |
| 5.3.1. How many inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) following serious adverse events or reactions, or suspicion thereof ? | 0 |
| 5.3.2. How many other type of inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | 0 |
| 5.3.3. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | 0 |
| 5.3.4. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where minor shortcomings were noted? | 40 |
| 5.3.5. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where major shortcomings were noted? | 24 |
| 5.3.6. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by suspension of authorisation? | 0 |
| 5.3.7. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by closure? | 0 |
| 5.3.8. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of other inspections carried out? Please specify. | 0 |
| 5.4. How many routine inspections were conducted in ART establishments (from 1/1/2011 to 31/12/2011)? | 29 |
| 5.4.1. How many inspections were conducted in ART establishments following serious adverse events or reactions, or suspicion thereof (from 1/1/2011 to 31/12/2011)? | 0 |
| 5.4.2. How many other type of inspections were conducted on ART establishments (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | 0 |
| 5.4.3. Outcome of inspections of ART tissue establishments carried out in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | 0 |
| 5.4.4. What was the number of inspections carried out in ART | 29 |

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| establishments where minor shortcomings were noted? | |
| 5.4.5. What was the number of inspections carried out in ART establishments where major shortcomings were noted? | 15 |
| 5.4.6. What was the number of inspections carried out in ART establishments followed by suspension of authorisation? | 0 |
| 5.4.7. What was the number of inspections carried out in ART establishments followed by closure of respective establishements? | 0 |
| 5.4.8. What was the number of other inspections of ART establishments? Please specify. | 0 |
| 5.5. Which type of routine inspections do you conduct? (more than 1 answer possible) | General system-oriented inspections<br>Thematic inspections |
| 5.6. How do you decide which type of routine inspection to conduct? | Every 2 years: a general system-oriented inspection or a thematic inspection. Every 4 years: a general system-oriented inspection for a extension of the agreement. |
| 5.7. Until 2011, did you implement the requirement concerning the time interval between two inspections (Art. 7.3.)? | Yes |
| 5.8. How many TEs were inspected at least twice between 2008-2011 (01/01/2008-31/12/2011)? | 65 |
| 5.9. Did you perform/conduct inspections of procurement sites outside tissue establishments? | Yes |
| 5.9.1. If yes, how many? | 1 |
| 5.10. Did you carry out inspections of third parties? | Yes |
| 5.10.1. If yes, how many? | 1 |
| 5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)? | Yes |
| 5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)? | Yes |
| 5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)? | 3 |
| 5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))? | No |
| 5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))? | No |
| 5.15. Did you organise any inspections of procurement centres or tissue establishments in third countries from which tissues and/or cells were imported in your country (as recorded by 31/12/2011)? | No |
| 5.16. Have you asked another MS, or have you been requested by any other MS, on the results and control measures of your inspections, as part of an enquiry/investigation? | No |
| 5.17. Would you be interested in developing joint inspections? Joint inspections should be understood as inspections of tissue establishments conducted jointly by two or more Member States' Competent Authorities on their territory or in third countries. | Yes |
| 5.18. Do you have any additional comments on inspections? | |
| **6. Import/export (Article 9 Directive 2004/23/EC)** | |
| 6.1. Do you have a register of authorised tissue establishments that are explicitly authorised to perform import/export of tissues and celles from/to third countries? | Yes |
| 6.2. Please specify the number of tissue establishments authorised to import tissues and cells from third countries (recorded by 31/12/2011). | 69 |
| 6.3. Please specify the number of tissue establishments authorised to export tissues and cells from third countries (recorded by 31/12/2011). | 69 |

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| 6.4. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of skin from third countries. | The import of skin is restricted to the TEs authorized for skin tissues. The importing TEs are responsible for verifying the equivalent standards of quality and safety. |
| 6.5. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of musculo-skeletal (bone, tendons, fascia etc.) tissues from third countries. | The import of musculoskeletal tissues is restricted to the TEs authorized for musculoskeletal tissues. The importing TEs are responsible for verifying the equivalent standards of quality and safety. |
| 6.6. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of ophtalmic (cornea, sclera, etc) tissues from third countries. | The import of ophtalmic tissues is restricted to the TEs authorized for ophtalmic tissues. The importing TEs are responsible for verifying the equivalent standards of quality and safety |
| 6.7. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cardio vascular tissues from third countries. | The import of cardiovascular tissues is restricted to the TEs authorized for cardiovascular tissues. The importing TEs are responsible for verifying the equivalent standards of quality and safety |
| 6.8. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) (other than cord blood) from third countries. | The import of HSC is restricted to the TEs authorized for HSC. The importing TEs are responsible for verifying the equivalent standards of quality and safety |
| 6.9. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cord blood from third countries. | The import of cord blood is restricted to the TEs authorized for cord blood or HSC. The importing TEs are responsible for verifying the equivalent standards of quality and safety. |
| 6.10. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of reproductive cells (sperm, egg cells) from third countries. | The import of reproductive cells is restricted to a& limited number of TEs authorized for reproductive cells. The importing TEs are responsible for verifying the equivalent standards of quality and safety. |
| 6.11. Did you import tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | Yes |
| 6.11.1. If yes, please provide the data concerning the number/volume of imported tissues and cells by country of origin. | Import to Belgium Type Units Country<br>Hematopoietic stem cells 23 USA - Australia<br>Musculo-skeletal tissue 159 USA |
| 6.12. Did you export tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | Yes |
| 6.12.1. If yes, please provide the data concerning the number/volume of exported tissues and cells by country of destination. | Export from Belgium: Hematopoietic stem cells: 41 USA; Cardiac valve: 1 New Zealand; Cord blodd: 9 USA, Canada, Australia; Sperm: 9 Koweit |
| 6.13. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on imports/exports of tissues/cells between your country and other third countries? | No |
| 6.14. What is the relation between import/export of tissues and cells and self-sufficiency? (more than 1 answer possible) | C. Export of tissues/cells is authorised irrespective of national needs |
| 6.15. Did you authorise direct imports of tissues/cells to hospitals/clinics in your country? | No |
| 6.16. Do you have any additional comments on import/export? | |
| **7. Distribution/intra community exchanges (Article 23 Directive 2004/23/EC)** | |
| 7.1. Do you have intra-community exchanges of tissues and cells? | Yes |
| 7.1.1. If yes, how do you address the possible more stringent quality and safety measures established by other Member States? Please specify. | The country that imports verifies that the criteria of quality and safety are in line with national legislation. |
| 7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States? | Yes |
| 7.1.2.1. How do you address this difference for tissues and cells coming from a MS with minimum quality requirements? Please specify. | All tissues and cells coming from another MS needs to be in line with the Belgium law |
| 7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify. | By inspection |
| 7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible). | Yes, no restrictions apply |
| 7.4. Have you authorised direct distribution to the recipient of specific tissues and cells (Art. 6, Directive 2006/17/EC)? | No |

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| 7.5. Do you collect data regarding the cross-border exchange of tissue/cells between your country and other EU MS? | Yes |
| 7.5.1. Please provide us with data (country of destination, type of tissue/cell and number of units distributed) concerning distribution to other MS in 2011 (01/01/2011-31/12/2011). | Hematopoietic stem cells: 11 units , Ireland, Germany Sperm: 46 (straw), The Netherlands, France, Spain, Danemark, Germany Embryo: 43, Spain, United Kingdom Cardiac valve: 170, France, germany, Luxembourg, Austria, The Netherlands, Lettonia, Slovenia,Switzerland Ocular tissue: 33, ? Cord Blood: 35,The Netherlands, Spain, France, United Kingdom, Sweden, Denmark, Germany, Italy,Hungary |
| 7.5.2. Please provide us with data (country of origin, type of tissue/cell and number of units distributed) concerning distribution to other MS in 2011 (01/01/2011-31/12/2011) | Hematopoietic stem cells: 91, Germany,United kingdom, Spain, The Nederlands, Germany, Italy, Portugal, France Sperm: 7824 (straw), Denmark, Italy, Germany, France, Spain, The Nederlands Oocyte: 760, The Nederlands Embryo: 28, Spain, United Kingdom Male gonad: 89, The Nederlands Cardiac valve: 128, Luxembourg, france, Germany, Switzerland Ocular tissue: 129, france, The Nederlands Cord blood: 2, Spain, Italy |
| 7.6. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on cross-border exchanges of tissues/cells between your country and other EU MS? | No |
| 7.7. Do you allow brokerage companies for either distribution in EU and/or import/export of tissues/cells? In this context, a brokerage company means a body that arranges transactions between a supplier (tissue establishment/company selling tissues or cells) and a buyer (a tissue establishment/a hospital or clinic/an individual) without undertaking activities of processing, preservation or storage. | No |
| 7.8. Are brokers actively supplying health professionals/establishments in your country? | No |
| 7.9. Do you have any additional comments on distribution? | |
| **8. Register of tissue establishments and reporting obligations (Article 10, Directive 2004/23/EC)** | |
| 8.1. Do you have an annual report model/template on the activities of tissue establishments in your Member State? (Article 10(1)). If yes, please upload the template. | Yes |
| 8.2. How many tissue establishments submitted annual reports of their activities during 2011. Please provide an estimation. (1 answer possible) | 100% (all) |
| 8.3. Are these reports publicly available? (Article 10(1)) | Yes |
| 8.3.1. If yes, please insert the link(s) to the report(s). | www.fagg-afmps.be |
| 8.4. Do you publish a national annual report of the consolidated activities of all tissue establishments in your country? | Yes |
| 8.4.1. Please insert the link to the published national annual report. | www.fagg-afmps.be |
| 8.5. Is there a publicly accessible register of authorised tissue establishements in place? (Article 10(2)) | Yes |
| 8.5.1. If yes, please provide us with the link to the register's web site. | www.fagg-afmps.be |
| 8.6. Do you provide data regarding tissues and cells activities to the EUROCET registry (non-mandatory reporting)? | Yes |
| 8.6.1. If yes, what data are provided to EUROCET? Please specify. | The data requested by Eurocet and that are reported in the annual report from each TE |
| 8.7. Do you have any additional comments on reporting? | |
| **9. Traceability (Article 8, Directive 2004/23/EC; and Directive 2006/86/EC)** | |
| 9.1. Was the donor identification system (Art. 8(2)) implemented in your country? | Yes |
| 9.2. Who assigns the unique code for each donation? (only 1 answer possible) | Tissue establishment |
| 9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible) | Both paper records and electronic forms |
| 9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify. | In the law and during inspection. |
| 9.5. Do you have any additional comments on traceability? | |
| **10. Notification of serious adverse events and reactions (Article 11 Directive 2004/23, Article 6 Directive 2006/76)** | |
| 10.1. Do you have a national vigilance system in place (for the | Yes |

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| reporting of serious adverse events and reactions (Article 11(1))? | |
| 10.1.1. If yes, which CA/institution is responsible? | FAMHP |
| 10.1.2. If yes, please provide a short description of its organisation. | Establishments responsible for the application of tissues and cells have to report to the biovigilance cell of the FAMHP and to the supplying tissue establishment serious adverse reactions and serious adverse events concerning to human tissues and cells. Tissue establishments have also to report the SARs and SAEs including SARs in living donors and SAEs that may influence the quality and safety of thee tissues and cells. Furthermore, standard notification forms, definitions and instructions for use were elaborated and distributed by the FAMHP. |
| 10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use the SAR/E (to the CA (2006/76 art 6.4)) templates developed to the Annual reporting ot the EC also at national level? | No |
| 10.2.1. If no, what template do you use? You are welcome to upload the template if you wish. | The template used in point 8.1 |
| 10.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level? | Yes |
| 10.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all TEs? | Yes |
| 10.5. How many tissue establishments provided in 2011 the SAR/SAE data as requested (please provide the % from the total number of TEs authorised in your country). | 100% |
| 10.6. Do you have a mandatory procedure for the transplantation centres when reporting SAR/SAE to the TEs which distributed the tissues/cells (Art 11.2)? | Yes |
| 10.6.1. If yes, please provide a brief description. | see point 10.2.1 |
| 10.7. Do you give feedback to the TEs regarding SAR/SAE recorded at national level? | Yes |
| 10.7.1. Please specify. | When necessary specific information notes are distributed to all or the concerned part of the tissue establishments |
| 10.8. Do you give feedback to the TEs regarding SAR/SAE recorded at EU level? | Yes |
| 10.8.1. Please specify. | When necessary specific information notes are distributed to all or the concerned part of the tissue establishments |
| 10.9. Do you require your TEs to have a recall procedure? | Yes |
| 10.10. How many recalls related to safety and quality of tissues/cells were issued in your country in 2011? Please specify the number and which tissues were recalled and why (e.g. missing consent, quality defects etc). | No recalls in 2011. |
| 10.11. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites in case of a national rapid alert? | Yes |
| 10.11.1. If yes, please give a short description of the system/procedure. | When necessary specific information notes are distributed to all or to the concerned part of the tissue establishments |
| 10.12. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites when a rapid alert is issued via the EU RATC platform? | Yes |
| 10.12.1. If yes, please give a short description of the system/procedure. | When necessary specific information notes are distributed to all or to the concerned part of the tissue establishments |
| 10.13. Do you provide data regarding SAR/SAE to the EUROCET registry (non-mandatory reporting)? | Yes |
| 10.13.1. If yes, please specify what data. | N.A. |
| 10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems? | Yes |
| 10.14.1. If yes, please specify which of the following systems are usually contacted. (more than 1 answer possible) | Medical devices |
| 10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S? | No |

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| 10.15.2. If no, please specify why not. | We are convinced of the value of this training. We would have liked to send a new vigilance officer, but the selection procedure for this one still running. And for the current biovigilance officer the training was not useful |
| 10.16. Do you have any additional comments on SARE reporting? | |
| **11. Consent and personal data protection (Article 13 and 14, Directive 2004/23/EC)** | |
| 11.1. What consent system for living tissue/cell donation do you have in place within your Member State? | Explicit consent (opt-in) |
| 11.1.1. Please specify your choice of consent system for living tissue/cell donation. | The presumed consent is the basis, the explicit consent allows – in addition to the presumed consent - to express ones consent explicitly. |
| 11.2. What consent system for deceased tissue/cell donation do you have in place within your Member State? | Presumed (opt-out) and explicit (opt-in) consent |
| 11.2.1. If you have chosen both consent systems for deceased tissue/cell dontation, please specify. | The presumed consent is the basis, the explicit consent allows – in addition to the presumed consent - to express ones consent explicitly. |
| 11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible) | No further authorisation is needed |
| 11.4. Is the consent system for deceased tissue donation the same as for organs? | Yes |
| 11.5. How is this consent verified during inspections? (more than 1 answer possible) | Analysis of documentation<br>Interviews with personnel |
| 11.6. What measures are in place to ensure that donors/relatives/authorising persons on behalf of donors are provided with the appropriate information, as requested by Art. 13(2)? (more than 1 answer possible) | Only trained personnel is allowed to provide such information |
| 11.7. What measures are in place to ensure that both donors and recipients remain unidentifiable when access is given to third parties (Art. 14(1)). Please specify. | A unique donor identification system is implemented, assigning after procurement or (at the latest) at reception in the tissue establishment a unique code to each donation and to each human body material collected in order to guarantee donor identification and traceability of all human body materiel.The identity of the donor may not be disclosed to third parties. Assigning of the identification code is the responsibility of the responsible person. The inspector controls the information over the code during the inspection. |
| 11.8. Please specify what measures are in place to ensure that the identity of the receipient is not disclosed to the donor and vice versa. | The necessary steps are taken to ensure that in allogenic donation, data on the (s) recipient (s), including genetic data, which could identify the recipient cannot be accessed by third parties. The necessary steps are taken to ensure that in allogenic donation, the identity of the recipient is not disclosed to the donor or his family and vice versa. The inspector controls the different steps taken to respond to these obligation during the inspection |
| 11.9. Does your national legislation allows disclosure of donor data in case of gametes donation? | No |
| 11.9.1. If no, please specify the circumstances and measures in place. | If yes instead of no. |
| 11.10. Do you have any additional comments on consent and data protection? | |
| **12. Selection, evaluation and procurement (Article 15 Directive 2004/23; Annexes I-IV Directive 2006/17)** | |
| 12.1. How do you ensure that all requirements related to the evaluation and selection of donors (except donors of reproductive cells) are respected in your country (Art. 15(1), Annex I Directive 2006/17/EC)? (more than 1 answer possible) | Inspections of TEs and procurement sites |
| 12.2. How do you ensure that all requirements related to the evaluation and selection of donors of reproductive cells are respected in your country (Art 15 (1), Annex III of Directive 2006/17/EC)? (more than 1 answer possible) | Inspections of ART centres |
| 12.3. Do you have more stringent criteria for donor selection than those listed in Annex I of the Directive 2006/17/EC? | Yes |
| 12.3.1. If yes, please specify. | One extra selection criterium: “persons that have undergone |

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| | documented or undocumented neurosurgery |
| 12.4. What sources are required in your MS for the evaluation of a deceased donor of tissues/cells? (more than 1 answer possible) | Interview with the donor's family or a person who knew the donor well<br>Medical records of the donor<br>Interview with the treating physician<br>Interview with the general practitioner<br>Autopsy report<br>Other |
| Please specify 'other'. | A physical examination of the body |
| 12.5. Do you have more stringent criteria for selection of donors of reproductive cells than those listed in Annex III of the Directive 2006/17/EC? | Yes |
| 12.5.1. Please specify. | Test for Treponema Pallidum |
| 12.6. Do you have more stringent criteria for autologous donation than those listed in Annex I of the Directive 2006/17/EC? | No |
| 12.7. Do you require more information on the donation of tissues/cells than the mandatory one as laid down in the Annex of Directive 2004/23/EC (Art 15(3)? | No |
| 12.8. How do you ensure that all requirements regarding tissues and cells' procurement, packaging and transport are complied with by tissue establishments in your country (Art 15(1), Annex IV of Directive 2006/17/EC? (more than 1 answer possible)(For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)) | Inspection of tissue establishment |
| 12.9. Do you have any additional comments on selection, evaluation and procurement? | |
| **13. Quality management, responsible person, personnel (Article 16, 17, 18 Directive 2004/23/EC)** | |
| 13.1. How do you ensure that tissue establishments in your country have in place a quality system respecting the provisions of the Directive 2004/23/EC Art 16.1? (more than 1 answer possible). (For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)). | Inspections |
| 13.2. How do you ensure that tissue establishments have a responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible) | Authorisation requirement<br>Inspections |
| 13.3. How do you ensure an appropriate training for the personnel directly involved in the activities of tissue establishments? (more than 1 answer possible) | Inspections |
| 13.4. Do you have national/regional/local training programmes for the personnel of tissue establishments? | Yes |
| 13.4.1. If yes, please specify. | The TE has a training for his personnel. It is checked during the inspection. |
| 13.5. Any additional comments on quality management, responsible person, personnel? | |
| **14. Reception, processing, storage, labelling and packaging (Art 19-22 Directive 2004/23/EC)** | |
| 14.1. How do you ensure that tissue establishments in your country fulfill the requirments of the Art. 19 (Tissue and cell reception) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | Inspections of tissue establishments |
| 14.2. How do you ensure that tissue establishments in your country fulfill the requirements of the Art. 20 (Tissue and cell processing) of Directive 2004/23/EC? (more than 1 answer possible) | Inspections of tissue establishments |

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| 14.3. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 21 (tissue and cell storage conditions) of Directive 2004/23/EC? (more than 1 answer possible) | Inspections of tissue establishments |
| 14.4. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | Inspections of tissue establishments |
| 14.5. Any additional comments on reception, processing, storage, labelling and packaging? | |
| **15. Third party agreements (Art. 24 Directive 2004/23/EC)** | |
| 15.1. Are third party agreements foreseen/allowed in your national legislation? | Yes |
| 15.1.1. If yes, have tissue establishments in your Member State notified third party agreements? | Yes |
| 15.1.1.1. Under which circumstances and for which responsibilities? | Agreements between institutions and third parties must comply with the Belgian legislation. Agreements with third parties must specify the terms of cooperation and responsibility, as well as the protocols to be followed to meet the performance requirements. |
| 15.1.1.2. How are third party agreements controlled (Art 6.2) by the Competent Auhtority(ies) in your MS? Please specify. | The agreement between the TE and the third party are seen during the inspections of tissue establishments and if needed, an inspection takes place of the third party. Copies of the agreements have also to be sent to the FAMHP. |
| 15.2. Any additional comments on third party agreements? | |
| **16. General comments - implementation** | |
| 16.1. Do you have at national level more stringent quality and safety requirements than those requested by the EU legislation in this field (e.g. restrictions concerning the donation/use of certain tissues/cells, mandatory unpaid donation etc.)? | Yes |
| 16.1.1. Please specify. | NAT Tests for HIV1, HBV and HCV. |
| 16.2. Has your Member State encountered any difficulties in implementing the requirements in the EU Tissues and Cells Directives? Please choose from the options below. | Import-export |
| 16.2.1. For all selected options in question 16.2., please provide a short description. | How to force a TE in an other EU member state to meet the extra Belgian law requirements if that TE distributes tissues or cells directly to a hospital in Belgium |
| 16.3. In your opinion, in which of the following Directives are there shortcomings (if any)? (more than 1 answer possible) | Directive 2006/17/EC |
| 16.3.2. How would you suggest to solve these issues in Directive 2006/17/EC? | Annexes II and III: the requirement “HTLV-I antibody testing must be performed for donors living in or originating from high-incidence areas or with sexual partners originating from those areas or where the donor’s parents originate from those areas;” For some tissues /cells this requirement should be modified, because unnecessary (see ECDC document). |

### *A.1.3. Survey response Bulgaria*

| **1. Public information** | |
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| 1.1. Name of National Competent Authority (NCA) 1: | Bulgarian Executive Agency for Tansplantation |
| 1.1.2. Address of NCA 1: | 1202 Sofia, Bulgaria, 112 Bratia Miladinovi Str. |
| 1.1.3. Telephone (central access point): | tel.: +359 2 813 50 10, fax: +359 2 931 61 51 |
| 1.1.4. E-mail (central access point): | iat@bgtransplant.bg |
| 1.1.5. Website: | www.bgtransplant.bg |
| 1.1.6. The NCA is responsible for? (more than 1 answer possible) | Non-reproductive tissues and cells<br>Reproductive tissues and cells<br>Human organs |
| 1.1.7. What are the role/tasks of the NCA? (more than 1 answer possible) | Accreditation, authorisation, licensing of TEs<br>Inspection<br>Vigilance |
| 1.2. National Competent Authority 2? | No |
| 1.5. Please give a short description of the legal status and organisation of the National Competent Authority(ies) (e.g. departments, staffing, number of senior and junior inspectors, staff working on EU affairs and legal matters, vigilance officers, budget, independence from government etc.). | The Executive Agency for Transplantation is a public body, second rank budget operator. The overall budget: 312000 Euro Number of staff of the Executive Agency for Transplantation - 30 positions Executive Director - 1 Deputy Executive Director-1 General Secretary -1 Security Officer of information -1 General Administration : Department "Financial,-economic and administrative activity "- 6 positions Specialized Administration: Department "Registers, information, control and development of transplant"-20 positions Staff working on EU affairs and legal matters: 5 persons but not fully engaged in the EU activity Number of fully engaged inspectors-2 Number of Senior experts - 3. Their responsibilities also include inspection activities. Number of Junior experts - 3. Their responsibilities also include inspection activities. Vigilance officers - We have not such a position. This activities is also included in the responsibilities of all experts and inspectors. |
| 1.6. In case of MS with federal or decentralised systems, please indicate the roles/tasks of the Regional Competent Authority(ies). (more than 1 answer possible) | Not applicable |
| 1.7. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies) for tissues and cells: | There are no Regional CAs. It is a centralized system by Executive Agency for Transplantation. |
| **2. Procurement (Article 5 Directive 2004/23/EC)** | |
| 2.1. Do you authorise the "conditions of procurement"? | Yes |
| 2.1.1. How do you authorise the "conditions of procurement"? (more than 1 answer possible) | By inspecting all procurement centres<br>By inspecting the documentation associated with procurement that is available in the tissue establishment working with procurement centres<br>Other |
| Please specify 'other': | The authorisation is given by Ministry of Health for hospitals and by Regional Health Inspections for outpatient health establishments. |
| 2.1.2. How many such authorisations were granted in 2011 (01/01-31/12/2011)? | 5 |
| 2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011). | 5 |
| 2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011). | 13 |
| 2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues were carried out in 2011 (01/01-31/12/2011). | 26 |
| 2.2.4. Please provide the number of procurement centers in which procurement of tissues/cells for ATMP manufacturing were carried out in 2011 (01/01-31/12/2011). | We couldnt provide the data. ATMP is out of our competence. It is within the scope of Drug Agency. |

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| 2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC and its implementing Directive 2006/17/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) ? (more than 1 answer possible) | Inspections of the site/centre<br>Analysis of the mandatory documentation |
| 2.4. Are you also responsible for the accreditation, designation, authorisation or licensing of laboratories performing donor testing? | No |
| 2.4.2. Which National Authority is in charge of this activity? | This accreditation is done by Bulgarian Service for Accreditation. |
| 2.5. How do you ensure, as CA for T&C, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art. 5(2))? (more than 1 answer possible) | Analysis of the mandatory documentation requested from the tissue establishment |
| 2.6. Please provide data on qualified laboratories accredited, authorised or licensed in your country (e.g. number, year of accreditation/authorisation/license, which donor tests are performed etc.). | We could not provide such data because we do not maintain such registry but every TE is obliged to have a contract agreement only with qualified accredited laboratories. We inspect the relevant documentation at site |
| 2.7. Do you have any additional comments on procurement? | |
| **3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)** | |
| 3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>HBs AG<br>Anti HBc<br>Anti HCV-Ab<br>Treponema Pallidum |
| 3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>HBs AG<br>Anti HBc<br>Anti HCV-Ab<br>NAT Chlamydia<br>Treponema Pallidum |
| 3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to encourage its use? Please specify why or why not (e.g. number of additional cases detected, cost-benefit etc.). | NAT testing is mandatory for Chlamydia in case of reproductive tissues and cells. It is recommended that HIV1/2, HBV and HCV are tested via NAT. |
| 3.4. Do you have concerns on accuracy of the available tests and test procedures for deceased donors? | No |
| 3.5. Are any other laboratory tests required for donors of non-reproductive tissues and cells in your Member State? | Yes |
| 3.5.1. Please specify. | CMV antibody, EBV antibodies and Toxoplasma antibodies are required in immunosuppressed patients. Testing for antibodies to HTLV-I is performed for donors who were born or lived in areas with high risk or have sexual partners originating from those regions, as well as the donor's parents are from such regions. When Anti HBc is positive and HBsAg is negative, TEs are obliged to conduct additional studies to assess the risk and to establish eligibility for clinical use. Scientifically validated algorithm for testing is applied for the exclusion of active infection with Treponema pallidum. Non-reactive specific or non-specific test can allow tissues to be released. When performing a non-specific test positive result will not prevent the taking or release if a specific Treponema test is negative. Donors by whom Treponema specific test is positive, require a thorough risk assessment to determine eligibility for clinical use. In some circumstances, further studies are carried out according to the medical record of the donor and the characteristics of the donations (E.g. RhD, HLA, malaria, CMV, toxoplasma, EBV, Trypanosoma cruzi. |
| 3.6. Are any other laboratory tests required for donors of reproductive tissues and cells in your Member State? | Yes |
| 3.6.1. Please specify. | Testing for antibodies to HTLV-I is performed for donors who were born or lived in areas with high risk or have sexual partners |

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| | originating from those regions, as well as the donor's parents are from such regions. Further testing for malaria, CMV, RhD, Tripanosoma cruzi are required if a history of foreign travel or the presence of other risk factors for these diseases. The anonymous donor is performed genetic screening for common autosomal recessive genetic disease in ethnicity, which requires it, or ancestry with genetic problems. Genetic screening is performed after written informed consent of the donor. Recipients are fully informed about the risks of transmission of genetic diseases and the measures to reduce the risk of them. |
| 3.7. Do you request/use international accreditation systems for testing laboratories? | No |
| 3.8. Do you have any additional comments on testing? | |
| **4. Accreditation, designation, authorisation or licensing of tissue establishments (Article 6, Directive 2004/23/EC)** | |
| 4.1. Do you have a system of designation, authorisation, accreditation or licensing for all types of tissue establishments under your responsability? | Yes |
| 4.2. Is inspection a prerequisite for the designation, authorisation, accreditation or licensing of tissue establishments? | Yes |
| 4.2.1. How many inspections were performed in 2011 for authorising/accrediting/licensing/designating TEs? | 14 |
| 4.3. Are preparation processes authorised? | Yes |
| 4.3.1. How are they authorised? (more than 1 answer possible) | During routine inspections<br>By review of a submitted application with supporting documentation |
| 4.4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were suspended in 2011? | There were no licenses suspended. |
| 4.5. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011? | There were no licenses revoked. |
| 4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)? | No |
| **4bis. Overview of tissue/cells establishments authorised by the NCA** | |
| 4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible): | Cord blood tissue establishments |
| 4.7.6. How many cord blood tissue establishments? | 1 |
| 4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible): | Multi-tissue establishments |
| 4.8.8. How many multi-tissue establishments? | 1 |
| 4.9. Tissue establishments first time authorised between 01/01/2011 and 31/12/2011 (more than 1 answer possible): | Cord blood tissue establishments<br>ART tissue establishments<br>Multi-tissue establishments |
| 4.9.6. How many cord blood tissue establishments? | 2 |
| 4.9.7. How many ART tissue establishments? | 11 |
| 4.9.8. How many multi-tissue establishments? | 1 |
| 4.10. All tissue establishments authorised by 31/12/2011 (more than 1 answer possible): | Musculo-skeletal tissue establishments<br>Ocular tissue establishments<br>HSC tissue establishments<br>Cord blood tissue establishments<br>ART tissue establishments<br>Multi-tissue establishments |
| 4.10.2.1. How many public musculo-skeletal tissue establishments? | 0 |
| 4.10.2.2. How many private musculo-skeletal tissue establishments? | 1 |
| 4.10.3.1. How many public ocular tissue establishments? | 0 |
| 4.10.3.2. How many private ocular tissue establishments? | 1 |
| 4.10.5.1. How many public HSC tissue establishments? | 2 |
| 4.10.5.2. How many private HSC tissue establishments? | 5 |
| 4.10.6.1. How many public cord blood tissue establishments? | 1 |
| 4.10.6.2. How many private cord blood tissue establishments? | 5 |
| 4.10.7.1. How many public ART tissue establishments? | 2 |

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| 4.10.7.2. How many private ART tissue establishments? | 24 |
| 4.10.8.1. How many public multi-tissue establishments? | 1 |
| 4.10.8.2. How many private multi-tissue establishments? | 2 |
| 4.11. How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Art. 6(5) during 2011? Please provide number(s) per type tissues/cells. | None |
| **4ter. Sanctions** | |
| 4.16. Have penalties for infringements of the national provisions pursuant to the Directive been defined (Article 27)? | Yes |
| 4.16.1. Have penalties already been imposed? | No |
| 4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing? | |
| **5. Inspections (Article 7, Directive 2004/23/EC)** | |
| 5.1. Is a system in place for organising inspections and control measures of tissue establishments? | Yes |
| 5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections. | In the Department "Registers, information, control and development of transplant" there is a unit of two fully engaged inspectors. In addition there are 3 senior and 2 junior experts whose responsibilities include inspections. |
| 5.1.2. If yes, please specify staffing (how many inspectors). | 7 |
| 5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible) | Yes |
| 5.2.1. If yes, please specify. (more than 1 answer possible) | Organs<br>Hospitals |
| 5.3. How many routine inspections of tissue establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011)? | 10 |
| 5.3.1. How many inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) following serious adverse events or reactions, or suspicion thereof ? | 0 |
| 5.3.2. How many other type of inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | 2 |
| 5.3.3. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | 1 |
| 5.3.4. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where minor shortcomings were noted? | 9 |
| 5.3.5. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where major shortcomings were noted? | 0 |
| 5.3.6. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by suspension of authorisation? | 0 |
| 5.3.7. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by closure? | 0 |
| 5.3.8. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of other inspections carried out? Please specify. | 0 |

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| 5.4. How many routine inspections were conducted in ART establishments (from 1/1/2011 to 31/12/2011)? | 18 |
| 5.4.1. How many inspections were conducted in ART establishments following serious adverse events or reactions, or suspicion thereof (from 1/1/2011 to 31/12/2011)? | 3 |
| 5.4.2. How many other type of inspections were conducted on ART establishments (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | 2 |
| 5.4.3. Outcome of inspections of ART tissue establishments carried out in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | 3 |
| 5.4.4. What was the number of inspections carried out in ART establishments where minor shortcomings were noted? | 12 |
| 5.4.5. What was the number of inspections carried out in ART establishments where major shortcomings were noted? | 3 |
| 5.4.6. What was the number of inspections carried out in ART establishments followed by suspension of authorisation? | 0 |
| 5.4.7. What was the number of inspections carried out in ART establishments followed by closure of respective establishements? | 0 |
| 5.4.8. What was the number of other inspections of ART establishments? Please specify. | 0 |
| 5.5. Which type of routine inspections do you conduct? (more than 1 answer possible) | General system-oriented inspections<br>Thematic inspections |
| 5.6. How do you decide which type of routine inspection to conduct? | It depends on the risk assessment of the TE activities. |
| 5.7. Until 2011, did you implement the requirement concerning the time interval between two inspections (Art. 7.3.)? | Yes |
| 5.8. How many TEs were inspected at least twice between 2008-2011 (01/01/2008-31/12/2011)? | 9 |
| 5.9. Did you perform/conduct inspections of procurement sites outside tissue establishments? | Yes |
| 5.9.1. If yes, how many? | 4 |
| 5.10. Did you carry out inspections of third parties? | Yes |
| 5.10.1. If yes, how many? | 2 |
| 5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)? | Yes |
| 5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)? | Yes |
| 5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)? | 5 |
| 5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))? | No |
| 5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))? | Yes |
| 5.14.1. Could you please explain why? | The Bulgarian TE for this period was subsidiary of French TE. French competent authorities asked Bulgarian competent authorities for conducting a joint general inspection. |
| 5.15. Did you organise any inspections of procurement centres or tissue establishments in third countries from which tissues and/or cells were imported in your country (as recorded by 31/12/2011)? | No |
| 5.16. Have you asked another MS, or have you been requested by any other MS, on the results and control measures of your inspections, as part of an enquiry/investigation? | No |
| 5.17. Would you be interested in developing joint inspections? Joint inspections should be understood as inspections of tissue | Yes |

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| establishments conducted jointly by two or more Member States' Competent Authorities on their territory or in third countries. | |
| 5.18. Do you have any additional comments on inspections? | |
| **6. Import/export (Article 9 Directive 2004/23/EC)** | |
| 6.1. Do you have a register of authorised tissue establishments that are explicitly authorised to perform import/export of tissues and celles from/to third countries? | Yes |
| 6.2. Please specify the number of tissue establishments authorised to import tissues and cells from third countries (recorded by 31/12/2011). | 0 |
| 6.3. Please specify the number of tissue establishments authorised to export tissues and cells from third countries (recorded by 31/12/2011). | 1 |
| 6.4. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of skin from third countries. | We don't have specific procedure for skin but the import of skin should meet the general requirements for diceased donors according to our Law of the Transplatation of Organs, Tissues and Cells and two ordinances: Ordinance 6 on establishing medical standards for organ transplants, tissues and cells and Ordinance 13 on the terms to be met by the quality of tissues and cells under international exchanges for the needs of the Republic of Bulgaria. |
| 6.5. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of musculo-skeletal (bone, tendons, fascia etc.) tissues from third countries. | We don't have specific procedure for musculo-skeletal tissues but the import of bone, tendons, fascia should meet the general requirements for diceased donors according to our Law of the Transplatation of Organs, Tissues and Cells and two ordinances: Ordinance 6 on establishing medical standards for organ transplants, tissues and cells and Ordinance 13 on the terms to be met by the quality of tissues and cells under international exchanges for the needs of the Republic of Bulgaria. |
| 6.6. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of ophtalmic (cornea, sclera, etc) tissues from third countries. | We don't have specific procedure for ophtalmic tissues but their import should meet the general requirements for diceased donors according to our Law of the Transplatation of Organs, Tissues and Cells and two ordinances: Ordinance 6 on establishing medical standards for organ transplants, tissues and cells and Ordinance 13 on the terms to be met by the quality of tissues and cells under international exchanges for the needs of the Republic of Bulgaria. |
| 6.7. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cardio vascular tissues from third countries. | We don't have specific procedure for cardio vascular tissues but their import should meet the general requirements for diceased donors according to our Law of the Transplatation of Organs, Tissues and Cells and two ordinances: Ordinance 6 on establishing medical standards for organ transplants, tissues and cells and Ordinance 13 on the terms to be met by the quality of tissues and cells under international exchanges for the needs of the Republic of Bulgaria. |
| 6.8. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) (other than cord blood) from third countries. | We don't have specific procedure for haematopoietic stem cells (HSC) but their import should meet the general requirements for living donors according to our Law of the Transplatation of Organs, Tissues and Cells and two ordinances: Ordinance 6 on establishing medical standards for organ transplants, tissues and cells and Ordinance 13 on the terms to be met by the quality of tissues and cells under international exchanges for the needs of the Republic of Bulgaria. |
| 6.9. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cord blood from third countries. | We don't have specific procedure for cord blood but their import should meet the general requirements for living donors according to our Law of the Transplatation of Organs, Tissues and Cells and two ordinances: Ordinance 6 on establishing medical standards for organ transplants, tissues and cells and Ordinance 13 on the terms to be met by the quality of tissues and cells under international exchanges for the needs of the Republic of Bulgaria. |
| 6.10. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of reproductive cells (sperm, egg cells) from third countries. | We don't have specific procedure for cord blood but their import should meet the general requirements for living donors according to our Law of the Transplatation of Organs, Tissues and Cells and two ordinances: Ordinance 28 on activities of assisted reproduction and |

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| | Ordinance 13 on the terms to be met by the quality of tissues and cells under international exchanges for the needs of the Republic of Bulgaria. |
| 6.11. Did you import tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | No |
| 6.12. Did you export tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | No |
| 6.13. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on imports/exports of tissues/cells between your country and other third countries? | No |
| 6.14. What is the relation between import/export of tissues and cells and self-sufficiency? (more than 1 answer possible) | A. Export of tissues/cells is authorised only after checking that local/national needs are fulfilled.<br>B. Export of tissues/cells is authorised based on estimations performed on an annual basis<br>D. Import of tissues/cells is authorised only after checking that local/national needs are not fulfilled<br>E. Import of tissues/cells is authorised based on estimations showing that there is chronic deficiency of those tissues/cells |
| 6.14.1. If A or D were selected, please explain how you quantify local/national needs. | After the assessment and the written conclusions made by the head of the public multi-tissue bank we release or not tissues and cells for import or export.. |
| 6.15. Did you authorise direct imports of tissues/cells to hospitals/clinics in your country? | No |
| 6.16. Do you have any additional comments on import/export? | |
| **7. Distribution/intra community exchanges (Article 23 Directive 2004/23/EC)** | |
| 7.1. Do you have intra-community exchanges of tissues and cells? | Yes |
| 7.1.1. If yes, how do you address the possible more stringent quality and safety measures established by other Member States? Please specify. | We try immediately to fulfil the stringent quality and safety measures established by other MS |
| 7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States? | No |
| 7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify. | We demand licensing, authorisation or accreditation of the local CA; contract agreements between TEs; relevant SOPs for the activities the TE apply for; documentations verifying the qualification of the staff donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, etc. |
| 7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible). | Yes, but only via an authorised TE in my MS |
| 7.4. Have you authorised direct distribution to the recipient of specific tissues and cells (Art. 6, Directive 2006/17/EC)? | No |
| 7.5. Do you collect data regarding the cross-border exchange of tissue/cells between your country and other EU MS? | Yes |
| 7.5.1. Please provide us with data (country of destination, type of tissue/cell and number of units distributed) concerning distribution to other MS in 2011 (01/01/2011-31/12/2011). | Great Britain, Cord blood, 314 distributed units Belgium, Cord blood, 520 distributed units Greece, Cord blood, 61 distr. units Germany, CB, 13 distributed units Great Britain, fragment from umbilical cord, 175 distributed units Belgium, fragment from umbilical cord, 336 distributed units Greece, fragment from umbilical cord, 54 distributed units Greece, Teeth, 6 teeth Germany, Bones, 843 units Germany, Tendons, 407 Germany, Skin, 6 Germany, Fascia, 12 Netherlands, Skin, 93 Italy, Bones, 15 Italy, Tendons, 12 Italy, Fascia, 4 |
| 7.5.2. Please provide us with data (country of origin, type of tissue/cell and number of units distributed) concerning distribution to other MS in 2011 (01/01/2011-31/12/2011) | No |
| 7.6. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on cross-border exchanges of tissues/cells between your country and other EU MS? | No |
| 7.7. Do you allow brokerage companies for either distribution in EU and/or import/export of tissues/cells? In this context, a brokerage company means a body that arranges transactions between a supplier (tissue establishment/company selling tissues or cells) and a buyer (a | No |

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| tissue establishment/a hospital or clinic/an individual) without undertaking activities of processing, preservation or storage. | |
| 7.8. Are brokers actively supplying health professionals/establishments in your country? | No |
| 7.9. Do you have any additional comments on distribution? | |
| **8. Register of tissue establishments and reporting obligations (Article 10, Directive 2004/23/EC)** | |
| 8.1. Do you have an annual report model/template on the activities of tissue establishments in your Member State? (Article 10(1)). If yes, please upload the template. | Yes |
| 8.2. How many tissue establishments submitted annual reports of their activities during 2011. Please provide an estimation. (1 answer possible) | 100% (all) |
| 8.3. Are these reports publicly available? (Article 10(1)) | Yes |
| 8.3.1. If yes, please insert the link(s) to the report(s). | http://www.bgtransplant.bg/iat/registers%20and%20statistics.php?target_f=statistics.htm |
| 8.4. Do you publish a national annual report of the consolidated activities of all tissue establishments in your country? | Yes |
| 8.4.1. Please insert the link to the published national annual report. | http://www.bgtransplant.bg/iat/registers%20and%20statistics.php?target_f=%D0%A2%D1%8A%D0%BA%D0%B0%D0%BD%D0%B8%20%D0%B8%20%D0%BA%D0%BB%D0%B5%D1%82%D0%BA%D0%B8.html ; http://www.bgtransplant.bg/iat/registers%20and%20statistics.php?target_f=%D0%90%D1%81%D0%B8%D1%81%D1%82%D0%B8%D1%80%D0%B0%D0%BD%D0%B0%20%D1%80%D0%B5%D0%BF%D1%80%D0%BE%D0%B4%D1%83%D0%BA%D1%86%D0%B8%D1%8F.html |
| 8.5. Is there a publicly accessible register of authorised tissue establishements in place? (Article 10(2)) | Yes |
| 8.5.1. If yes, please provide us with the link to the register's web site. | http://www.bgtransplant.bg/iat/transplantation.php?target_f=%D0%9B%D0%B5%D1%87%D0%B5%D0%B1%D0%BD%D0%B8%20%D0%B7%D0%B0%D0%B2%D0%B5%D0%B4%D0%B5%D0%BD%D0%B8%D1%8F%20%D0%B8%D0%B7%D0%B2%D1%8A%D1%80%D1%88%D0%B2%D0%B0%D1%89%D0%B8%20%D0%B4%D0%B5%D0%B9%D0%BD%D0%BE%D1%81%D1%82%D0%B8%20%D0%BF%D0%BE%20%D1%82%D1%80%D0%B0%D0%BD%D1%81%D0%BF%D0%BB%D0%B0%D0%BD%D1%82%D0%B0%D1%86%D0%B8%D1%8F%20%D0%BD%D0%B0%20%D1%82%D1%8A%D0%BA%D0%B0%D0%BD%D0%B8%20%D0%B8%20%D0%BA%D0%BB%D0%B5%D1%82%D0%BA%D0%B8.html |
| 8.6. Do you provide data regarding tissues and cells activities to the EUROCET registry (non-mandatory reporting)? | Yes |
| 8.6.1. If yes, what data are provided to EUROCET? Please specify. | During the years we have submited all kind of data which they required from us. |
| 8.7. Do you have any additional comments on reporting? | |
| **9. Traceability (Article 8, Directive 2004/23/EC; and Directive 2006/86/EC)** | |
| 9.1. Was the donor identification system (Art. 8(2)) implemented in your country? | Yes |
| 9.2. Who assigns the unique code for each donation? (only 1 answer possible) | Tissue establishment |
| 9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible) | Both paper records and electronic forms |
| 9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify. | This requirement is laid down in our law for transplatation and we check this obligation during every inspection. |
| 9.5. Do you have any additional comments on traceability? | |
| **10. Notification of serious adverse events and reactions (Article 11 Directive 2004/23, Article 6 Directive 2006/86)** | |
| 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))? | Yes |
| 10.1.1. If yes, which CA/institution is responsible? | Executive Agency for Transplantation. |
| 10.1.2. If yes, please provide a short description of its organisation. | We have special Ordinance 10 on the conditions and procedure for |

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| | reporting, recording and transmission of information on SAR/E and barring, withdrawal and destroying tissues and cells. (1) Medical specialist who observed or suspected SAE/SAR is required to fill immediately report according to Annex No 1 and submit it to the responsible person assigned to a hospital. (2) The responsible person immediately label all the tissues and cells taken from the donor with "quarantine" and notifies the head of the TE and the Executive Agency for Transplantation, providing them with all the information regarding the case. (3) The head of the TE is required to report immediately to all relevant health establishments. (4) All the notified health establishments shall promptly labeled "quarantine" all tissues and cells derived from the same donor, and place them in a designated container marked "quarantine". (5) The responsible person of the TE notified the already established committee of the TE investigating the case. (6) The committee shall hold a hearing within three days where it analyzes the causes, circumstances and the outcome related to suspected serious adverse reaction and produces a report. (7) In case of occurred serious adverse reaction commission is obliged to propose measures in order to solve and prevent the issue and write them down in the report which is then submitted to the responsible person, the head of the TE and the person under Art. 10, para. 5 from the Ordinance mentioned above.. (8) The responsible person notifies within 7 days the Executive Agency for Transplantation about the results actions from the investigation of the committee and the undertaken by sending a copy of the notice under par. 1 and report under par. 6 from above mentioned ordinance. (9) The head of the TE shall immediately notify all concerned health establishments for confirming results of SAE/R. (10) When the committeefinds out that a SAE/R can affect the quality and safety of the retrieved tissues and cells, the responsible person and the Executive Agency for Transplantation take immediate actions to block, recall and destroy tissues and cells under quarantine. (11) When the committee finds that the SAE/R can not influence the quality and safety of the retrieved tissues and cells, the responsible person releases them from quarantine. |
| 10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use the SAR/E (to the CA (2006/86 art 6.4)) templates developed to the Annual reporting ot the EC also at national level? | Yes |
| 10.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level? | Yes |
| 10.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all TEs? | No |
| 10.4.1. Why not? | It is a matter of our budget. |
| 10.5. How many tissue establishments provided in 2011 the SAR/SAE data as requested (please provide the % from the total number of TEs authorised in your country). | 100% |
| 10.6. Do you have a mandatory procedure for the transplantation centres when reporting SAR/SAE to the TEs which distributed the tissues/cells (Art 11.2)? | Yes |
| 10.6.1. If yes, please provide a brief description. | The procedure follows the items described in p. 10.1.2. |
| 10.7. Do you give feedback to the TEs regarding SAR/SAE recorded at national level? | Yes |
| 10.7.1. Please specify. | We inform only the concerned TE regarding relevant SAR/SAE. |
| 10.8. Do you give feedback to the TEs regarding SAR/SAE recorded at EU level? | Yes |
| 10.8.1. Please specify. | We inform only TEs which provide the activities as the recorded SAR/SAE. |
| 10.9. Do you require your TEs to have a recall procedure? | Yes |
| 10.10. How many recalls related to safety and quality of tissues/cells were issued in your country in 2011? Please specify the number and which tissues were recalled and why (e.g. missing consent, quality | 0 |

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| defects etc). | |
| 10.11. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites in case of a national rapid alert? | No |
| 10.11.2. If no, please specify why not. | It is still under construction. For now we are using only email correspondence. |
| 10.12. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites when a rapid alert is issued via the EU RATC platform? | No |
| 10.12.2. If no, please specify why not. | For now we are using email correspondence with short desctiption in case of relevant activities of the TEs. Because part of the information is confidential. |
| 10.13. Do you provide data regarding SAR/SAE to the EUROCET registry (non-mandatory reporting)? | Yes |
| 10.13.1. If yes, please specify what data. | We fulfil all data which can be extracted from our registries and transfer it to the EUROCET nomenclature. |
| 10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems? | No |
| 10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S? | Yes |
| 10.15.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (insufficient) - 2 (sufficient) 3 (good) - 4 (very good) to 5 (essential)? | 5 |
| 10.16. Do you have any additional comments on SARE reporting? | The vigilance officers are engaged in other activities as experts. |
| **11. Consent and personal data protection (Article 13 and 14, Directive 2004/23/EC)** | |
| 11.1. What consent system for living tissue/cell donation do you have in place within your Member State? | Explicit consent (opt-in) |
| 11.1.1. Please specify your choice of consent system for living tissue/cell donation. | Explicit written consent system |
| 11.2. What consent system for deceased tissue/cell donation do you have in place within your Member State? | Presumed (opt-out) and explicit (opt-in) consent |
| 11.2.1. If you have chosen both consent systems for deceased tissue/cell dontation, please specify. | Presumed consent: According to the Bulgarian Law of the Transplantation of Organs, Tissues and Cells: (1) Shall not be admitted retrieving organs, tissues and cells for implantation if the person has expressed dissent in writing thereof during his/her lifetime. (2) Not admitted shall be taking of organs, tissues and cells from a corpse of a person under 18 years of age or of a person under judicial disability, except by the written consent of his/her parents, guardian or trustee. (3) Not admitted shall be taking of organs, tissues and cells for implanting from a corpse of a person with unknown identity. (4) If the corpse is subject to a forensic expertise the taking of organs, tissues and cells from him/her shall be performed upon a permit in writing by a forensic expert, who shall not participate in transplantation activities. Explicit consent: Taking of organs, tissues and cells from the person, who passed away, may be performed if the following requirements are met: 1. in the health insurance book of the person, in the cases where there is such, there is not a registered dissent of the person for taking organs, tissues and cells after his/her death; 2. the name of the person has not been entered in the official register of the Executive Agency for Transplantations under Art. 39, para 1, item 2; 3. the forthcoming taking of organs, tissues or cells obligatorily is announced and there is no dissent in writing presented within reasonably short term from his/her: a) spouse or parent; b) child; c) brother or sister. (2) The manner of ascertainment and certification of the circumstances under para 1 shall be determined by an ordinance of the Minister if Health. |
| 11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible) | First degree relatives (including spouse) |
| 11.4. Is the consent system for deceased tissue donation the same as | Yes |

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| for organs? | |
| 11.5. How is this consent verified during inspections? (more than 1 answer possible) | Analysis of documentation |
| 11.6. What measures are in place to ensure that donors/relatives/authorising persons on behalf of donors are provided with the appropriate information, as requested by Art. 13(2)? (more than 1 answer possible) | Only trained personnel is allowed to provide such information<br>Information for donors are standardised at national/regional level |
| 11.7. What measures are in place to ensure that both donors and recipients remain unidentifiable when access is given to third parties (Art. 14(1)). Please specify. | According to the Bulgarian Law of the Transplantation of Organs, Tissues and Cells: Prohibited is the spreading of data allowing the identification of the donor or of the recipient. |
| 11.8. Please specify what measures are in place to ensure that the identity of the receipient is not disclosed to the donor and vice versa. | The information is official secret. Only restricted access is allowed. |
| 11.9. Does your national legislation allows disclosure of donor data in case of gametes donation? | No |
| 11.9.1. If no, please specify the circumstances and measures in place. | The information is official secret. Only restricted access is allowed. |
| 11.10. Do you have any additional comments on consent and data protection? | |
| **12. Selection, evaluation and procurement (Article 15 Directive 2004/23; Annexes I-IV Directive 2006/17)** | |
| 12.1. How do you ensure that all requirements related to the evaluation and selection of donors (except donors of reproductive cells) are respected in your country (Art. 15(1), Annex I Directive 2006/17/EC)? (more than 1 answer possible) | Stadardised questionnaires at national levels<br>Inspections of TEs and procurement sites<br>Regular evaluation of medical personnel |
| 12.2. How do you ensure that all requirements related to the evaluation and selection of donors of reproductive cells are respected in your country (Art 15 (1), Annex III of Directive 2006/17/EC)? (more than 1 answer possible) | Standardised questionnaires at national level<br>Inspections of ART centres<br>Regular evaluation of medical personnel |
| 12.3. Do you have more stringent criteria for donor selection than those listed in Annex I of the Directive 2006/17/EC? | No |
| 12.4. What sources are required in your MS for the evaluation of a deceased donor of tissues/cells? (more than 1 answer possible) | Interview with the donor's family or a person who knew the donor well<br>Medical records of the donor<br>Interview with the treating physician<br>Interview with the general practitioner<br>Autopsy report |
| 12.5. Do you have more stringent criteria for selection of donors of reproductive cells than those listed in Annex III of the Directive 2006/17/EC? | No |
| 12.6. Do you have more stringent criteria for autologous donation than those listed in Annex I of the Directive 2006/17/EC? | No |
| 12.7. Do you require more information on the donation of tissues/cells than the mandatory one as laid down in the Annex of Directive 2004/23/EC (Art 15(3)? | No |
| 12.8. How do you ensure that all requirements regarding tissues and cells' procurement, packaging and transport are complied with by tissue establishments in your country (Art 15(1), Annex IV of Directive 2006/17/EC? (more than 1 answer possible)(For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)) | Inspection of tissue establishment<br>Inspection of the centre of human application (e.g. transplantation centre, ART centre) |
| 12.9. Do you have any additional comments on selection, evaluation and procurement? | |
| **13. Quality management, responsible person, personnel (Article 16, 17, 18 Directive 2004/23/EC)** | |
| 13.1. How do you ensure that tissue establishments in your country have in place a quality system respecting the provisions of the Directive 2004/23/EC Art 16.1? (more than 1 answer possible). (For this question "audit" means a documented review of procedures, | Authorisation requirement<br>Inspections |

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| records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)). | |
| 13.2. How do you ensure that tissue establishments have a responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible) | Authorisation requirement<br>Inspections<br>Regular evaluation of personnel<br>Mandatory trainings |
| 13.3. How do you ensure an appropriate training for the personnel directly involved in the activities of tissue establishments? (more than 1 answer possible) | Authorisation requirement<br>Inspections<br>Regular evaluation of personnel<br>Mandatory trainings |
| 13.4. Do you have national/regional/local training programmes for the personnel of tissue establishments? | Yes |
| 13.4.1. If yes, please specify. | According to Bulgarian Law for Transplantation of Organs, Tissues and Cells: Art. 4 (7) the personnel shall be trained within every two years; Art. 11 (5) p. 17 BEAT organizes training on quality and safety in carrying out transplantation activities for responsible persons and personnel engaged in procurement, testing, processing, labeling, storage, transportation and distribution of organs, tissues and cells. |
| 13.5. Any additional comments on quality management, responsible person, personnel? | |
| **14. Reception, processing, storage, labelling and packaging (Art 19-22 Directive 2004/23/EC)** | |
| 14.1. How do you ensure that tissue establishments in your country fulfill the requirments of the Art. 19 (Tissue and cell reception) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | National regulation/policy for reception of tissues/cells<br>Inspections of tissue establishments |
| 14.2. How do you ensure that tissue establishments in your country fulfill the requirements of the Art. 20 (Tissue and cell processing) of Directive 2004/23/EC? (more than 1 answer possible) | SOPs for all processes affecting quality and safety are mandatory for authorisation<br>Inspections of tissue establishments |
| 14.3. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 21 (tissue and cell storage conditions) of Directive 2004/23/EC? (more than 1 answer possible) | SOPs for procedures associated with storage of tissues and cells are mandatory for authorisation<br>Inspections of tissue establishments |
| 14.4. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | SOPs for procedures associated with labelling and packaging are mandatory for authorisation<br>Inspections of tissue establishments |
| 14.5. Any additional comments on reception, processing, storage, labelling and packaging? | |
| **15. Third party agreements (Art. 24 Directive 2004/23/EC)** | |
| 15.1. Are third party agreements foreseen/allowed in your national legislation? | Yes |
| 15.1.1. If yes, have tissue establishments in your Member State notified third party agreements? | Yes |
| 15.1.1.1. Under which circumstances and for which responsibilities? | According to our Law of Transplantation of Organs, Tissues and Cells: Art. 15a. (new - SG 71/06, in force from 01.01.2007) (1) The tissue establishments shall conclude written contracts between them, in case they carry out jointly activities related to taking, treatment, processing, storing and/or implantation of organs, tissues and cells. (2) The tissue establishments shall conclude written contracts with third parties for providing goods and services, which can influence the quality and the safety of the organs, tissues or the cells. (3) The tissue establishments shall create and maintain a register of the contracts concluded under para 1 and 2. (4) The tissue establishments shall send copies of the contracts under para 1 and 2 to the Executive Agency for Transplantation in 7-days term from their conclusion. |
| 15.1.1.2. How are third party agreements controlled (Art 6.2) by the Competent Auhtority(ies) in your MS? Please specify. | Authorisation requirements, Inspections of TE, All third-party agreements shall be registered within 7 days from their contracting |

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| | and stored in official registries of CA (BEAT), TEs shall maintain registries themselves. |
| 15.2. Any additional comments on third party agreements? | |
| **16. General comments - implementation** | |
| 16.1. Do you have at national level more stringent quality and safety requirements than those requested by the EU legislation in this field (e.g. restrictions concerning the donation/use of certain tissues/cells, mandatory unpaid donation etc.)? | No |
| 16.2. Has your Member State encountered any difficulties in implementing the requirements in the EU Tissues and Cells Directives? Please choose from the options below. | Import-export |
| 16.2.1. For all selected options in question 16.2., please provide a short description. | Import-export: Directive 2004/23/EC Art. 9 p. 3 (c) "The competent authority or authorities shall take all necessary measures to ensure that imports and exports of tissues and cells referred to in subparagraphs (a) and (b) meet quality and safety standards equivalent to those laid down in this Directive." What kind of "necessary measures" should be fulfiled to ensure that imports from third countries met the requirements of EU T&C Directives? |
| 16.3. In your opinion, in which of the following Directives are there shortcomings (if any)? (more than 1 answer possible) | Directive 2004/23/EC |
| 16.3.1. How would you suggest to solve these issues in Directive 2004/23/EC? | We suggest the following: Directive 2004/23/EC Art. 9 p. 3 (c) "The competent authority or authorities shall take all necessary measures to ensure that imports and exports of tissues and cells referred to in subparagraphs (a) and (b) meet quality and safety standards equivalent to those laid down in this Directive." In Art. 9 p.3 it should be included the following text: ... shall take all necessary measures: Inspection at site by CA of MS or written declaration by CA of the third country which ensures that they fulfil all requirements for safety and quality of all the three EU T&C Directives ... |

## *A.1.4. Survey response Croatia*

| 1. Public information | |
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| 1.1. Name of National Competent Authority (NCA) 1: | Ministry of Health |
| 1.1.2. Address of NCA 1: | Ksaver 200a, 10000 Zagreb, Croatia |
| 1.1.3. Telephone (central access point): | +385 1 460 7671 |
| 1.1.4. E-mail (central access point): | vanja.nikolac@miz.hr |
| 1.1.5. Website: | |
| 1.1.6. The NCA is responsible for? (more than 1 answer possible) | Non-reproductive tissues and cells<br>Reproductive tissues and cells<br>Blood and blood components<br>Human organs |
| 1.1.7. What are the role/tasks of the NCA? (more than 1 answer possible) | Accreditation, authorisation, licensing of TEs<br>Inspection<br>Vigilance<br>Other |
| Please specify 'other': | 1.Regulation (proposing laws and strategic documents, enacting sub-laws) 2. Monitoring of activities 3. Managemet of capital investitions in the field |
| 1.2. National Competent Authority 2? | No |
| 1.5. Please give a short description of the legal status and organisation of the National Competent Authority(ies) (e.g. departments, staffing, number of senior and junior inspectors, staff working on EU affairs and legal matters, vigilance officers, budget, independence from government etc.). | Ministry of Health is a central state administration body. Activities are financed from the state budget. Additionaly, for the costs of authorization TE are paying fee. Two units share responsibility for T&C. 1. Health Protection Directorate 1.1. Service for Blood, Tissues and Cells Inspection (1 head od Service and 2 inspectors) 2. Institute for transplantation and biomedicine (head of Institute – assistant of Minister) 2.1. Service for transplantation (3 employees) 2.2. Service for biomedicine (3 employees) |
| 1.6. In case of MS with federal or decentralised systems, please indicate the roles/tasks of the Regional Competent Authority(ies). (more than 1 answer possible) | Not applicable |
| 1.7. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies) for tissues and cells: | no regional CA |
| 2. Procurement (Article 5 Directive 2004/23/EC) | |
| 2.1. Do you authorise the "conditions of procurement"? | Yes |
| 2.1.1. How do you authorise the "conditions of procurement"? (more than 1 answer possible) | By inspecting all procurement centres<br>By inspecting the documentation associated with procurement that is available in the tissue establishment working with procurement centres |
| 2.1.2. How many such authorisations were granted in 2011 (01/01-31/12/2011)? | 10 |
| 2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011). | 4 |
| 2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011). | 4 |
| 2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues were carried out in 2011 (01/01-31/12/2011). | non-partner ART: 0, partner ART: 13 |
| 2.2.4. Please provide the number of procurement centers in which procurement of tissues/cells for ATMP manufacturing were carried out in 2011 (01/01-31/12/2011). | 0 |
| 2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC and its implementing Directive 2006/17/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) ? (more than 1 answer possible) | Inspections of the site/centre<br>Analysis of the mandatory documentation |

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| 2.4. Are you also responsible for the accreditation, designation, authorisation or licensing of laboratories performing donor testing? | Yes |
| 2.4.1. Please provide the number of the laboratories performing donor testing. | 1 |
| 2.5. How do you ensure, as CA for T&C, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art. 5(2))? (more than 1 answer possible) | Inspections of the laboratories<br>Analysis of the mandatory documentation requested from the tissue establishment<br>Other |
| Please specify 'other': | Inspections of the TEs |
| 2.6. Please provide data on qualified laboratories accredited, authorised or licensed in your country (e.g. number, year of accreditation/authorisation/license, which donor tests are performed etc.). | Laboratory is authorised for blood donors' testing from 2005. Testing cca 100 000 blood donors per year. In process for the authorisation for T&C donors' testing, according to the new legislation (enacted in June 2013.) Tests: Minimum testing requirements - HIV 1 i 2 – Anti-HIV-1,2 – Hepatitis B – HBsAg iAnti-HBc – Hepatitis C – Anti-HCV – Syphilis - NAT HIV 1, HBV i HCV. Additional tests - HTLV-I - ABO - RhD - HLA antigens and antibodies |
| 2.7. Do you have any additional comments on procurement? | |
| 3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC) | |
| 3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>NAT HIV 1<br>HBs AG<br>Anti HBc<br>NAT HBV<br>Anti HCV-Ab<br>NAT HCV<br>Treponema Pallidum |
| 3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>Ag HIV<br>HBs AG<br>Anti HBc<br>Anti HCV-Ab<br>NAT Chlamydia<br>Treponema Pallidum |
| 3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to encourage its use? Please specify why or why not (e.g. number of additional cases detected, cost-benefit etc.). | NAT is mandatory for non-reproductive tissues and cells but not for reproductive tissues and cells. NAT for reproductive T&C is not foreseen since only partner donation occurs. For non-partner donation CA will propose NAT testing to scientific bodies for consideration. |
| 3.4. Do you have concerns on accuracy of the available tests and test procedures for deceased donors? | Yes |
| 3.4.1. Please specify why: | Limited number of manufacturers and tests which are validated for deceased donors, short period of validation, relatively small number of examinees. |
| 3.5. Are any other laboratory tests required for donors of non-reproductive tissues and cells in your Member State? | Yes |
| 3.5.1. Please specify. | HTLV 1, Anti HBs, Malaria, CMV, Toxoplasma, EBV, Tripanosoma cruzi |
| 3.6. Are any other laboratory tests required for donors of reproductive tissues and cells in your Member State? | Yes |
| 3.6.1. Please specify. | HTLV 1, Anti HBs, Malaria, Toxoplasma, Tripanosoma cruzi Dengue fever, CMV, WEB |
| 3.7. Do you request/use international accreditation systems for testing laboratories? | Yes |
| 3.7.1. Please specify. | ISO 15 189 for each method performing |
| 3.8. Do you have any additional comments on testing? | |
| 4. Accreditation, designation, authorisation or licensing of tissue establishments (Article 6, Directive 2004/23/EC) | |
| 4.1. Do you have a system of designation, authorisation, | Yes |

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| accreditation or licensing for all types of tissue establishments under your responsability? | |
| 4.2. Is inspection a prerequisite for the designation, authorisation, accreditation or licensing of tissue establishments? | Yes |
| 4.2.1. How many inspections were performed in 2011 for authorising/accrediting/licensing/designating TEs? | 1 TE; 8 ART centers |
| 4.3. Are preparation processes authorised? | Yes |
| 4.3.1. How are they authorised? (more than 1 answer possible) | During routine inspections<br>During inspections organised for this purpose<br>By review of a submitted application with supporting documentation |
| 4.4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were suspended in 2011? | 0 |
| 4.5. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011? | 0 |
| 4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)? | Yes |
| 4.6.1. What is the relation between the indpendent certification(s) (e.g. ISO, JACIE, FACT) and the CA authorisation of the tissue establishments? (more than 1 answer possible) | Mandatory for authorisation |
| 4bis. Overview of tissue/cells establishments authorised by the NCA | |
| 4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible): | Skin tissue establishments<br>Musculo-skeletal tissue establishments<br>ART tissue establishments |
| 4.7.1. How many skin tissue establishments? | 1 |
| 4.7.2. How many musculo-skeletal tissue establishments? | 3 |
| 4.7.7. How many ART tissue establishments? | 3 |
| 4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible): | Skin tissue establishments<br>Musculo-skeletal tissue establishments |
| 4.8.1. How many skin tissue establishments? | 1 |
| 4.8.2. How many musculo-skeletal tissue establishments? | 3 |
| 4.9. Tissue establishments first time authorised between 01/01/2011 and 31/12/2011 (more than 1 answer possible): | Cardiovascular tissue establishments<br>HSC tissue establishments<br>ART tissue establishments |
| 4.9.4. How many cardiovascular tissue establishments? | 1 |
| 4.9.5. How many HSC tissue establishments? | 1 |
| 4.9.7. How many ART tissue establishments? | 3 |
| 4.10. All tissue establishments authorised by 31/12/2011 (more than 1 answer possible): | Cardiovascular tissue establishments<br>HSC tissue establishments<br>ART tissue establishments |
| 4.10.4.1. How many public cardiovascular tissue establishments? | 1 |
| 4.10.4.2. How many private cardiovascular tissue establishments? | 1 |
| 4.10.5.1. How many public HSC tissue establishments? | 1 |
| 4.10.5.2. How many private HSC tissue establishments? | 0 |
| 4.10.7.1. How many public ART tissue establishments? | 1 |
| 4.10.7.2. How many private ART tissue establishments? | 2 |
| 4.11. How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Art. 6(5) during 2011? Please provide number(s) per type tissues/cells. | 0 |
| 4ter. Sanctions | |
| 4.16. Have penalties for infringements of the national provisions pursuant to the Directive been defined (Article 27)? | No |
| 4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing? | |
| 5. Inspections (Article 7, Directive 2004/23/EC) | |
| 5.1. Is a system in place for organising inspections and control measures of tissue establishments? | Yes |
| 5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections. | Service for Blood, Tissues and Cells Inspection |

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| 5.1.2. If yes, please specify staffing (how many inspectors). | 1 head of Service and 2 inspectors |
| 5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible) | Yes |
| 5.2.1. If yes, please specify. (more than 1 answer possible) | Blood<br>Organs<br>Pharmaceuticals<br>Advanced therapies<br>Hospitals |
| 5.3. How many routine inspections of tissue establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011)? | 0 |
| 5.3.1. How many inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) following serious adverse events or reactions, or suspicion thereof ? | 1 |
| 5.3.2. How many other type of inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | licensing inspections (4) |
| 5.3.3. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | 0 |
| 5.3.4. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where minor shortcomings were noted? | 3 |
| 5.3.5. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where major shortcomings were noted? | 1 |
| 5.3.6. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by suspension of authorisation? | 0 |
| 5.3.7. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by closure? | 1 |
| 5.3.8. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of other inspections carried out? Please specify. | 4 |
| 5.4. How many routine inspections were conducted in ART establishments (from 1/1/2011 to 31/12/2011)? | 0 |
| 5.4.1. How many inspections were conducted in ART establishments following serious adverse events or reactions, or suspicion thereof (from 1/1/2011 to 31/12/2011)? | 0 |
| 5.4.2. How many other type of inspections were conducted on ART establishments (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | licensing inspections (8) |
| 5.4.3. Outcome of inspections of ART tissue establishments carried out in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | 0 |
| 5.4.4. What was the number of inspections carried out in ART establishments where minor shortcomings were noted? | 0 |
| 5.4.5. What was the number of inspections carried out in ART establishments where major shortcomings were noted? | 8 |
| 5.4.6. What was the number of inspections carried out in ART establishments followed by suspension of authorisation? | 0 |

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| 5.4.7. What was the number of inspections carried out in ART establishments followed by closure of respective establishements? | 0 |
| 5.4.8. What was the number of other inspections of ART establishments? Please specify. | 8 |
| 5.5. Which type of routine inspections do you conduct? (more than 1 answer possible) | General system-oriented inspections<br>Thematic inspections<br>Desk based reviews |
| 5.6. How do you decide which type of routine inspection to conduct? | Report(s) of previous inspection(s): number and qualification of non-conformities Report(s) of SAREs Report(s) of activities Complexity of activity Various data collected due to everyday close communication |
| 5.7. Until 2011, did you implement the requirement concerning the time interval between two inspections (Art. 7.3.)? | No |
| 5.7.1. Why not? | Unit dedicated to T&C' inspection was established in the end of 2009. Licensing inspections have started in second half of 2010. |
| 5.7.2. How do you prioritise tissue establishments to be inspected? | Decision based on: Number of tissue types processing Number of tissues of each type processing/distributing Method of processing Report(s) of previous inspection(s): number and qualification of non-conformities Report(s) of SAREs Various data collected due to everyday close communication |
| 5.8. How many TEs were inspected at least twice between 2008-2011 (01/01/2008-31/12/2011)? | 0 |
| 5.9. Did you perform/conduct inspections of procurement sites outside tissue establishments? | No |
| 5.9.2. If no, why not? | Procurement rarely takes a place outside TEs since TEs are established only in the main (biggest) hospitals which are concurrently main procurement sources. Program for countrywide tissue procurement, foreseeing larger number of procurement-only hospitals is under development. |
| 5.10. Did you carry out inspections of third parties? | Yes |
| 5.10.1. If yes, how many? | 1 |
| 5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)? | Yes |
| 5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)? | Yes |
| 5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)? | 5 |
| 5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))? | No |
| 5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))? | No |
| 5.15. Did you organise any inspections of procurement centres or tissue establishments in third countries from which tissues and/or cells were imported in your country (as recorded by 31/12/2011)? | No |
| 5.16. Have you asked another MS, or have you been requested by any other MS, on the results and control measures of your inspections, as part of an enquiry/investigation? | No |
| 5.17. Would you be interested in developing joint inspections? Joint inspections should be understood as inspections of tissue establishments conducted jointly by two or more Member States' Competent Authorities on their territory or in third countries. | Yes |
| 5.18. Do you have any additional comments on inspections? | |
| 6. Import/export (Article 9 Directive 2004/23/EC) | |
| 6.1. Do you have a register of authorised tissue establishments that | Yes |

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| are explicitly authorised to perform import/export of tissues and celles from/to third countries? | |
| 6.2. Please specify the number of tissue establishments authorised to import tissues and cells from third countries (recorded by 31/12/2011). | 0 |
| 6.3. Please specify the number of tissue establishments authorised to export tissues and cells from third countries (recorded by 31/12/2011). | 0 |
| 6.4. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of skin from third countries. | Importation from a third countries is prohibited except for emergency. |
| 6.5. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of musculo-skeletal (bone, tendons, fascia etc.) tissues from third countries. | Importation from a third countries is prohibited except for emergency. |
| 6.6. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of ophtalmic (cornea, sclera, etc) tissues from third countries. | Importation from a third countries is prohibited except for emergency. |
| 6.7. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cardio vascular tissues from third countries. | Importation from a third countries is prohibited except for emergency. |
| 6.8. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) (other than cord blood) from third countries. | Importation from a third countries is prohibited except for emergency. Whenever is possible JACIE accreditation is required. |
| 6.9. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cord blood from third countries. | Importation from a third countries is prohibited except for emergency. Whenever is possible FACT-NetCord accreditation is required. |
| 6.10. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of reproductive cells (sperm, egg cells) from third countries. | There are no procedures for importation of reproductive cells. |
| 6.11. Did you import tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | Yes |
| 6.11.1. If yes, please provide the data concerning the number/volume of imported tissues and cells by country of origin. | 57 corneas from USA |
| 6.12. Did you export tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | No |
| 6.13. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on imports/exports of tissues/cells between your country and other third countries? | No |
| 6.14. What is the relation between import/export of tissues and cells and self-sufficiency? (more than 1 answer possible) | A. Export of tissues/cells is authorised only after checking that local/national needs are fulfilled.<br>D. Import of tissues/cells is authorised only after checking that local/national needs are not fulfilled<br>F. Other |
| Please specify 'other': | Import is authorised, additional to point D, only in emergency situations. |
| 6.14.1. If A or D were selected, please explain how you quantify local/national needs. | 1. waiting lists for: a) transplantation (corneas, heart valve) b) procedures including use of tissues (e.g. hip prostheses revision) 2. donor registers for matching tissues |
| 6.15. Did you authorise direct imports of tissues/cells to hospitals/clinics in your country? | Yes |
| 6.15.1. If yes, please specify the number of cases and for which type of tissues/cells. | 57 corneas |
| 6.16. Do you have any additional comments on import/export? | |
| 7. Distribution/intra community exchanges (Article 23 Directive 2004/23/EC) | |
| 7.1. Do you have intra-community exchanges of tissues and cells? | Yes |
| 7.1.1. If yes, how do you address the possible more stringent quality and safety measures established by other Member States? Please | Authorised TE is responisible for compliance check |

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| specify. | |
| 7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States? | Yes |
| 7.1.2.1. How do you address this difference for tissues and cells coming from a MS with minimum quality requirements? Please specify. | NA |
| 7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify. | By inspection |
| 7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible). | No |
| 7.4. Have you authorised direct distribution to the recipient of specific tissues and cells (Art. 6, Directive 2006/17/EC)? | No |
| 7.5. Do you collect data regarding the cross-border exchange of tissue/cells between your country and other EU MS? | Yes |
| 7.5.1. Please provide us with data (country of destination, type of tissue/cell and number of units distributed) concerning distribution to other MS in 2011 (01/01/2011-31/12/2011). | No T/C distributed to other MS |
| 7.5.2. Please provide us with data (country of origin, type of tissue/cell and number of units distributed) concerning distribution to other MS in 2011 (01/01/2011-31/12/2011) | No T/C distributed to other MS |
| 7.6. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on cross-border exchanges of tissues/cells between your country and other EU MS? | No |
| 7.7. Do you allow brokerage companies for either distribution in EU and/or import/export of tissues/cells? In this context, a brokerage company means a body that arranges transactions between a supplier (tissue establishment/company selling tissues or cells) and a buyer (a tissue establishment/a hospital or clinic/an individual) without undertaking activities of processing, preservation or storage. | No |
| 7.8. Are brokers actively supplying health professionals/establishments in your country? | No |
| 7.9. Do you have any additional comments on distribution? | |
| 8. Register of tissue establishments and reporting obligations (Article 10, Directive 2004/23/EC) | |
| 8.1. Do you have an annual report model/template on the activities of tissue establishments in your Member State? (Article 10(1)). If yes, please upload the template. | Yes |
| 8.2. How many tissue establishments submitted annual reports of their activities during 2011. Please provide an estimation. (1 answer possible) | 60-99% |
| 8.3. Are these reports publicly available? (Article 10(1)) | No |
| 8.4. Do you publish a national annual report of the consolidated activities of all tissue establishments in your country? | No |
| 8.4.2. If no, why not? | Insuficient administrative capacity of CA |
| 8.5. Is there a publicly accessible register of authorised tissue establishements in place? (Article 10(2)) | Yes |
| 8.5.1. If yes, please provide us with the link to the register's web site. | ART: http://www.zdravlje.hr/ministarstvo/zdravstvene_ustanove_u_republici_hrvatskoj/ustanove_s_odobrenjem_za_obavljanje_djelatnosti_medicinski_pomognute_oplodnje T&C: http://www.zdravlje.hr/ministarstvo/zdravstvene_ustanove_u_republici_hrvatskoj/ustanove_s_odobrenjem_za_obavljanje_djelatnosti_uzimanja_pohranjivanja_i_presadivanja_tkiva_i_stanica |
| 8.6. Do you provide data regarding tissues and cells activities to the EUROCET registry (non-mandatory reporting)? | Yes |
| 8.6.1. If yes, what data are provided to EUROCET? Please specify. | HSC, ART, TISSUES |
| 8.7. Do you have any additional comments on reporting? | |
| 9. Traceability (Article 8, Directive 2004/23/EC; and Directive 2006/86/EC) | |
| 9.1. Was the donor identification system (Art. 8(2)) implemented in your country? | Yes |

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| 9.2. Who assigns the unique code for each donation? (only 1 answer possible) | Tissue establishment |
| 9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible) | Both paper records and electronic forms |
| 9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify. | TE are responsible for ensurance of data storage |
| 9.5. Do you have any additional comments on traceability? | |
| 10. Notification of serious adverse events and reactions (Article 11 Directive 2004/23, Article 6 Directive 2006/76) | |
| 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))? | Yes |
| 10.1.1. If yes, which CA/institution is responsible? | Ministry of Health |
| 10.1.2. If yes, please provide a short description of its organisation. | Responsible person from TE or procurement/application center informs CA . CA is responsible for monitoring of investigation process, data distribution and corrective actions implementation. |
| 10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use the SAR/E (to the CA (2006/76 art 6.4)) templates developed to the Annual reporting ot the EC also at national level? | Yes |
| 10.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level? | Yes |
| 10.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all TEs? | No |
| 10.4.1. Why not? | Insuficient administrative capacity of CA |
| 10.5. How many tissue establishments provided in 2011 the SAR/SAE data as requested (please provide the % from the total number of TEs authorised in your country). | 100% |
| 10.6. Do you have a mandatory procedure for the transplantation centres when reporting SAR/SAE to the TEs which distributed the tissues/cells (Art 11.2)? | Yes |
| 10.6.1. If yes, please provide a brief description. | Responsible person from transplantation center reports to the responsible person of TE and to CA in written or electronic form or by phone, without delay. |
| 10.7. Do you give feedback to the TEs regarding SAR/SAE recorded at national level? | Yes |
| 10.7.1. Please specify. | SAREs are presented and discussed at Ministry's Expert Committee (regular and ad hoc) |
| 10.8. Do you give feedback to the TEs regarding SAR/SAE recorded at EU level? | Yes |
| 10.8.1. Please specify. | SAREs are presented and discussed via e-mail communication or at regular Ministry's Expert Committee meetings in the case not affecting national users. In cases affecting national users ad hoc meetings can be convened |
| 10.9. Do you require your TEs to have a recall procedure? | Yes |
| 10.10. How many recalls related to safety and quality of tissues/cells were issued in your country in 2011? Please specify the number and which tissues were recalled and why (e.g. missing consent, quality defects etc). | 0 |
| 10.11. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites in case of a national rapid alert? | Yes |
| 10.11.1. If yes, please give a short description of the system/procedure. | CA notifies responsible persons in TE, in written and electronic/phone form. Ministry's Expert Committee proposes measures, which Ministry imposes. |
| 10.12. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites when a rapid alert is issued via the EU RATC platform? | Yes |
| 10.12.1. If yes, please give a short description of the system/procedure. | CA notifies responsible persons in TE, in written and electronic/phone form. Ministry's Expert Committee proposes measures, which Ministry imposes. |
| 10.13. Do you provide data regarding SAR/SAE to the EUROCET registry (non-mandatory reporting)? | Yes |

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| 10.13.1. If yes, please specify what data. | HSC, ART, TISSUES |
| 10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems? | Yes |
| 10.14.1. If yes, please specify which of the following systems are usually contacted. (more than 1 answer possible) | Pharmacovilance<br>Medical devices |
| 10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S? | Yes |
| 10.15.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (insufficient) - 2 (sufficient) 3 (good) - 4 (very good) to 5 (essential)? | 4 |
| 10.16. Do you have any additional comments on SARE reporting? | |
| 11. Consent and personal data protection (Article 13 and 14, Directive 2004/23/EC) | |
| 11.1. What consent system for living tissue/cell donation do you have in place within your Member State? | Explicit consent (opt-in) |
| 11.1.1. Please specify your choice of consent system for living tissue/cell donation. | Explicit consent (opt-in) |
| 11.2. What consent system for deceased tissue/cell donation do you have in place within your Member State? | Presumed consent (opt-out) |
| 11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible) | No further authorisation is needed |
| 11.4. Is the consent system for deceased tissue donation the same as for organs? | Yes |
| 11.5. How is this consent verified during inspections? (more than 1 answer possible) | Other |
| Please specify 'other'. | Deceased donors: Presumed consent system is in place, no need for verification Living donors: Analysis of documentation |
| 11.6. What measures are in place to ensure that donors/relatives/authorising persons on behalf of donors are provided with the appropriate information, as requested by Art. 13(2)? (more than 1 answer possible) | Only trained personnel is allowed to provide such information |
| 11.7. What measures are in place to ensure that both donors and recipients remain unidentifiable when access is given to third parties (Art. 14(1)). Please specify. | All stakeholders are obliged to protect personal data according to the special legislation. |
| 11.8. Please specify what measures are in place to ensure that the identity of the receipient is not disclosed to the donor and vice versa. | Establishment of coding system according to which only TE can connect data of recipient with donor data. |
| 11.9. Does your national legislation allows disclosure of donor data in case of gametes donation? | Yes |
| 11.10. Do you have any additional comments on consent and data protection? | |
| 12. Selection, evaluation and procurement (Article 15 Directive 2004/23; Annexes I-IV Directive 2006/17) | |
| 12.1. How do you ensure that all requirements related to the evaluation and selection of donors (except donors of reproductive cells) are respected in your country (Art. 15(1), Annex I Directive 2006/17/EC)? (more than 1 answer possible) | Inspections of TEs and procurement sites<br>Audit of documentation<br>Regular evaluation of medical personnel |
| 12.2. How do you ensure that all requirements related to the evaluation and selection of donors of reproductive cells are respected in your country (Art 15 (1), Annex III of Directive 2006/17/EC)? (more than 1 answer possible) | Inspections of ART centres<br>Audit documentation<br>Regular evaluation of medical personnel |
| 12.3. Do you have more stringent criteria for donor selection than those listed in Annex I of the Directive 2006/17/EC? | No |
| 12.4. What sources are required in your MS for the evaluation of a deceased donor of tissues/cells? (more than 1 answer possible) | Interview with the donor's family or a person who knew the donor well<br>Medical records of the donor<br>Interview with the treating physician<br>Interview with the general practitioner<br>Autopsy report<br>Other |
| Please specify 'other'. | family and close friends |

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| 12.5. Do you have more stringent criteria for selection of donors of reproductive cells than those listed in Annex III of the Directive 2006/17/EC? | No |
| 12.6. Do you have more stringent criteria for autologous donation than those listed in Annex I of the Directive 2006/17/EC? | No |
| 12.7. Do you require more information on the donation of tissues/cells than the mandatory one as laid down in the Annex of Directive 2004/23/EC (Art 15(3)? | No |
| 12.8. How do you ensure that all requirements regarding tissues and cells' procurement, packaging and transport are complied with by tissue establishments in your country (Art 15(1), Annex IV of Directive 2006/17/EC? (more than 1 answer possible)(For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)) | Inspection of tissue establishment<br>Audit of tissue establishment<br>Inspection of the centre of human application (e.g. transplantation centre, ART centre)<br>Audit of the centre of human application |
| 12.9. Do you have any additional comments on selection, evaluation and procurement? | |
| 13. Quality management, responsible person, personnel (Article 16, 17, 18 Directive 2004/23/EC) | |
| 13.1. How do you ensure that tissue establishments in your country have in place a quality system respecting the provisions of the Directive 2004/23/EC Art 16.1? (more than 1 answer possible). (For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)). | Authorisation requirement<br>Inspections<br>Internal audits<br>External audits |
| 13.2. How do you ensure that tissue establishments have a responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible) | Authorisation requirement<br>Inspections<br>Regular evaluation of personnel<br>Mandatory trainings |
| 13.3. How do you ensure an appropriate training for the personnel directly involved in the activities of tissue establishments? (more than 1 answer possible) | Authorisation requirement<br>Inspections<br>Regular evaluation of personnel<br>Mandatory trainings |
| 13.4. Do you have national/regional/local training programmes for the personnel of tissue establishments? | Yes |
| 13.4.1. If yes, please specify. | Professional society meetings Pre-accession instruments (TAIEX, IPA) |
| 13.5. Any additional comments on quality management, responsible person, personnel? | |
| 14. Reception, processing, storage, labelling and packaging (Art 19-22 Directive 2004/23/EC) | |
| 14.1. How do you ensure that tissue establishments in your country fulfill the requirments of the Art. 19 (Tissue and cell reception) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | National regulation/policy for reception of tissues/cells<br>Inspections of tissue establishments<br>Internal audits of tissue establishments<br>External audits of tissue establishments (e.g. ISO) |
| 14.2. How do you ensure that tissue establishments in your country fulfill the requirements of the Art. 20 (Tissue and cell processing) of Directive 2004/23/EC? (more than 1 answer possible) | SOPs for all processes affecting quality and safety are mandatory for authorisation<br>Inspections of tissue establishments<br>Internal audits of tissue establishments<br>External audits of tissue establishments (e.g. ISO) |
| 14.3. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 21 (tissue and cell storage conditions) of Directive 2004/23/EC? (more than 1 answer possible) | SOPs for procedures associated with storage of tissues and cells are mandatory for authorisation<br>Inspections of tissue establishments<br>Internal audits of tissue establishments<br>External audits of tissue establishments (e.g. ISO) |
| 14.4. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 22 (labelling, documentation and | SOPs for procedures associated with labelling and packaging are mandatory for authorisation |

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| packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | Inspections of tissue establishments<br>Internal audits of tissue establishments<br>External audits of tissue establishments(e.g. ISO) |
| 14.5. Any additional comments on reception, processing, storage, labelling and packaging? | |
| 15. Third party agreements (Art. 24 Directive 2004/23/EC) | |
| 15.1. Are third party agreements foreseen/allowed in your national legislation? | Yes |
| 15.1.1. If yes, have tissue establishments in your Member State notified third party agreements? | Yes |
| 15.1.1.1. Under which circumstances and for which responsibilities? | For the cessation of activity, procurement of cord blood and testing |
| 15.1.1.2. How are third party agreements controlled (Art 6.2) by the Competent Auhtority(ies) in your MS? Please specify. | By inspection |
| 15.2. Any additional comments on third party agreements? | |
| 16. General comments - implementation | |
| 16.1. Do you have at national level more stringent quality and safety requirements than those requested by the EU legislation in this field (e.g. restrictions concerning the donation/use of certain tissues/cells, mandatory unpaid donation etc.)? | Yes |
| 16.1.1. Please specify. | • prohibition of third countries tissue importation, • mandatory unpaid donation, • requirement for international accreditation for HSC banks, CB banks and testing laboratories, • mandatory NAT testing for T&C donors |
| 16.2. Has your Member State encountered any difficulties in implementing the requirements in the EU Tissues and Cells Directives? Please choose from the options below. | ART provisions<br>Import-export<br>Vigilance<br>Authorisation-accreditation-licensing of TEs<br>Inspections |
| 16.2.1. For all selected options in question 16.2., please provide a short description. | ART provisions –problems in fulfiling requirements for personel, quality system and facilities Vigilance – insufficient number of CA employees Authorisation-accreditation-licensing of TEs¸and inspections – insufficient number of inspectors, in 2011 was one inpector for blood, tissues and cells and ART Import-export- vague EU legislation allowing broad interpretations |
| 16.3. In your opinion, in which of the following Directives are there shortcomings (if any)? (more than 1 answer possible) | Directive 2004/23/EC |

### *A.1.5. Survey response Cyprus*

| **1. Public information** | |
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| 1.1. Name of National Competent Authority (NCA) 1: | Ministry of Health, Cyprus |
| 1.1.2. Address of NCA 1: | 1, Prodromou and 17, Chilonos str, Nicosia 1449, Cyprus |
| 1.1.3. Telephone (central access point): | 22605600 |
| 1.1.4. E-mail (central access point): | cgregoriadou@moh.gov.cy, emakrigiorgi@moh.gov.cy, cstylianou@mphs.moh.gov.cy |
| 1.1.5. Website: | www.moh.gov.cy |
| 1.1.6. The NCA is responsible for? (more than 1 answer possible) | Non-reproductive tissues and cells<br>Reproductive tissues and cells |
| 1.1.7. What are the role/tasks of the NCA? (more than 1 answer possible) | Accreditation, authorisation, licensing of TEs<br>Inspection<br>Vigilance |
| 1.2. National Competent Authority 2? | No |
| 1.5. Please give a short description of the legal status and organisation of the National Competent Authority(ies) (e.g. departments, staffing, number of senior and junior inspectors, staff working on EU affairs and legal matters, vigilance officers, budget, independence from government etc.). | 3 inspectors/vigilance officers, no separate budget (Ministry of Health) |
| 1.6. In case of MS with federal or decentralised systems, please indicate the roles/tasks of the Regional Competent Authority(ies). (more than 1 answer possible) | Not applicable |
| 1.7. Could you please describe the competence/mandate of the | N/A |

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| Regional Competent Authority(ies) and their relation with the National Competent Authority(ies) for tissues and cells: | |
| **2. Procurement (Article 5 Directive 2004/23/EC)** | |
| 2.1. Do you authorise the "conditions of procurement"? | Yes |
| 2.1.1. How do you authorise the "conditions of procurement"? (more than 1 answer possible) | By inspecting all procurement centres<br>By inspecting the documentation associated with procurement that is available in the tissue establishment working with procurement centres |
| 2.1.2. How many such authorisations were granted in 2011 (01/01-31/12/2011)? | 3 |
| 2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011). | 0 |
| 2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011). | 3 |
| 2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues were carried out in 2011 (01/01-31/12/2011). | 0 |
| 2.2.4. Please provide the number of procurement centers in which procurement of tissues/cells for ATMP manufacturing were carried out in 2011 (01/01-31/12/2011). | 0 |
| 2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC and its implementing Directive 2006/17/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) ? (more than 1 answer possible) | Inspections of the site/centre<br>Analysis of the mandatory documentation |
| 2.4. Are you also responsible for the accreditation, designation, authorisation or licensing of laboratories performing donor testing? | No |
| 2.4.2. Which National Authority is in charge of this activity? | Ministry of Health, under different legislation |
| 2.5. How do you ensure, as CA for T&C, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art. 5(2))? (more than 1 answer possible) | Analysis of the mandatory documentation requested from the tissue establishment<br>Other |
| Please specify 'other': | licensed laboratories only under the Licensing of Clinical Laboratories Law |
| 2.6. Please provide data on qualified laboratories accredited, authorised or licensed in your country (e.g. number, year of accreditation/authorisation/license, which donor tests are performed etc.). | Under a different inspection and licensing system. there are 136 licensed clinical laboratories, 2 EFI accredited laboratories |
| 2.7. Do you have any additional comments on procurement? | |
| **3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)** | |
| 3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>HBs AG<br>Anti HBc<br>Anti HCV-Ab<br>Treponema Pallidum |
| 3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>HBs AG<br>Anti HBc<br>Anti HCV-Ab<br>NAT Chlamydia<br>Treponema Pallidum |
| 3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to encourage its use? Please specify why or why not (e.g. number of | We require this testing if tissues or cells will be issued without retesting of donors after 180 days of collection |

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| additional cases detected, cost-benefit etc.). | |
| 3.4. Do you have concerns on accuracy of the available tests and test procedures for deceased donors? | No |
| 3.5. Are any other laboratory tests required for donors of non-reproductive tissues and cells in your Member State? | No |
| 3.6. Are any other laboratory tests required for donors of reproductive tissues and cells in your Member State? | No |
| 3.7. Do you request/use international accreditation systems for testing laboratories? | Yes |
| 3.7.1. Please specify. | ISO, EFI |
| 3.8. Do you have any additional comments on testing? | Licensed Testing Laboratories under the Clinical Laboratories Legis |
| **4. Accreditation, designation, authorisation or licensing of tissue establishments (Article 6, Directive 2004/23/EC)** | |
| 4.1. Do you have a system of designation, authorisation, accreditation or licensing for all types of tissue establishments under your responsability? | Yes |
| 4.2. Is inspection a prerequisite for the designation, authorisation, accreditation or licensing of tissue establishments? | Yes |
| 4.2.1. How many inspections were performed in 2011 for authorising/accrediting/licensing/designating TEs? | 3 |
| 4.3. Are preparation processes authorised? | Yes |
| 4.3.1. How are they authorised? (more than 1 answer possible) | During inspections organised for this purpose<br>By review of a submitted application with supporting documentation |
| 4.4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were suspended in 2011? | 2 |
| 4.5. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011? | 0 |
| 4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)? | Yes |
| 4.6.1. What is the relation between the indpendent certification(s) (e.g. ISO, JACIE, FACT) and the CA authorisation of the tissue establishments? (more than 1 answer possible) | Optional, but TEs are encouraged to get a certification |
| **4bis. Overview of tissue/cells establishments authorised by the NCA** | |
| 4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible): | ART tissue establishments |
| 4.7.7. How many ART tissue establishments? | 1 |
| 4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible): | ART tissue establishments |
| 4.8.7. How many ART tissue establishments? | 1 |
| 4.9. Tissue establishments first time authorised between 01/01/2011 and 31/12/2011 (more than 1 answer possible): | Cord blood tissue establishments |
| 4.9.6. How many cord blood tissue establishments? | 1 |
| 4.10. All tissue establishments authorised by 31/12/2011 (more than 1 answer possible): | Ocular tissue establishments<br>HSC tissue establishments<br>Cord blood tissue establishments<br>ART tissue establishments |
| 4.10.3.1. How many public ocular tissue establishments? | 0 |
| 4.10.3.2. How many private ocular tissue establishments? | 3 |
| 4.10.5.1. How many public HSC tissue establishments? | 2 |
| 4.10.5.2. How many private HSC tissue establishments? | 0 |
| 4.10.6.1. How many public cord blood tissue establishments? | 1 |
| 4.10.6.2. How many private cord blood tissue establishments? | 5 |
| 4.10.7.1. How many public ART tissue establishments? | 0 |
| 4.10.7.2. How many private ART tissue establishments? | 8 |
| 4.11. How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Art. 6(5) during 2011? Please provide number(s) per type tissues/cells. | 2 |
| **4ter. Sanctions** | |
| 4.16. Have penalties for infringements of the national provisions | Yes |

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| pursuant to the Directive been defined (Article 27)? | |
| 4.16.1. Have penalties already been imposed? | No |
| 4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing? | |
| **5. Inspections (Article 7, Directive 2004/23/EC)** | |
| 5.1. Is a system in place for organising inspections and control measures of tissue establishments? | Yes |
| 5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections. | Inpectors |
| 5.1.2. If yes, please specify staffing (how many inspectors). | 3 |
| 5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible) | No |
| 5.3. How many routine inspections of tissue establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011)? | 11 |
| 5.3.1. How many inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) following serious adverse events or reactions, or suspicion thereof ? | 0 |
| 5.3.2. How many other type of inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | 2 for new processes not licensed |
| 5.3.3. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | 0 |
| 5.3.4. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where minor shortcomings were noted? | 4 |
| 5.3.5. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where major shortcomings were noted? | 0 |
| 5.3.6. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by suspension of authorisation? | 0 |
| 5.3.7. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by closure? | 0 |
| 5.3.8. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of other inspections carried out? Please specify. | 1 for new process |
| 5.4. How many routine inspections were conducted in ART establishments (from 1/1/2011 to 31/12/2011)? | 6 |
| 5.4.1. How many inspections were conducted in ART establishments following serious adverse events or reactions, or suspicion thereof (from 1/1/2011 to 31/12/2011)? | 0 |
| 5.4.2. How many other type of inspections were conducted on ART establishments (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | 0 |
| 5.4.3. Outcome of inspections of ART tissue establishments carried out in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | 0 |
| 5.4.4. What was the number of inspections carried out in ART | 4 |

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| establishments where minor shortcomings were noted? | |
| 5.4.5. What was the number of inspections carried out in ART establishments where major shortcomings were noted? | 0 |
| 5.4.6. What was the number of inspections carried out in ART establishments followed by suspension of authorisation? | 0 |
| 5.4.7. What was the number of inspections carried out in ART establishments followed by closure of respective establishements? | 0 |
| 5.4.8. What was the number of other inspections of ART establishments? Please specify. | 0 |
| 5.5. Which type of routine inspections do you conduct? (more than 1 answer possible) | General system-oriented inspections<br>Thematic inspections<br>Desk based reviews |
| 5.6. How do you decide which type of routine inspection to conduct? | General system for licensing and re issue of license, and every year, thematic for new process applications, desk based for import only |
| 5.7. Until 2011, did you implement the requirement concerning the time interval between two inspections (Art. 7.3.)? | Yes |
| 5.8. How many TEs were inspected at least twice between 2008-2011 (01/01/2008-31/12/2011)? | 16 |
| 5.9. Did you perform/conduct inspections of procurement sites outside tissue establishments? | No |
| 5.9.2. If no, why not? | Procurement for autologous cord blood banks occurs only outside licensed tissue establishments. Clinics were cord cord blood is procured need to be licensed under the Private Clinic Act |
| 5.10. Did you carry out inspections of third parties? | No |
| 5.10.2. If no, why not? | Third parties are usually testing laboratories. Clinical laboratories have to be licensed by a different legislation in order for TEs to have a third party agreement |
| 5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)? | Yes |
| 5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)? | Yes |
| 5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)? | 5 |
| 5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))? | No |
| 5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))? | No |
| 5.15. Did you organise any inspections of procurement centres or tissue establishments in third countries from which tissues and/or cells were imported in your country (as recorded by 31/12/2011)? | No |
| 5.16. Have you asked another MS, or have you been requested by any other MS, on the results and control measures of your inspections, as part of an enquiry/investigation? | No |
| 5.17. Would you be interested in developing joint inspections? Joint inspections should be understood as inspections of tissue establishments conducted jointly by two or more Member States' Competent Authorities on their territory or in third countries. | No |
| 5.17.1. Could you please explain why not? | Lack of resources |
| 5.18. Do you have any additional comments on inspections? | |
| **6. Import/export (Article 9 Directive 2004/23/EC)** | |
| 6.1. Do you have a register of authorised tissue establishments that are explicitly authorised to perform import/export of tissues and celles from/to third countries? | Yes |
| 6.2. Please specify the number of tissue establishments authorised to | 3 |

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| import tissues and cells from third countries (recorded by 31/12/2011). | |
| 6.3. Please specify the number of tissue establishments authorised to export tissues and cells from third countries (recorded by 31/12/2011). | 1 |
| 6.4. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of skin from third countries. | no skin is imported |
| 6.5. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of musculo-skeletal (bone, tendons, fascia etc.) tissues from third countries. | no bone is imported |
| 6.6. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of ophtalmic (cornea, sclera, etc) tissues from third countries. | FDA licence, AATB valid acredidation |
| 6.7. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cardio vascular tissues from third countries. | no cadio vascular tissues are imported |
| 6.8. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) (other than cord blood) from third countries. | no haematopoietic cells are imported |
| 6.9. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cord blood from third countries. | cord blood procured in third countries is imporetd for processing and storage. |
| 6.10. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of reproductive cells (sperm, egg cells) from third countries. | no gametes are imported |
| 6.11. Did you import tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | No |
| 6.12. Did you export tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | Yes |
| 6.12.1. If yes, please provide the data concerning the number/volume of exported tissues and cells by country of destination. | 2 Donations of Peripheral stem cells |
| 6.13. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on imports/exports of tissues/cells between your country and other third countries? | No |
| 6.14. What is the relation between import/export of tissues and cells and self-sufficiency? (more than 1 answer possible) | F. Other |
| Please specify 'other': | only export of highly matched stem cell donations |
| 6.15. Did you authorise direct imports of tissues/cells to hospitals/clinics in your country? | Yes |
| 6.15.1. If yes, please specify the number of cases and for which type of tissues/cells. | Patient's own gametes or embryos due to relocation |
| 6.16. Do you have any additional comments on import/export? | |
| **7. Distribution/intra community exchanges (Article 23 Directive 2004/23/EC)** | |
| 7.1. Do you have intra-community exchanges of tissues and cells? | No |
| 7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify. | SOPs review and records |
| 7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible). | Yes, but only via an authorised TE in my MS |
| 7.4. Have you authorised direct distribution to the recipient of specific tissues and cells (Art. 6, Directive 2006/17/EC)? | No |
| 7.5. Do you collect data regarding the cross-border exchange of tissue/cells between your country and other EU MS? | No |
| 7.6. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on cross-border exchanges of tissues/cells | No |

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| between your country and other EU MS? | |
| 7.7. Do you allow brokerage companies for either distribution in EU and/or import/export of tissues/cells? In this context, a brokerage company means a body that arranges transactions between a supplier (tissue establishment/company selling tissues or cells) and a buyer (a tissue establishment/a hospital or clinic/an individual) without undertaking activities of processing, preservation or storage. | No |
| 7.8. Are brokers actively supplying health professionals/establishments in your country? | No |
| 7.9. Do you have any additional comments on distribution? | No brokers were licensed yet |
| **8. Register of tissue establishments and reporting obligations (Article 10, Directive 2004/23/EC)** | |
| 8.1. Do you have an annual report model/template on the activities of tissue establishments in your Member State? (Article 10(1)). If yes, please upload the template. | No |
| 8.1.1. If no, why not? | use the Eurocite templates |
| 8.2. How many tissue establishments submitted annual reports of their activities during 2011. Please provide an estimation. (1 answer possible) | 100% (all) |
| 8.3. Are these reports publicly available? (Article 10(1)) | No |
| 8.4. Do you publish a national annual report of the consolidated activities of all tissue establishments in your country? | No |
| 8.4.2. If no, why not? | Interested parties can view these reports at the Ministry of Health offices |
| 8.5. Is there a publicly accessible register of authorised tissue establishements in place? (Article 10(2)) | Yes |
| 8.5.1. If yes, please provide us with the link to the register's web site. | www.moh.gov.cy |
| 8.6. Do you provide data regarding tissues and cells activities to the EUROCET registry (non-mandatory reporting)? | Yes |
| 8.6.1. If yes, what data are provided to EUROCET? Please specify. | Tissues, HPCs, ART |
| 8.7. Do you have any additional comments on reporting? | |
| **9. Traceability (Article 8, Directive 2004/23/EC; and Directive 2006/86/EC)** | |
| 9.1. Was the donor identification system (Art. 8(2)) implemented in your country? | Yes |
| 9.2. Who assigns the unique code for each donation? (only 1 answer possible) | Tissue establishment |
| 9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible) | Both paper records and electronic forms |
| 9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify. | Through inpections |
| 9.5. Do you have any additional comments on traceability? | |
| **10. Notification of serious adverse events and reactions (Article 11 Directive 2004/23, Article 6 Directive 2006/76)** | |
| 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))? | Yes |
| 10.1.1. If yes, which CA/institution is responsible? | Same |
| 10.1.2. If yes, please provide a short description of its organisation. | Inspectors act as vigilance officers |
| 10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use the SAR/E (to the CA (2006/76 art 6.4)) templates developed to the Annual reporting ot the EC also at national level? | Yes |
| 10.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level? | Yes |
| 10.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all TEs? | No |
| 10.4.1. Why not? | Inspectors act as vigilance officers |
| 10.5. How many tissue establishments provided in 2011 the SAR/SAE data as requested (please provide the % from the total number of TEs authorised in your country). | 100% |
| 10.6. Do you have a mandatory procedure for the transplantation centres when reporting SAR/SAE to the TEs which distributed the tissues/cells (Art 11.2)? | Yes |
| 10.6.1. If yes, please provide a brief description. | In the legislation for tissues and cells |

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| 10.7. Do you give feedback to the TEs regarding SAR/SAE recorded at national level? | No |
| 10.7.2. Please specify why not. | Only for those concerned |
| 10.8. Do you give feedback to the TEs regarding SAR/SAE recorded at EU level? | No |
| 10.8.2. Please specify why not. | only if involved |
| 10.9. Do you require your TEs to have a recall procedure? | Yes |
| 10.10. How many recalls related to safety and quality of tissues/cells were issued in your country in 2011? Please specify the number and which tissues were recalled and why (e.g. missing consent, quality defects etc). | 0 |
| 10.11. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites in case of a national rapid alert? | Yes |
| 10.11.1. If yes, please give a short description of the system/procedure. | Through the responsible person of TE via email, mail, tel |
| 10.12. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites when a rapid alert is issued via the EU RATC platform? | Yes |
| 10.12.1. If yes, please give a short description of the system/procedure. | As above if affected |
| 10.13. Do you provide data regarding SAR/SAE to the EUROCET registry (non-mandatory reporting)? | No |
| 10.13.2. If no, please specify why not. | Not required |
| 10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems? | Yes |
| 10.14.1. If yes, please specify which of the following systems are usually contacted. (more than 1 answer possible) | Haemovigilance<br>Pharmacovilance<br>Medical devices |
| 10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S? | Yes |
| 10.15.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (insufficient) - 2 (sufficient) 3 (good) - 4 (very good) to 5 (essential)? | 5 |
| 10.16. Do you have any additional comments on SARE reporting? | |
| **11. Consent and personal data protection (Article 13 and 14, Directive 2004/23/EC)** | |
| 11.1. What consent system for living tissue/cell donation do you have in place within your Member State? | Explicit consent (opt-in) |
| 11.1.1. Please specify your choice of consent system for living tissue/cell donation. | Mostly living donation for HPCs and Gametes |
| 11.2. What consent system for deceased tissue/cell donation do you have in place within your Member State? | Explicit consent (opt-in) |
| 11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible) | First degree relatives (including spouse)<br>Other relatives |
| 11.4. Is the consent system for deceased tissue donation the same as for organs? | Yes |
| 11.5. How is this consent verified during inspections? (more than 1 answer possible) | Analysis of documentation<br>Interviews with personnel<br>Interviews with living donors |
| 11.6. What measures are in place to ensure that donors/relatives/authorising persons on behalf of donors are provided with the appropriate information, as requested by Art. 13(2)? (more than 1 answer possible) | Only trained personnel is allowed to provide such information |
| 11.7. What measures are in place to ensure that both donors and recipients remain unidentifiable when access is given to third parties (Art. 14(1)). Please specify. | Assignement of unique codes |
| 11.8. Please specify what measures are in place to ensure that the identity of the receipient is not disclosed to the donor and vice versa. | Penalty if any information regarding donors or recipients is disclosed in legislation |

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| 11.9. Does your national legislation allows disclosure of donor data in case of gametes donation? | No |
| 11.9.1. If no, please specify the circumstances and measures in place. | Financial and imprisonment sentences in legislation |
| 11.10. Do you have any additional comments on consent and data protection? | |
| **12. Selection, evaluation and procurement (Article 15 Directive 2004/23; Annexes I-IV Directive 2006/17)** | |
| 12.1. How do you ensure that all requirements related to the evaluation and selection of donors (except donors of reproductive cells) are respected in your country (Art. 15(1), Annex I Directive 2006/17/EC)? (more than 1 answer possible) | Inspections of TEs and procurement sites<br>Audit of documentation<br>Regular evaluation of medical personnel |
| 12.2. How do you ensure that all requirements related to the evaluation and selection of donors of reproductive cells are respected in your country (Art 15 (1), Annex III of Directive 2006/17/EC)? (more than 1 answer possible) | Inspections of ART centres<br>Audit documentation |
| 12.3. Do you have more stringent criteria for donor selection than those listed in Annex I of the Directive 2006/17/EC? | No |
| 12.4. What sources are required in your MS for the evaluation of a deceased donor of tissues/cells? (more than 1 answer possible) | Interview with the donor's family or a person who knew the donor well<br>Medical records of the donor<br>Autopsy report |
| 12.5. Do you have more stringent criteria for selection of donors of reproductive cells than those listed in Annex III of the Directive 2006/17/EC? | No |
| 12.6. Do you have more stringent criteria for autologous donation than those listed in Annex I of the Directive 2006/17/EC? | No |
| 12.7. Do you require more information on the donation of tissues/cells than the mandatory one as laid down in the Annex of Directive 2004/23/EC (Art 15(3)? | No |
| 12.8. How do you ensure that all requirements regarding tissues and cells' procurement, packaging and transport are complied with by tissue establishments in your country (Art 15(1), Annex IV of Directive 2006/17/EC? (more than 1 answer possible)(For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)) | Inspection of tissue establishment<br>Audit of tissue establishment |
| 12.9. Do you have any additional comments on selection, evaluation and procurement? | |
| **13. Quality management, responsible person, personnel (Article 16, 17, 18 Directive 2004/23/EC)** | |
| 13.1. How do you ensure that tissue establishments in your country have in place a quality system respecting the provisions of the Directive 2004/23/EC Art 16.1? (more than 1 answer possible). (For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)). | Authorisation requirement<br>Inspections<br>External audits |
| 13.2. How do you ensure that tissue establishments have a responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible) | Authorisation requirement<br>Inspections<br>Regular evaluation of personnel |
| 13.3. How do you ensure an appropriate training for the personnel directly involved in the activities of tissue establishments? (more than 1 answer possible) | Authorisation requirement<br>Inspections<br>Regular evaluation of personnel |
| 13.4. Do you have national/regional/local training programmes for the personnel of tissue establishments? | Yes |
| 13.4.1. If yes, please specify. | ISO training programmes |

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| 13.5. Any additional comments on quality management, responsible person, personnel? | |
| **14. Reception, processing, storage, labelling and packaging (Art 19-22 Directive 2004/23/EC)** | |
| 14.1. How do you ensure that tissue establishments in your country fulfill the requirments of the Art. 19 (Tissue and cell reception) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | Inspections of tissue establishments<br>Internal audits of tissue establishments<br>External audits of tissue establishments (e.g. ISO) |
| 14.2. How do you ensure that tissue establishments in your country fulfill the requirements of the Art. 20 (Tissue and cell processing) of Directive 2004/23/EC? (more than 1 answer possible) | SOPs for all processes affecting quality and safety are mandatory for authorisation<br>Inspections of tissue establishments<br>Internal audits of tissue establishments<br>External audits of tissue establishments (e.g. ISO) |
| 14.3. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 21 (tissue and cell storage conditions) of Directive 2004/23/EC? (more than 1 answer possible) | SOPs for procedures associated with storage of tissues and cells are mandatory for authorisation<br>Inspections of tissue establishments<br>Internal audits of tissue establishments<br>External audits of tissue establishments (e.g. ISO) |
| 14.4. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | SOPs for procedures associated with labelling and packaging are mandatory for authorisation<br>Inspections of tissue establishments<br>Internal audits of tissue establishments<br>External audits of tissue establishments(e.g. ISO) |
| 14.5. Any additional comments on reception, processing, storage, labelling and packaging? | |
| **15. Third party agreements (Art. 24 Directive 2004/23/EC)** | |
| 15.1. Are third party agreements foreseen/allowed in your national legislation? | Yes |
| 15.1.1. If yes, have tissue establishments in your Member State notified third party agreements? | No |
| 15.2. Any additional comments on third party agreements? | Usually with testing laboratories |
| **16. General comments - implementation** | |
| 16.1. Do you have at national level more stringent quality and safety requirements than those requested by the EU legislation in this field (e.g. restrictions concerning the donation/use of certain tissues/cells, mandatory unpaid donation etc.)? | No |
| 16.2. Has your Member State encountered any difficulties in implementing the requirements in the EU Tissues and Cells Directives? Please choose from the options below. | Vigilance<br>Inspections |
| 16.2.1. For all selected options in question 16.2., please provide a short description. | Need ongoing inspectors/vigilance european training programs as personel may change sectors |
| 16.3. In your opinion, in which of the following Directives are there shortcomings (if any)? (more than 1 answer possible) | Directive 2004/23/EC<br>Directive 2006/17/EC<br>Directive 2006/86/EC |
| 16.3.1. How would you suggest to solve these issues in Directive 2004/23/EC? | Please take into account suggestions of the 1st Informal Competent Authorities meeting in 2012 |
| 16.3.2. How would you suggest to solve these issues in Directive 2006/17/EC? | Please take into account suggestions of the 1st Informal Competent Authorities meeting in 2012 |
| 16.3.3. How would you suggest to solve these issues in Directive 2006/86/EC? | Please take into account suggestions of the 1st Informal Competent Authorities meeting in 2012 |

## *A.1.6. Survey response Czech Republic*

| **1. Public information** | |
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| 1.1. Name of National Competent Authority (NCA) 1: | State Institute for Drug Control |
| 1.1.2. Address of NCA 1: | Srobarova 48 100 41 Prague 10 Czech Republic |
| 1.1.3. Telephone (central access point): | +420 272185111 |
| 1.1.4. E-mail (central access point): | posta@sukl.cz |
| 1.1.5. Website: | www.sukl.cz |
| 1.1.6. The NCA is responsible for? (more than 1 answer possible) | Non-reproductive tissues and cells<br>Reproductive tissues and cells<br>Blood and blood components<br>Pharmaceuticals<br>Medical devices<br>Other |
| Please specify 'other': | Regulation of prices and reimbursements of pharmaceuticals |
| 1.1.7.What are the role/tasks of the NCA? (more than 1 answer possible) | Accreditation, authorisation, licensing of TEs<br>Inspection<br>Vigilance |
| 1.2. National Competent Authority 2? | Yes |
| 1.2.1. Name of National Competent Authority 2: | Ministar of Health of the Czech Republic |
| 1.2.2. Address of NCA 2: | Palackeho namesti 4 128 01 Prague 2 Czech Republic |
| 1.2.3. Telephone (central access point): | +420 224971111 |
| 1.2.4. E-mail (central access point): | mzcr@mzcr.cz |
| 1.2.5. Website: | www.mzcr.cz |
| 1.2.6. The NCA is responsible for? (more than 1 answer possible) | Non-reproductive tissues and cells<br>Reproductive tissues and cells<br>Blood and blood components<br>Human organs<br>Pharmaceuticals<br>Medical devices<br>Other |
| Please specify 'other': | Regulation of prices and reimbursements of pharmaceuticals |
| 1.2.7. What are the role/tasks of the NCA? (more than 1 answer possible) | Other |
| Please specify 'other': | Licencing of import and export ,contacts with EC, preparation of legal matters in national legislation |
| 1.3. National Competent Authority 3? | No |
| 1.5. Please give a short description of the legal status and organisation of the National Competent Authority(ies) (e.g. departments, staffing, number of senior and junior inspectors, staff working on EU affairs and legal matters, vigilance officers, budget, independence from government etc.). | State Institute Survaillance Branch Inspection Division Clinical Practice and Survaillance over Buiological Material Proccessing (2 inspectors), Pharmacovigilance Department |
| 1.6. In case of MS with federal or decentralised systems, please indicate the roles/tasks of the Regional Competent Authority(ies). (more than 1 answer possible) | Not applicable |
| 1.7. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies) for tissues and cells: | NA |
| **2. Procurement (Article 5 Directive 2004/23/EC)** | |
| 2.1. Do you authorise the "conditions of procurement"? | Yes |
| 2.1.1. How do you authorise the "conditions of procurement"? (more than 1 answer possible) | By inspecting all procurement centres<br>Other |
| Please specify 'other': | Approval licence issued by State Institute for Drug Control |
| 2.1.2. How many such authorisations were granted in 2011 (01/01-31/12/2011)? | 102 |
| 2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011). | 45 |

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| 2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011). | 67 |
| 2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues were carried out in 2011 (01/01-31/12/2011). | 35 |
| 2.2.4. Please provide the number of procurement centers in which procurement of tissues/cells for ATMP manufacturing were carried out in 2011 (01/01-31/12/2011). | 4 |
| 2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC and its implementing Directive 2006/17/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) ? (more than 1 answer possible) | Inspections of the site/centre<br>Other |
| Please specify 'other': | Approval licence issued by State Institute for Drug Control |
| 2.4. Are you also responsible for the accreditation, designation, authorisation or licensing of laboratories performing donor testing? | Yes |
| 2.4.1. Please provide the number of the laboratories performing donor testing. | 26 |
| 2.5. How do you ensure, as CA for T&C, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art. 5(2))? (more than 1 answer possible) | Inspections of the laboratories<br>Other |
| Please specify 'other': | Approval licence issued by State Institute for Drug Control |
| 2.6. Please provide data on qualified laboratories accredited, authorised or licensed in your country (e.g. number, year of accreditation/authorisation/license, which donor tests are performed etc.). | 26 |
| 2.7. Do you have any additional comments on procurement? | No |
| **3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)** | |
| 3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>Ag HIV<br>HBs AG<br>Anti HBc<br>Anti HCV-Ab<br>Treponema Pallidum |
| 3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>Ag HIV<br>HBs AG<br>Anti HBc<br>Anti HCV-Ab<br>NAT Chlamydia<br>Treponema Pallidum |
| 3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to encourage its use? Please specify why or why not (e.g. number of additional cases detected, cost-benefit etc.). | NAT testing is not allowed by the Czech national legislation |
| 3.4. Do you have concerns on accuracy of the available tests and test procedures for deceased donors? | No |
| 3.5. Are any other laboratory tests required for donors of non-reproductive tissues and cells in your Member State? | Yes |
| 3.5.1. Please specify. | HTLV for donor living in or originate from high incidence areas (sexual partners, parents) |
| 3.6. Are any other laboratory tests required for donors of reproductive tissues and cells in your Member State? | Yes |
| 3.6.1. Please specify. | HTLV for donor living in or originate from high incidence areas (sexual partners, parents) |
| 3.7. Do you request/use international accreditation systems for testing laboratories? | No |

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| 3.8. Do you have any additional comments on testing? | No |
| **4. Accreditation, designation, authorisation or licensing of tissue establishments (Article 6, Directive 2004/23/EC)** | |
| 4.1. Do you have a system of designation, authorisation, accreditation or licensing for all types of tissue establishments under your responsability? | Yes |
| 4.2. Is inspection a prerequisite for the designation, authorisation, accreditation or licensing of tissue establishments? | Yes |
| 4.2.1. How many inspections were performed in 2011 for authorising/accrediting/licensing/designating TEs? | 86 |
| 4.3. Are preparation processes authorised? | Yes |
| 4.3.1. How are they authorised? (more than 1 answer possible) | During routine inspections<br>By review of a submitted application with supporting documentation |
| 4.4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were suspended in 2011? | 0 |
| 4.5. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011? | 0 |
| 4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)? | No |
| **4bis. Overview of tissue/cells establishments authorised by the NCA** | |
| 4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible): | Ocular tissue establishments<br>HSC tissue establishments<br>ART tissue establishments<br>Multi-tissue establishments |
| 4.7.3. How many ocular tissue establishments? | 2 |
| 4.7.5. How many HSC tissue establishments? | 1 |
| 4.7.7. How many ART tissue establishments? | 7 |
| 4.7.8. How many multi-tissue establishments? | 2 |
| 4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible): | Multi-tissue establishments |
| 4.8.8. How many multi-tissue establishments? | 2 |
| 4.9. Tissue establishments first time authorised between 01/01/2011 and 31/12/2011 (more than 1 answer possible): | Musculo-skeletal tissue establishments<br>ART tissue establishments<br>Multi-tissue establishments<br>Other tissue establishments |
| 4.9.2. How many musculo-skeletal tissue establishments? | 2 |
| 4.9.7. How many ART tissue establishments? | 4 |
| 4.9.8. How many multi-tissue establishments? | 1 |
| 4.9.9. Please specify the type of tissues/cells and how many. | Adipose tissues- 2 TE Distribution - 2 TE |
| 4.10. All tissue establishments authorised by 31/12/2011 (more than 1 answer possible): | Musculo-skeletal tissue establishments<br>Ocular tissue establishments<br>HSC tissue establishments<br>Cord blood tissue establishments<br>ART tissue establishments<br>Multi-tissue establishments<br>Other tissue establishments |
| 4.10.2.1. How many public musculo-skeletal tissue establishments? | 10 |
| 4.10.2.2. How many private musculo-skeletal tissue establishments? | 0 |
| 4.10.3.1. How many public ocular tissue establishments? | 1 |
| 4.10.3.2. How many private ocular tissue establishments? | 0 |
| 4.10.5.1. How many public HSC tissue establishments? | 2 |
| 4.10.5.2. How many private HSC tissue establishments? | 0 |
| 4.10.6.1. How many public cord blood tissue establishments? | 0 |
| 4.10.6.2. How many private cord blood tissue establishments? | 1 |
| 4.10.7.1. How many public ART tissue establishments? | 3 |
| 4.10.7.2. How many private ART tissue establishments? | 28 |
| 4.10.8.1. How many public multi-tissue establishments? | 5 |
| 4.10.8.2. How many private multi-tissue establishments? | 0 |
| 4.10.9.1. Please specify the type of 'other' public tissues/cells | 0 |

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| establishements and how many. | |
| 4.10.9.2. Please specify the type of 'other' private tissues/cells establishements and how many. | 1 storage of TCs, 2 distribution, 2 adipose tissues |
| 4.11. How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Art. 6(5) during 2011? Please provide number(s) per type tissues/cells. | 0 |
| **4ter. Sanctions** | |
| 4.16. Have penalties for infringements of the national provisions pursuant to the Directive been defined (Article 27)? | Yes |
| 4.16.1. Have penalties already been imposed? | Yes |
| 4.16.1.1. How many penalties have been imposed in 2011 (from 01/01/2011-31/12/2011)? | 0 |
| 4.16.1.2. What were the reasons for imposing the penalties? Please describe. | NA |
| 4.16.1.3. What kind of penalties were imposed? Please describe (e.g. suspension of authorisation, criminal penalty etc.) | NA |
| 4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing? | No |
| **5. Inspections (Article 7, Directive 2004/23/EC)** | |
| 5.1. Is a system in place for organising inspections and control measures of tissue establishments? | Yes |
| 5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections. | Clinical Practice and Survaillance over Biological Materila Processing (part of Inspection Division) |
| 5.1.2. If yes, please specify staffing (how many inspectors). | 2 |
| 5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible) | Yes |
| 5.2.1. If yes, please specify. (more than 1 answer possible) | Blood<br>Pharmaceuticals<br>Advanced therapies |
| 5.3. How many routine inspections of tissue establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011)? | 78 |
| 5.3.1. How many inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) following serious adverse events or reactions, or suspicion thereof ? | 0 |
| 5.3.2. How many other type of inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | 3 - suspection of illegal activities (procurement, processing and use) concerning TC without any licence reguested by the law |
| 5.3.3. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | 0 |
| 5.3.4. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where minor shortcomings were noted? | 72 |
| 5.3.5. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where major shortcomings were noted? | 6 |
| 5.3.6. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by suspension of authorisation? | 0 |
| 5.3.7. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What | 0 |

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| was the number of inspections carried out that were followed by closure? | |
| 5.3.8. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of other inspections carried out? Please specify. | 3 |
| 5.4. How many routine inspections were conducted in ART establishments (from 1/1/2011 to 31/12/2011)? | 9 |
| 5.4.1. How many inspections were conducted in ART establishments following serious adverse events or reactions, or suspicion thereof (from 1/1/2011 to 31/12/2011)? | 0 |
| 5.4.2. How many other type of inspections were conducted on ART establishments (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | 0 |
| 5.4.3. Outcome of inspections of ART tissue establishments carried out in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | 0 |
| 5.4.4. What was the number of inspections carried out in ART establishments where minor shortcomings were noted? | 6 |
| 5.4.5. What was the number of inspections carried out in ART establishments where major shortcomings were noted? | 3 |
| 5.4.6. What was the number of inspections carried out in ART establishments followed by suspension of authorisation? | 0 |
| 5.4.7. What was the number of inspections carried out in ART establishments followed by closure of respective establishements? | 0 |
| 5.4.8. What was the number of other inspections of ART establishments? Please specify. | 0 |
| 5.5. Which type of routine inspections do you conduct? (more than 1 answer possible) | General system-oriented inspections |
| 5.6. How do you decide which type of routine inspection to conduct? | According to the AIDE MEMOIRE of the inspection (standard inspection protocol) |
| 5.7. Until 2011, did you implement the requirement concerning the time interval between two inspections (Art. 7.3.)? | Yes |
| 5.8. How many TEs were inspected at least twice between 2008-2011 (01/01/2008-31/12/2011)? | 8 |
| 5.9. Did you perform/conduct inspections of procurement sites outside tissue establishments? | Yes |
| 5.9.1. If yes, how many? | 92 |
| 5.10. Did you carry out inspections of third parties? | Yes |
| 5.10.1. If yes, how many? | 28 |
| 5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)? | Yes |
| 5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)? | Yes |
| 5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)? | 3 |
| 5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))? | Yes |
| 5.13.1. Could you please explain why? | To share experience, to get more information about the regulatory approach in another MS |
| 5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))? | Yes |
| 5.14.1. Could you please explain why? | At the request of another NCA |
| 5.15. Did you organise any inspections of procurement centres or tissue establishments in third countries from which tissues and/or | No |

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| cells were imported in your country (as recorded by 31/12/2011)? | |
| 5.16. Have you asked another MS, or have you been requested by any other MS, on the results and control measures of your inspections, as part of an enquiry/investigation? | No |
| 5.17. Would you be interested in developing joint inspections? Joint inspections should be understood as inspections of tissue establishments conducted jointly by two or more Member States' Competent Authorities on their territory or in third countries. | Yes |
| 5.18. Do you have any additional comments on inspections? | No |
| **6. Import/export (Article 9 Directive 2004/23/EC)** | |
| 6.1. Do you have a register of authorised tissue establishments that are explicitly authorised to perform import/export of tissues and celles from/to third countries? | Yes |
| 6.2. Please specify the number of tissue establishments authorised to import tissues and cells from third countries (recorded by 31/12/2011). | 17 |
| 6.3. Please specify the number of tissue establishments authorised to export tissues and cells from third countries (recorded by 31/12/2011). | 16 |
| 6.4. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of skin from third countries. | TE has written SOPs for import including verifying quality and safety requirements according to the Czech law |
| 6.5. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of musculo-skeletal (bone, tendons, fascia etc.) tissues from third countries. | TE has written SOPs for import including verifying quality and safety requirements according to the Czech law |
| 6.6. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of ophtalmic (cornea, sclera, etc) tissues from third countries. | TE has written SOPs for import including verifying quality and safety requirements according to the Czech law |
| 6.7. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cardio vascular tissues from third countries. | TE has written SOPs for import including verifying quality and safety requirements according to the Czech law |
| 6.8. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) (other than cord blood) from third countries. | TE has written SOPs for import including verifying quality and safety requirements according to the Czech law |
| 6.9. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cord blood from third countries. | TE has written SOPs for import including verifying quality and safety requirements according to the Czech law |
| 6.10. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of reproductive cells (sperm, egg cells) from third countries. | TE has written SOPs for import including verifying quality and safety requirements according to the Czech law |
| 6.11. Did you import tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | Yes |
| 6.11.1. If yes, please provide the data concerning the number/volume of imported tissues and cells by country of origin. | PBSC 82, BMSC 2, DLI 6 (SI, DE, USA, UK, CAN) |
| 6.12. Did you export tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | No |
| 6.13. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on imports/exports of tissues/cells between your country and other third countries? | No |
| 6.14. What is the relation between import/export of tissues and cells and self-sufficiency? (more than 1 answer possible) | C. Export of tissues/cells is authorised irrespective of national needs<br>F. Other |
| Please specify 'other': | Import of TCs is authorised irrespective of national needs, upon the request of TE |
| 6.15. Did you authorise direct imports of tissues/cells to hospitals/clinics in your country? | No |
| 6.16. Do you have any additional comments on import/export? | Rules for import/export of TCs are the same in case of 3rd countries and EU MS, the same approval licence |

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| **7. Distribution/intra community exchanges (Article 23 Directive 2004/23/EC)** | |
| 7.1. Do you have intra-community exchanges of tissues and cells? | No |
| 7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify. | TEs can provide distrobution by their own or by approved distributor, both inspected |
| 7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible). | No |
| 7.4. Have you authorised direct distribution to the recipient of specific tissues and cells (Art. 6, Directive 2006/17/EC)? | No |
| 7.5. Do you collect data regarding the cross-border exchange of tissue/cells between your country and other EU MS? | No |
| 7.6. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on cross-border exchanges of tissues/cells between your country and other EU MS? | No |
| 7.7. Do you allow brokerage companies for either distribution in EU and/or import/export of tissues/cells? In this context, a brokerage company means a body that arranges transactions between a supplier (tissue establishment/company selling tissues or cells) and a buyer (a tissue establishment/a hospital or clinic/an individual) without undertaking activities of processing, preservation or storage. | No |
| 7.8. Are brokers actively supplying health professionals/establishments in your country? | No |
| 7.9. Do you have any additional comments on distribution? | No. |
| **8. Register of tissue establishments and reporting obligations (Article 10, Directive 2004/23/EC)** | |
| 8.1. Do you have an annual report model/template on the activities of tissue establishments in your Member State? (Article 10(1)). If yes, please upload the template. | No |
| 8.1.1. If no, why not? | Content of annual report is established in legislation |
| 8.2. How many tissue establishments submitted annual reports of their activities during 2011. Please provide an estimation. (1 answer possible) | 60-99% |
| 8.3. Are these reports publicly available? (Article 10(1)) | Yes |
| 8.3.1. If yes, please insert the link(s) to the report(s). | Available on website of each TE |
| 8.4. Do you publish a national annual report of the consolidated activities of all tissue establishments in your country? | No |
| 8.4.2. If no, why not? | Not requested by national legislation |
| 8.5. Is there a publicly accessible register of authorised tissue establishements in place? (Article 10(2)) | Yes |
| 8.5.1. If yes, please provide us with the link to the register's web site. | www.sukl.cz/Rewievs and Lists/List of subjects from human tissues, cells and blood branch/List of holders of licence according the law on human TC |
| 8.6. Do you provide data regarding tissues and cells activities to the EUROCET registry (non-mandatory reporting)? | Yes |
| 8.6.1. If yes, what data are provided to EUROCET? Please specify. | Detailed information of TE, upon the request of EUROCET |
| 8.7. Do you have any additional comments on reporting? | No. |
| **9. Traceability (Article 8, Directive 2004/23/EC; and Directive 2006/86/EC)** | |
| 9.1. Was the donor identification system (Art. 8(2)) implemented in your country? | Yes |
| 9.2. Who assigns the unique code for each donation? (only 1 answer possible) | Tissue establishment |
| 9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible) | Both paper records and electronic forms |
| 9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify. | Established in written SOPs of TEs, requested by national legislation |
| 9.5. Do you have any additional comments on traceability? | No. |
| **10. Notification of serious adverse events and reactions (Article 11 Directive 2004/23, Article 6 Directive 2006/76)** | |
| 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))? | Yes |
| 10.1.1. If yes, which CA/institution is responsible? | State Institute for Drug Control |
| 10.1.2. If yes, please provide a short description of its organisation. | See above - Pharmacovigilance Department |

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| 10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use the SAR/E (to the CA (2006/76 art 6.4)) templates developed to the Annual reporting ot the EC also at national level? | Yes |
| 10.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level? | Yes |
| 10.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all TEs? | Yes |
| 10.5. How many tissue establishments provided in 2011 the SAR/SAE data as requested (please provide the % from the total number of TEs authorised in your country). | <50% |
| 10.6. Do you have a mandatory procedure for the transplantation centres when reporting SAR/SAE to the TEs which distributed the tissues/cells (Art 11.2)? | Yes |
| 10.6.1. If yes, please provide a brief description. | SAR - TE - State Institute for Drug Control, requested by national legislation |
| 10.7. Do you give feedback to the TEs regarding SAR/SAE recorded at national level? | No |
| 10.7.2. Please specify why not. | System has not been established yet, no reports. |
| 10.8. Do you give feedback to the TEs regarding SAR/SAE recorded at EU level? | No |
| 10.8.2. Please specify why not. | System has not been established yet, no reports. |
| 10.9. Do you require your TEs to have a recall procedure? | Yes |
| 10.10. How many recalls related to safety and quality of tissues/cells were issued in your country in 2011? Please specify the number and which tissues were recalled and why (e.g. missing consent, quality defects etc). | 0 |
| 10.11. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites in case of a national rapid alert? | No |
| 10.11.2. If no, please specify why not. | System has not been established yet, no RA yet. in case of RA is possible to use established RA system for pharmaceuticals or medical devices |
| 10.12. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites when a rapid alert is issued via the EU RATC platform? | No |
| 10.12.2. If no, please specify why not. | System has not been established yet, no RA yet, in case of RA is possible to use established RA system for pharmaceuticals or medical devices |
| 10.13. Do you provide data regarding SAR/SAE to the EUROCET registry (non-mandatory reporting)? | Yes |
| 10.13.1. If yes, please specify what data. | Requested data (no SAR/SAE reported) |
| 10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems? | Yes |
| 10.14.1. If yes, please specify which of the following systems are usually contacted. (more than 1 answer possible) | Haemovigilance<br>Pharmacovilance<br>Medical devices |
| 10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S? | No |
| 10.15.2. If no, please specify why not. | No specialised vigilance officer for TCs |
| 10.16. Do you have any additional comments on SARE reporting? | No. |
| **11. Consent and personal data protection (Article 13 and 14, Directive 2004/23/EC)** | |
| 11.1. What consent system for living tissue/cell donation do you have in place within your Member State? | Explicit consent (opt-in) |
| 11.1.1. Please specify your choice of consent system for living tissue/cell donation. | Written informed consent for each donation, requested by national legislation. |
| 11.2. What consent system for deceased tissue/cell donation do you have in place within your Member State? | Presumed consent (opt-out) |
| 11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the | No further authorisation is needed<br>Other |

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| tissue donation? (more than 1 answer possible) | |
| Please specify 'other'. | National Register for Persons Withagreeing with Post-mortem Removal of Organs and Tissues, responsible person verifies information from this register before procurement |
| 11.4. Is the consent system for deceased tissue donation the same as for organs? | Yes |
| 11.5. How is this consent verified during inspections? (more than 1 answer possible) | Analysis of documentation<br>Interviews with personnel |
| 11.6. What measures are in place to ensure that donors/relatives/authorising persons on behalf of donors are provided with the appropriate information, as requested by Art. 13(2)? (more than 1 answer possible) | Only trained personnel is allowed to provide such information |
| 11.7. What measures are in place to ensure that both donors and recipients remain unidentifiable when access is given to third parties (Art. 14(1)). Please specify. | Established in written SOPs of TEs, inspected by NCA berofe TE licencing, requested by national legislation |
| 11.8. Please specify what measures are in place to ensure that the identity of the receipient is not disclosed to the donor and vice versa. | Established in written SOPs of TEs, inspected by NCA berofe TE licencing, requested by national legislation |
| 11.9. Does your national legislation allows disclosure of donor data in case of gametes donation? | No |
| 11.9.1. If no, please specify the circumstances and measures in place. | Established in written SOPs of TEs, inspected by NCA berofe TE licencing, requested by national legislation |
| 11.10. Do you have any additional comments on consent and data protection? | No |
| **12. Selection, evaluation and procurement (Article 15 Directive 2004/23; Annexes I-IV Directive 2006/17)** | |
| 12.1. How do you ensure that all requirements related to the evaluation and selection of donors (except donors of reproductive cells) are respected in your country (Art. 15(1), Annex I Directive 2006/17/EC)? (more than 1 answer possible) | Inspections of TEs and procurement sites<br>Other |
| Please specify 'other'. | Approval licence from NCA for procurement centers |
| 12.2. How do you ensure that all requirements related to the evaluation and selection of donors of reproductive cells are respected in your country (Art 15 (1), Annex III of Directive 2006/17/EC)? (more than 1 answer possible) | Inspections of ART centres<br>Other |
| Please specify 'other'. | Approval licence from NCA |
| 12.3. Do you have more stringent criteria for donor selection than those listed in Annex I of the Directive 2006/17/EC? | No |
| 12.4. What sources are required in your MS for the evaluation of a deceased donor of tissues/cells? (more than 1 answer possible) | Interview with the donor's family or a person who knew the donor well<br>Medical records of the donor<br>Interview with the treating physician<br>Interview with the general practitioner<br>Autopsy report |
| 12.5. Do you have more stringent criteria for selection of donors of reproductive cells than those listed in Annex III of the Directive 2006/17/EC? | Yes |
| 12.5.1. Please specify. | HIV p 24 laboratory testing, NAT is not acceptable |
| 12.6. Do you have more stringent criteria for autologous donation than those listed in Annex I of the Directive 2006/17/EC? | No |
| 12.7. Do you require more information on the donation of tissues/cells than the mandatory one as laid down in the Annex of Directive 2004/23/EC (Art 15(3)? | No |
| 12.8. How do you ensure that all requirements regarding tissues and cells' procurement, packaging and transport are complied with by tissue establishments in your country (Art 15(1), Annex IV of Directive 2006/17/EC? (more than 1 answer possible)(For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, | Inspection of tissue establishment<br>Audit of tissue establishment<br>Inspection of the centre of human application (e.g. transplantation centre, ART centre)<br>Other |

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| Tissues and Cells, 2011)) | |
| 12.8.1. Please specify. | Written SOPs, approval licence |
| 12.9. Do you have any additional comments on selection, evaluation and procurement? | No. |
| **13. Quality management, responsible person, personnel (Article 16, 17, 18 Directive 2004/23/EC)** | |
| 13.1. How do you ensure that tissue establishments in your country have in place a quality system respecting the provisions of the Directive 2004/23/EC Art 16.1? (more than 1 answer possible). (For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)). | Authorisation requirement<br>Inspections<br>Internal audits<br>External audits |
| 13.2. How do you ensure that tissue establishments have a responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible) | Authorisation requirement<br>Inspections<br>Regular evaluation of personnel |
| 13.3. How do you ensure an appropriate training for the personnel directly involved in the activities of tissue establishments? (more than 1 answer possible) | Authorisation requirement<br>Inspections<br>Regular evaluation of personnel |
| 13.4. Do you have national/regional/local training programmes for the personnel of tissue establishments? | No |
| 13.4.2. If no, in which country(ies) is your personnel trained? | EU countries<br>Non-EU countries |
| 13.4.2.1. Please specify EU-countries. | No |
| 13.4.2.2. Please specify non EU-countries. | No |
| 13.5. Any additional comments on quality management, responsible person, personnel? | No request for personnel training in EU, Non-EU countries |
| **14. Reception, processing, storage, labelling and packaging (Art 19-22 Directive 2004/23/EC)** | |
| 14.1. How do you ensure that tissue establishments in your country fulfill the requirments of the Art. 19 (Tissue and cell reception) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | Inspections of tissue establishments<br>Internal audits of tissue establishments |
| 14.2. How do you ensure that tissue establishments in your country fulfill the requirements of the Art. 20 (Tissue and cell processing) of Directive 2004/23/EC? (more than 1 answer possible) | SOPs for all processes affecting quality and safety are mandatory for authorisation<br>Inspections of tissue establishments<br>Internal audits of tissue establishments |
| 14.3. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 21 (tissue and cell storage conditions) of Directive 2004/23/EC? (more than 1 answer possible) | SOPs for procedures associated with storage of tissues and cells are mandatory for authorisation<br>Inspections of tissue establishments<br>Internal audits of tissue establishments |
| 14.4. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | SOPs for procedures associated with labelling and packaging are mandatory for authorisation<br>Inspections of tissue establishments<br>Internal audits of tissue establishments |
| 14.5. Any additional comments on reception, processing, storage, labelling and packaging? | No |
| **15. Third party agreements (Art. 24 Directive 2004/23/EC)** | |
| 15.1. Are third party agreements foreseen/allowed in your national legislation? | Yes |
| 15.1.1. If yes, have tissue establishments in your Member State notified third party agreements? | Yes |
| 15.1.1.1. Under which circumstances and for which responsibilities? | Laboratory testing, storage, distribution, procurement Written agreements Issued in the approval licence of TE |
| 15.1.1.2. How are third party agreements controlled (Art 6.2) by the Competent Auhtority(ies) in your MS? Please specify. | Approval licence, inspected before approval, inspected every 2 years |
| 15.2. Any additional comments on third party agreements? | No. |
| **16. General comments - implementation** | |
| 16.1. Do you have at national level more stringent quality and safety requirements than those requested by the EU legislation in this field | No |

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| (e.g. restrictions concerning the donation/use of certain tissues/cells, mandatory unpaid donation etc.)? | |
| 16.2. Has your Member State encountered any difficulties in implementing the requirements in the EU Tissues and Cells Directives? Please choose from the options below. | ART provisions<br>Import-export<br>Vigilance |
| 16.2.1. For all selected options in question 16.2., please provide a short description. | Some ART refuse regulation Special approval licence for distributors Access into the DB |
| 16.3. In your opinion, in which of the following Directives are there shortcomings (if any)? (more than 1 answer possible) | No shortcomings |

## *A.1.7. Survey response Denmark*

| **1. Public information** | |
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| 1.1. Name of National Competent Authority (NCA) 1: | Danish Health & Medicines Authority |
| 1.1.2. Address of NCA 1: | Axel Heides Gade 1 2300 Copenhagen S Denmark |
| 1.1.3. Telephone (central access point): | +45 7222 7400 |
| 1.1.4. E-mail (central access point): | sst@sst.dk |
| 1.1.5. Website: | www.@sst.dk |
| 1.1.6. The NCA is responsible for? (more than 1 answer possible) | Non-reproductive tissues and cells<br>Reproductive tissues and cells<br>Blood and blood components<br>Human organs<br>Pharmaceuticals<br>Medical devices |
| 1.1.7. What are the role/tasks of the NCA? (more than 1 answer possible) | Accreditation, authorisation, licensing of TEs<br>Inspection<br>Vigilance<br>Other |
| Please specify 'other': | Development and implementation of national legislation, formulation of national health policies, etc. |
| 1.2. National Competent Authority 2? | No |
| 1.5. Please give a short description of the legal status and organisation of the National Competent Authority(ies) (e.g. departments, staffing, number of senior and junior inspectors, staff working on EU affairs and legal matters, vigilance officers, budget, independence from government etc.). | In Denmark, the Danish Health and Medicines Authority is the supreme authority in healthcare and regulatory control of medicines. We assist and advise the Ministry of Health as well as other authorities with the administration of healthcare services and inform Danish citizens on health issues. It is also our responsibility to ensure the availability of effective and safe medicines, medical devices and new therapies and to promote their proper use. We are here to create the best possible framework for the healthcare system to prevent and treat illness, suffering and functional limitations for the individual. We give advice on the Danish regions healthcare plans. We follow health conditions through monitoring and evaluation and endeavour to be at the cutting edge of professional knowledge within the healthcare area. We have the responsibility for education, authorisation, registration and supervision of Healthcare professionals. There are approximately 700 employees devided between 10 departments and with resides at 4 addresses. |
| 1.6. In case of MS with federal or decentralised systems, please indicate the roles/tasks of the Regional Competent Authority(ies). (more than 1 answer possible) | Not applicable |
| 1.7. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies) for tissues and cells: | The National Competent Authority has primary responsibility for all aspects of TE Directives. Regional Competent Authorities are not present in Denmark. |
| **2. Procurement (Article 5 Directive 2004/23/EC)** | |
| 2.1. Do you authorise the "conditions of procurement"? | Yes |
| 2.1.1. How do you authorise the "conditions of procurement"? (more than 1 answer possible) | By inspecting some procurement centres<br>By inspecting the documentation associated with procurement that is available in the tissue establishment working with procurement centres |
| 2.1.2. How many such authorisations were granted in 2011 (01/01-31/12/2011)? | Seven. |
| 2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011). | Forty-seven |
| 2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011). | Thirty-five |
| 2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues | Forty |

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| were carried out in 2011 (01/01-31/12/2011). | |
| 2.2.4. Please provide the number of procurement centers in which procurement of tissues/cells for ATMP manufacturing were carried out in 2011 (01/01-31/12/2011). | Ten |
| 2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC and its implementing Directive 2006/17/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) ? (more than 1 answer possible) | Analysis of the mandatory documentation |
| 2.4. Are you also responsible for the accreditation, designation, authorisation or licensing of laboratories performing donor testing? | Yes |
| 2.4.1. Please provide the number of the laboratories performing donor testing. | Nine testing laboratories in Denmark. |
| 2.5. How do you ensure, as CA for T&C, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art. 5(2))? (more than 1 answer possible) | Inspections of the laboratories |
| 2.6. Please provide data on qualified laboratories accredited, authorised or licensed in your country (e.g. number, year of accreditation/authorisation/license, which donor tests are performed etc.). | There are nine within Denmark. These were first authorised in 2007. HIV Ag/Ab NPU19649; Anti-HCV NPU12033, HBsAg NPU02349 ; Anti-HBc NPU02346; Ultrio Plus NAT NPU26888; Syfilis NPU12993; HCV RNA NPU14475; HIV RNA NPU26884; HBV DNA NPU12183 |
| 2.7. Do you have any additional comments on procurement? | Testing of donors is regulated as a tissue establishment in Denmark. |
| **3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)** | |
| 3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>HBs AG<br>Anti HBc<br>Treponema Pallidum |
| 3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>HBs AG<br>Anti HBc<br>NAT Chlamydia<br>Treponema Pallidum |
| 3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to encourage its use? Please specify why or why not (e.g. number of additional cases detected, cost-benefit etc.). | See 3.5 below as well. NAT testing is mandated nationally for deceased donors. Established by national scientifi committee several years to be beneficia in minimizing infection transmission. We intend to make NAT testing for HIV, HBV og HCV mandatory for egg donors |
| 3.4. Do you have concerns on accuracy of the available tests and test procedures for deceased donors? | No |
| 3.5. Are any other laboratory tests required for donors of non-reproductive tissues and cells in your Member State? | Yes |
| 3.5.1. Please specify. | NAT testing is mandated nationally for deceased donors. |
| 3.6. Are any other laboratory tests required for donors of reproductive tissues and cells in your Member State? | No |
| 3.7. Do you request/use international accreditation systems for testing laboratories? | No |
| 3.8. Do you have any additional comments on testing? | Testing laboratories should be included in Eurocet registry with authorised analyses listed with IUPAC numbers. |
| **4. Accreditation, designation, authorisation or licensing of tissue establishments (Article 6, Directive 2004/23/EC)** | |
| 4.1. Do you have a system of designation, authorisation, accreditation or licensing for all types of tissue establishments under your responsability? | Yes |
| 4.2. Is inspection a prerequisite for the designation, authorisation, accreditation or licensing of tissue establishments? | Yes |
| 4.2.1. How many inspections were performed in 2011 for authorising/accrediting/licensing/designating TEs? | Thirteen |
| 4.3. Are preparation processes authorised? | No |

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| 4.4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were suspended in 2011? | 0 |
| 4.5. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011? | 0 |
| 4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)? | No |
| **4bis. Overview of tissue/cells establishments authorised by the NCA** | |
| 4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible): | Other tissue establishments |
| 4.7.9. Please specify the type of tissues/cells and how many. | It is only possible to continue if accepting one pending in 4.7 |
| 4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible): | Other tissue establishments |
| 4.8.9. Please specify the type of tissues/cells and how many. | To accept Other tissue establishment in 4.8 is the only way to be able to continue this questionaire |
| 4.9. Tissue establishments first time authorised between 01/01/2011 and 31/12/2011 (more than 1 answer possible): | Musculo-skeletal tissue establishments |
| 4.9.2. How many musculo-skeletal tissue establishments? | 1 |
| 4.10. All tissue establishments authorised by 31/12/2011 (more than 1 answer possible): | Musculo-skeletal tissue establishments<br>Ocular tissue establishments<br>Cardiovascular tissue establishments<br>HSC tissue establishments<br>Cord blood tissue establishments<br>ART tissue establishments<br>Multi-tissue establishments |
| 4.10.2.1. How many public musculo-skeletal tissue establishments? | 13 |
| 4.10.2.2. How many private musculo-skeletal tissue establishments? | 0 |
| 4.10.3.1. How many public ocular tissue establishments? | 1 |
| 4.10.3.2. How many private ocular tissue establishments? | 0 |
| 4.10.4.1. How many public cardiovascular tissue establishments? | 1 |
| 4.10.4.2. How many private cardiovascular tissue establishments? | 0 |
| 4.10.5.1. How many public HSC tissue establishments? | 4 |
| 4.10.5.2. How many private HSC tissue establishments? | 1 |
| 4.10.6.1. How many public cord blood tissue establishments? | 3 |
| 4.10.6.2. How many private cord blood tissue establishments? | 2 |
| 4.10.7.1. How many public ART tissue establishments? | 12 |
| 4.10.7.2. How many private ART tissue establishments? | 14 |
| 4.10.8.1. How many public multi-tissue establishments? | 3 |
| 4.10.8.2. How many private multi-tissue establishments? | 0 |
| 4.11. How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Art. 6(5) during 2011? Please provide number(s) per type tissues/cells. | Corneas 5 |
| **4ter. Sanctions** | |
| 4.16. Have penalties for infringements of the national provisions pursuant to the Directive been defined (Article 27)? | No |
| 4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing? | Establishing and promoting an EU template for authorization will assist in the distribution of tissues/cells and encourage mutual recognition between Member States. |
| **5. Inspections (Article 7, Directive 2004/23/EC)** | |
| 5.1. Is a system in place for organising inspections and control measures of tissue establishments? | Yes |
| 5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections. | Inspection department of the Danish Medicines and Medicines Authority. |
| 5.1.2. If yes, please specify staffing (how many inspectors). | 1.5 whole time equivalents are dedicated to the tissue/cells sector. There are 16 inspectors in the inspection department for all types of GXP. |
| 5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, | Yes |

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| common documentation, etc.)? (more than 1 answer possible) | |
| 5.2.1. If yes, please specify. (more than 1 answer possible) | Blood<br>Organs<br>Pharmaceuticals<br>Advanced therapies<br>Medical devices |
| 5.3. How many routine inspections of tissue establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011)? | 9 |
| 5.3.1. How many inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) following serious adverse events or reactions, or suspicion thereof ? | 0 |
| 5.3.2. How many other type of inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | 0 |
| 5.3.3. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | 0 |
| 5.3.4. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where minor shortcomings were noted? | 7 |
| 5.3.5. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where major shortcomings were noted? | 2 |
| 5.3.6. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by suspension of authorisation? | 0 |
| 5.3.7. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by closure? | 0 |
| 5.3.8. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of other inspections carried out? Please specify. | 0 |
| 5.4. How many routine inspections were conducted in ART establishments (from 1/1/2011 to 31/12/2011)? | 9 |
| 5.4.1. How many inspections were conducted in ART establishments following serious adverse events or reactions, or suspicion thereof (from 1/1/2011 to 31/12/2011)? | 0 |
| 5.4.2. How many other type of inspections were conducted on ART establishments (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | 0 |
| 5.4.3. Outcome of inspections of ART tissue establishments carried out in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | 0 |
| 5.4.4. What was the number of inspections carried out in ART establishments where minor shortcomings were noted? | 7 |
| 5.4.5. What was the number of inspections carried out in ART establishments where major shortcomings were noted? | 2 |
| 5.4.6. What was the number of inspections carried out in ART establishments followed by suspension of authorisation? | 0 |
| 5.4.7. What was the number of inspections carried out in ART establishments followed by closure of respective establishements? | 0 |
| 5.4.8. What was the number of other inspections of ART establishments? Please specify. | 0 |

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| 5.5. Which type of routine inspections do you conduct? (more than 1 answer possible) | General system-oriented inspections<br>Thematic inspections<br>Desk based reviews |
| 5.6. How do you decide which type of routine inspection to conduct? | Routine inspections are typically planned for two year intervals and subsequently evaluated on a risk based approach with current information. |
| 5.7. Until 2011, did you implement the requirement concerning the time interval between two inspections (Art. 7.3.)? | No |
| 5.7.1. Why not? | Resources. |
| 5.7.2. How do you prioritise tissue establishments to be inspected? | Risk based approach and evaluation of current information. |
| 5.8. How many TEs were inspected at least twice between 2008-2011 (01/01/2008-31/12/2011)? | Eleven |
| 5.9. Did you perform/conduct inspections of procurement sites outside tissue establishments? | Yes |
| 5.9.1. If yes, how many? | 1 |
| 5.10. Did you carry out inspections of third parties? | No |
| 5.10.2. If no, why not? | Not practical or justified on the curent information. |
| 5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)? | Yes |
| 5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)? | Yes |
| 5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)? | 4 |
| 5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))? | No |
| 5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))? | No |
| 5.15. Did you organise any inspections of procurement centres or tissue establishments in third countries from which tissues and/or cells were imported in your country (as recorded by 31/12/2011)? | No |
| 5.16. Have you asked another MS, or have you been requested by any other MS, on the results and control measures of your inspections, as part of an enquiry/investigation? | No |
| 5.17. Would you be interested in developing joint inspections? Joint inspections should be understood as inspections of tissue establishments conducted jointly by two or more Member States' Competent Authorities on their territory or in third countries. | No |
| 5.17.1. Could you please explain why not? | Complexities of auditing TE's in third countries and priorities to fulfill requirements at national level. |
| 5.18. Do you have any additional comments on inspections? | The frequency of inspections should be based on a risk assessment scheme instead of a required 2 years frequency |
| **6. Import/export (Article 9 Directive 2004/23/EC)** | |
| 6.1. Do you have a register of authorised tissue establishments that are explicitly authorised to perform import/export of tissues and celles from/to third countries? | Yes |
| 6.2. Please specify the number of tissue establishments authorised to import tissues and cells from third countries (recorded by 31/12/2011). | 9 |
| 6.3. Please specify the number of tissue establishments authorised to export tissues and cells from third countries (recorded by 31/12/2011). | 9 |
| 6.4. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of skin from third countries. | By the routine inspection of the SOP's according to generic principles. |

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| 6.5. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of musculo-skeletal (bone, tendons, fascia etc.) tissues from third countries. | Not specific. |
| 6.6. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of ophtalmic (cornea, sclera, etc) tissues from third countries. | Not specific. |
| 6.7. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cardio vascular tissues from third countries. | Not specific. |
| 6.8. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) (other than cord blood) from third countries. | Not specific. |
| 6.9. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cord blood from third countries. | Not specific. |
| 6.10. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of reproductive cells (sperm, egg cells) from third countries. | Not specific. |
| 6.11. Did you import tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | Yes |
| 6.11.1. If yes, please provide the data concerning the number/volume of imported tissues and cells by country of origin. | Corneas 6 |
| 6.12. Did you export tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | No |
| 6.13. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on imports/exports of tissues/cells between your country and other third countries? | No |
| 6.14. What is the relation between import/export of tissues and cells and self-sufficiency? (more than 1 answer possible) | A. Export of tissues/cells is authorised only after checking that local/national needs are fulfilled.<br>C. Export of tissues/cells is authorised irrespective of national needs<br>D. Import of tissues/cells is authorised only after checking that local/national needs are not fulfilled |
| 6.14.1. If A or D were selected, please explain how you quantify local/national needs. | Advised by the tissue establishment. |
| 6.15. Did you authorise direct imports of tissues/cells to hospitals/clinics in your country? | Yes |
| 6.15.1. If yes, please specify the number of cases and for which type of tissues/cells. | Corneas 6 |
| 6.16. Do you have any additional comments on import/export? | None. |
| **7. Distribution/intra community exchanges (Article 23 Directive 2004/23/EC)** | |
| 7.1. Do you have intra-community exchanges of tissues and cells? | Yes |
| 7.1.1. If yes, how do you address the possible more stringent quality and safety measures established by other Member States? Please specify. | Responsible Person shall demonstrate they have established any supplementary national requirements of the receiving EU country, and demonstrate they meet them. |
| 7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States? | Yes |
| 7.1.2.1. How do you address this difference for tissues and cells coming from a MS with minimum quality requirements? Please specify. | Response to enquiries by sending the TE information on our national requirements. |
| 7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify. | Inspection of the procedures for distribution |
| 7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible). | Yes, no restrictions apply |
| 7.4. Have you authorised direct distribution to the recipient of specific tissues and cells (Art. 6, Directive 2006/17/EC)? | No |
| 7.5. Do you collect data regarding the cross-border exchange of | No |

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| tissue/cells between your country and other EU MS? | |
| 7.6. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on cross-border exchanges of tissues/cells between your country and other EU MS? | No |
| 7.7. Do you allow brokerage companies for either distribution in EU and/or import/export of tissues/cells? In this context, a brokerage company means a body that arranges transactions between a supplier (tissue establishment/company selling tissues or cells) and a buyer (a tissue establishment/a hospital or clinic/an individual) without undertaking activities of processing, preservation or storage. | Yes |
| 7.7.1. Please describe the legal requirements and your role (if any) as a Competent Authority, in their authorisation/monitoring or inspection. | Specific legislation not specified at this time. Our CA informs the brokerage company on the principles of TE legislation and periodically monitors their activities. |
| 7.8. Are brokers actively supplying health professionals/establishments in your country? | Yes |
| 7.8.1. Where are the brokers located? | Your country |
| 7.9. Do you have any additional comments on distribution? | Suitable draft legislation for brokerage companies should be developed to ensure quality, safety and traceability. |
| **8. Register of tissue establishments and reporting obligations (Article 10, Directive 2004/23/EC)** | |
| 8.1. Do you have an annual report model/template on the activities of tissue establishments in your Member State? (Article 10(1)). If yes, please upload the template. | No |
| 8.1.1. If no, why not? | Report format and style varies slightly from year to year. |
| 8.2. How many tissue establishments submitted annual reports of their activities during 2011. Please provide an estimation. (1 answer possible) | 100% (all) |
| 8.3. Are these reports publicly available? (Article 10(1)) | No |
| 8.4. Do you publish a national annual report of the consolidated activities of all tissue establishments in your country? | Yes |
| 8.4.1. Please insert the link to the published national annual report. | http://laegemiddelstyrelsen.dk/da/service-menu/produktomraader/vaev-og-celler/register-over-godkendte-vaevscentre |
| 8.5. Is there a publicly accessible register of authorised tissue establishements in place? (Article 10(2)) | Yes |
| 8.5.1. If yes, please provide us with the link to the register's web site. | http://laegemiddelstyrelsen.dk/da/service-menu/produktomraader/vaev-og-celler/register-over-godkendte-vaevscentre |
| 8.6. Do you provide data regarding tissues and cells activities to the EUROCET registry (non-mandatory reporting)? | No |
| 8.6.2. If no, why not? | Data request for clinical information on tissues/cells is not part of our work activities. |
| 8.7. Do you have any additional comments on reporting? | Individual reports (see 8.3) on activities of a TE are not deemed beneficial. |
| **9. Traceability (Article 8, Directive 2004/23/EC; and Directive 2006/86/EC)** | |
| 9.1. Was the donor identification system (Art. 8(2)) implemented in your country? | Yes |
| 9.2. Who assigns the unique code for each donation? (only 1 answer possible) | Tissue establishment |
| 9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible) | Both paper records and electronic forms |
| 9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify. | Verification by routine inspections of tissue establishments. |
| 9.5. Do you have any additional comments on traceability? | None. |
| **10. Notification of serious adverse events and reactions (Article 11 Directive 2004/23, Article 6 Directive 2006/76)** | |
| 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))? | Yes |
| 10.1.1. If yes, which CA/institution is responsible? | Danish Health and Medicines Authority. |
| 10.1.2. If yes, please provide a short description of its organisation. | The vigilance coordinator has responsibility for the receipt, management and assessment of SAR/E's to our Agency. In collaboration with internal colleagues a strategy is developed to |

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| | investigate probable cause and implement corrective actions as appropriate. The vigilance officer is fluent with the protocol and procedures of the RATC system, when applicable. |
| 10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use the SAR/E (to the CA (2006/76 art 6.4)) templates developed to the Annual reporting ot the EC also at national level? | Yes |
| 10.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level? | Yes |
| 10.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all TEs? | Yes |
| 10.5. How many tissue establishments provided in 2011 the SAR/SAE data as requested (please provide the % from the total number of TEs authorised in your country). | <50% |
| 10.6. Do you have a mandatory procedure for the transplantation centres when reporting SAR/SAE to the TEs which distributed the tissues/cells (Art 11.2)? | Yes |
| 10.6.1. If yes, please provide a brief description. | we have a procedure for ART |
| 10.7. Do you give feedback to the TEs regarding SAR/SAE recorded at national level? | No |
| 10.7.2. Please specify why not. | Low statistics at this time. |
| 10.8. Do you give feedback to the TEs regarding SAR/SAE recorded at EU level? | No |
| 10.8.2. Please specify why not. | Resources. |
| 10.9. Do you require your TEs to have a recall procedure? | Yes |
| 10.10. How many recalls related to safety and quality of tissues/cells were issued in your country in 2011? Please specify the number and which tissues were recalled and why (e.g. missing consent, quality defects etc). | Two, sperm straws, genetic. |
| 10.11. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites in case of a national rapid alert? | No |
| 10.11.2. If no, please specify why not. | Our national system is effective for notifying the TE's, which thereafter have responsibility for contacting the procurement centre/s. |
| 10.12. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites when a rapid alert is issued via the EU RATC platform? | No |
| 10.12.2. If no, please specify why not. | Our national system is effective for notifying the TE's, which thereafter have responsibility for contacting the procurement centre/s. |
| 10.13. Do you provide data regarding SAR/SAE to the EUROCET registry (non-mandatory reporting)? | No |
| 10.13.2. If no, please specify why not. | Resources. |
| 10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems? | Yes |
| 10.14.1. If yes, please specify which of the following systems are usually contacted. (more than 1 answer possible) | Medical devices |
| 10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S? | Yes |
| 10.15.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (insufficient) - 2 (sufficient) 3 (good) - 4 (very good) to 5 (essential)? | 4 |
| 10.16. Do you have any additional comments on SARE reporting? | A technical report of the SAR/E's at EU level, with recommendations/corrective actions, would be a useful tool to issue direct to tissue establishments. |
| **11. Consent and personal data protection (Article 13 and 14, Directive 2004/23/EC)** | |
| 11.1. What consent system for living tissue/cell donation do you have in place within your Member State? | Explicit consent (opt-in) |
| 11.1.1. Please specify your choice of consent system for living | Different types of consent must be complied with (e.g. for donation, |

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| tissue/cell donation. | for treatment, for storage, etc) |
| 11.2. What consent system for deceased tissue/cell donation do you have in place within your Member State? | Explicit consent (opt-in) |
| 11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible) | First degree relatives (including spouse) |
| 11.4. Is the consent system for deceased tissue donation the same as for organs? | No |
| 11.4.1. If no, please describe the difference. | Different perspectives apply here. |
| 11.5. How is this consent verified during inspections? (more than 1 answer possible) | Analysis of documentation |
| 11.6. What measures are in place to ensure that donors/relatives/authorising persons on behalf of donors are provided with the appropriate information, as requested by Art. 13(2)? (more than 1 answer possible) | Only trained personnel is allowed to provide such information |
| 11.7. What measures are in place to ensure that both donors and recipients remain unidentifiable when access is given to third parties (Art. 14(1)). Please specify. | This is the responsibility of the TE and different control systems apply. |
| 11.8. Please specify what measures are in place to ensure that the identity of the receipient is not disclosed to the donor and vice versa. | This is the responsibility of the TE and the treatment clinic to ensure. by their own hospital procedures. |
| 11.9. Does your national legislation allows disclosure of donor data in case of gametes donation? | Yes |
| 11.10. Do you have any additional comments on consent and data protection? | None. |
| **12. Selection, evaluation and procurement (Article 15 Directive 2004/23; Annexes I-IV Directive 2006/17)** | |
| 12.1. How do you ensure that all requirements related to the evaluation and selection of donors (except donors of reproductive cells) are respected in your country (Art. 15(1), Annex I Directive 2006/17/EC)? (more than 1 answer possible) | Inspections of TEs and procurement sites<br>Audit of documentation |
| 12.2. How do you ensure that all requirements related to the evaluation and selection of donors of reproductive cells are respected in your country (Art 15 (1), Annex III of Directive 2006/17/EC)? (more than 1 answer possible) | Inspections of ART centres<br>Audit documentation |
| 12.3. Do you have more stringent criteria for donor selection than those listed in Annex I of the Directive 2006/17/EC? | No |
| 12.4. What sources are required in your MS for the evaluation of a deceased donor of tissues/cells? (more than 1 answer possible) | Interview with the donor's family or a person who knew the donor well<br>Medical records of the donor |
| 12.5. Do you have more stringent criteria for selection of donors of reproductive cells than those listed in Annex III of the Directive 2006/17/EC? | No |
| 12.6. Do you have more stringent criteria for autologous donation than those listed in Annex I of the Directive 2006/17/EC? | No |
| 12.7. Do you require more information on the donation of tissues/cells than the mandatory one as laid down in the Annex of Directive 2004/23/EC (Art 15(3)? | No |
| 12.8. How do you ensure that all requirements regarding tissues and cells' procurement, packaging and transport are complied with by tissue establishments in your country (Art 15(1), Annex IV of Directive 2006/17/EC? (more than 1 answer possible)(For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)) | Inspection of tissue establishment<br>Audit of tissue establishment |
| 12.9. Do you have any additional comments on selection, evaluation and procurement? | |
| **13. Quality management, responsible person, personnel (Article 16, 17, 18 Directive 2004/23/EC)** | |
| 13.1. How do you ensure that tissue establishments in your country | Authorisation requirement |

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| have in place a quality system respecting the provisions of the Directive 2004/23/EC Art 16.1? (more than 1 answer possible). (For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)). | Inspections<br>Internal audits |
| 13.2. How do you ensure that tissue establishments have a responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible) | Authorisation requirement<br>Inspections |
| 13.3. How do you ensure an appropriate training for the personnel directly involved in the activities of tissue establishments? (more than 1 answer possible) | Inspections |
| 13.4. Do you have national/regional/local training programmes for the personnel of tissue establishments? | Yes |
| 13.4.1. If yes, please specify. | An independent organization performs a one day course, which is available for all types of tissue establishments. |
| 13.5. Any additional comments on quality management, responsible person, personnel? | None. |
| **14. Reception, processing, storage, labelling and packaging (Art 19-22 Directive 2004/23/EC)** | |
| 14.1. How do you ensure that tissue establishments in your country fulfill the requirments of the Art. 19 (Tissue and cell reception) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | Inspections of tissue establishments |
| 14.2. How do you ensure that tissue establishments in your country fulfill the requirements of the Art. 20 (Tissue and cell processing) of Directive 2004/23/EC? (more than 1 answer possible) | SOPs for all processes affecting quality and safety are mandatory for authorisation<br>Inspections of tissue establishments |
| 14.3. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 21 (tissue and cell storage conditions) of Directive 2004/23/EC? (more than 1 answer possible) | SOPs for procedures associated with storage of tissues and cells are mandatory for authorisation<br>Inspections of tissue establishments |
| 14.4. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | SOPs for procedures associated with labelling and packaging are mandatory for authorisation<br>Inspections of tissue establishments |
| 14.5. Any additional comments on reception, processing, storage, labelling and packaging? | None. |
| **15. Third party agreements (Art. 24 Directive 2004/23/EC)** | |
| 15.1. Are third party agreements foreseen/allowed in your national legislation? | Yes |
| 15.1.1. If yes, have tissue establishments in your Member State notified third party agreements? | Yes |
| 15.1.1.1. Under which circumstances and for which responsibilities? | Examples of circumstances are where; a) infectious marker testing is performed at a different testing centre, b) the TE arranges responsibility for stored tissue/cells and traceability data to a third party, if they should close, c) another third party performs specialized processing on behalf of the TE, d) the TE has an IT system and the software updates, the storage of data (ie patient files, lab results, materials in contact, etc are performed by an independent third party, e) the TE uses the courier services of a third party to fulfill distribution requirements. f) another TE in a different EU country performs earlier specified activities (donation/procurement/testing) and our TE continues with later specified activities. |
| 15.1.1.2. How are third party agreements controlled (Art 6.2) by the Competent Auhtority(ies) in your MS? Please specify. | A specific evaluation of the contractual agreements (see 15.1.1.1 above) to ensure details and responsibilities of both parties are specified, and agreement is signed and dated. This evaluation is performed at routine inspections and are specified in the TE dossier prior to the visit. |
| 15.2. Any additional comments on third party agreements? | None. |

| 16. General comments - implementation | |
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| 16.1. Do you have at national level more stringent quality and safety requirements than those requested by the EU legislation in this field (e.g. restrictions concerning the donation/use of certain tissues/cells, mandatory unpaid donation etc.)? | Yes |
| 16.1.1. Please specify. | NAT testing for deceased donors, specified in a guidance document. |
| 16.2. Has your Member State encountered any difficulties in implementing the requirements in the EU Tissues and Cells Directives? Please choose from the options below. | Testing provisions<br>Distribution provisions<br>Import-export<br>Inspections |
| 16.2.1. For all selected options in question 16.2., please provide a short description. | Status of testing laboratories in other countries and some national requirements are different in Europe Distribution; Interpretation is different across Europe. Import-eksport: Issues are being addressed in working group Inspections: The 2 year interval is a challenge to fulfill |
| 16.3. In your opinion, in which of the following Directives are there shortcomings (if any)? (more than 1 answer possible) | Directive 2004/23/EC<br>Directive 2006/17/EC<br>Directive 2006/86/EC |
| 16.3.1. How would you suggest to solve these issues in Directive 2004/23/EC? | Identify proposals for further consideration, review these in a working group to develop recommendations, then present the information to CA/Commission meetings. |
| 16.3.2. How would you suggest to solve these issues in Directive 2006/17/EC? | Identify proposals for further consideration, review these in a working group to develop recommendations, then present the information to CA/Commission meetings. |
| 16.3.3. How would you suggest to solve these issues in Directive 2006/86/EC? | Identify proposals for further consideration, review these in a working group to develop recommendations, then present the information to CA/Commission meetings. |

## *A.1.8. Survey response Estonia*

| **1. Public information** | |
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| 1.1. Name of National Competent Authority (NCA) 1: | State Agency of Medicines |
| 1.1.2. Address of NCA 1: | Nooruse 1, 50411 Tartu, Estonia |
| 1.1.3. Telephone (central access point): | +372 737 4140 |
| 1.1.4. E-mail (central access point): | info@ravimiamet.ee |
| 1.1.5. Website: | http://www.ravimiamet.ee/ |
| 1.1.6. The NCA is responsible for? (more than 1 answer possible) | Non-reproductive tissues and cells<br>Reproductive tissues and cells<br>Blood and blood components<br>Human organs<br>Pharmaceuticals |
| 1.1.7. What are the role/tasks of the NCA? (more than 1 answer possible) | Accreditation, authorisation, licensing of TEs<br>Inspection<br>Vigilance |
| 1.2. National Competent Authority 2? | No |
| 1.5. Please give a short description of the legal status and organisation of the National Competent Authority(ies) (e.g. departments, staffing, number of senior and junior inspectors, staff working on EU affairs and legal matters, vigilance officers, budget, independence from government etc.). | State Agency of Medicines is a governmental body under the Ministry of Social Affairs. Its main responsibility is the protection and promotion of public and animal health, through the supervision of medicines for human and veterinary use. Among other goals State Agency of Medicines aims to ensure that cells, tissues and organs used in the treatment of humans in Estonia are proven to be safe and of high quality. Department of Biologicals is a part of State Agency of Medicines. The staff consists of three persons who are all involved in EU affairs, legal matters and biovigilance. The inspections can also be carried out by all members of the department with the help of a senior inspector whose main focus is pharmaceutical manufacturing. As Department of Biologicals is a part of the State Agency of Medicines, it gets funded by the agency, which is funded by approximately ten percent by the government. |
| 1.6. In case of MS with federal or decentralised systems, please indicate the roles/tasks of the Regional Competent Authority(ies). (more than 1 answer possible) | Not applicable |
| 1.7. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies) for tissues and cells: | No Regional Competent Authority(ies) |
| **2. Procurement (Article 5 Directive 2004/23/EC)** | |
| 2.1. Do you authorise the "conditions of procurement"? | Yes |
| 2.1.1. How do you authorise the "conditions of procurement"? (more than 1 answer possible) | Other |
| Please specify 'other': | In Estonia only tissue establishments and special medical care providers in contract with tissue establishments are allowed to procure tissues. Tissue establishment is responsible for the procurement and conditions and documentation associated with procurement in the tissue establishment are inspected. |
| 2.1.2. How many such authorisations were granted in 2011 (01/01-31/12/2011)? | Two tissue establishments renewed their licences. |
| 2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011). | There were three tissue establishments responsible for procurement of "traditional tissues and cells" in 2011. |
| 2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011). | There were two tissue establishments responsible for procurement of haematopoietic stem cells in 2011. |
| 2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues were carried out in 2011 (01/01-31/12/2011). | There were five tissue establishments responsible for procurement of gametes, embryos and other reproductive tissues in 2011. |
| 2.2.4. Please provide the number of procurement centers in which procurement of tissues/cells for ATMP manufacturing were carried | 0. |

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| out in 2011 (01/01-31/12/2011). | |
| 2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC and its implementing Directive 2006/17/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) ? (more than 1 answer possible) | Inspections of the site/centre<br>Analysis of the mandatory documentation |
| 2.4. Are you also responsible for the accreditation, designation, authorisation or licensing of laboratories performing donor testing? | No |
| 2.4.2. Which National Authority is in charge of this activity? | Laboratories are accredited by Estonian Accreditation Centre. |
| 2.5. How do you ensure, as CA for T&C, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art. 5(2))? (more than 1 answer possible) | Analysis of the mandatory documentation requested from the tissue establishment |
| 2.6. Please provide data on qualified laboratories accredited, authorised or licensed in your country (e.g. number, year of accreditation/authorisation/license, which donor tests are performed etc.). | - East-Tallinn Central Hospital Ltd. - 25.06.2012 (first accred. 18.12.07) Detailed description - http://www.eak.ee/dokumendid/pdf/kasitlusala/L199.pdf - North Estonia Medical Centre Ltd Laboratory (03.06.2010) Detailed description – http://www.eak.ee/dokumendid/pdf/kasitlusala/L232.pdf - - Quattromed HTI Laborid Ltd - 20.05.2009 (first accred. 20.05.04) Detailed description - http://www.eak.ee/dokumendid/pdf/kasitlusala/L159.pdf - - Tartu University Clinics United Laboratories - 03.02.2010 (first accred. 03.02.05) Detailed description - http://www.eak.ee/dokumendid/pdf/kasitlusala/L167.pdf - West Tallinn Central Hospital Ltd Laboratory of Clinic of Diagnostics 26.02.2009 (first accred. 26.02.04) Detailed description - http://www.eak.ee/dokumendid/pdf/kasitlusala/L155.pdf |
| 2.7. Do you have any additional comments on procurement? | |
| **3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)** | |
| 3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>NAT HIV 1<br>HBs AG<br>Anti HBc<br>Anti HCV-Ab<br>NAT HCV<br>Treponema Pallidum |
| 3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>NAT HIV 1<br>HBs AG<br>Anti HBc<br>Anti HCV-Ab<br>NAT HCV<br>NAT Chlamydia<br>Treponema Pallidum |
| 3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to encourage its use? Please specify why or why not (e.g. number of additional cases detected, cost-benefit etc.). | The use is encouraged, but the resources of tissue establishments and the cost-benefit has to be taken into account. |
| 3.4. Do you have concerns on accuracy of the available tests and test procedures for deceased donors? | No |
| 3.5. Are any other laboratory tests required for donors of non-reproductive tissues and cells in your Member State? | Yes |
| 3.5.1. Please specify. | Anti-HTVL-I for donors coming from high risk areas or whose sexual partners come from high risk areas. |
| 3.6. Are any other laboratory tests required for donors of reproductive tissues and cells in your Member State? | Yes |
| 3.6.1. Please specify. | - Anti-HTVL-I for donors coming from high risk areas or whose sexual partners come from high risk areas. - Trichomoniasis |

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| 3.7. Do you request/use international accreditation systems for testing laboratories? | No |
| 3.8. Do you have any additional comments on testing? | |
| **4. Accreditation, designation, authorisation or licensing of tissue establishments (Article 6, Directive 2004/23/EC)** | |
| 4.1. Do you have a system of designation, authorisation, accreditation or licensing for all types of tissue establishments under your responsability? | Yes |
| 4.2. Is inspection a prerequisite for the designation, authorisation, accreditation or licensing of tissue establishments? | Yes |
| 4.2.1. How many inspections were performed in 2011 for authorising/accrediting/licensing/designating TEs? | 5. |
| 4.3. Are preparation processes authorised? | Yes |
| 4.3.1. How are they authorised? (more than 1 answer possible) | During routine inspections<br>During inspections organised for this purpose |
| 4.4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were suspended in 2011? | 0. |
| 4.5. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011? | 0. |
| 4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)? | No |
| **4bis. Overview of tissue/cells establishments authorised by the NCA** | |
| 4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible): | Other tissue establishments |
| 4.7.9. Please specify the type of tissues/cells and how many. | None. |
| 4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible): | Other tissue establishments |
| 4.8.9. Please specify the type of tissues/cells and how many. | None. |
| 4.9. Tissue establishments first time authorised between 01/01/2011 and 31/12/2011 (more than 1 answer possible): | Other tissue establishments |
| 4.9.9. Please specify the type of tissues/cells and how many. | None. |
| 4.10. All tissue establishments authorised by 31/12/2011 (more than 1 answer possible): | ART tissue establishments<br>Multi-tissue establishments |
| 4.10.7.1. How many public ART tissue establishments? | 0 |
| 4.10.7.2. How many private ART tissue establishments? | 3 |
| 4.10.8.1. How many public multi-tissue establishments? | 3 |
| 4.10.8.2. How many private multi-tissue establishments? | 0 |
| 4.11. How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Art. 6(5) during 2011? Please provide number(s) per type tissues/cells. | No tissues requiring special direct agreement were distributed. |
| **4ter. Sanctions** | |
| 4.16. Have penalties for infringements of the national provisions pursuant to the Directive been defined (Article 27)? | Yes |
| 4.16.1. Have penalties already been imposed? | No |
| 4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing? | |
| **5. Inspections (Article 7, Directive 2004/23/EC)** | |
| 5.1. Is a system in place for organising inspections and control measures of tissue establishments? | Yes |
| 5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections. | State Agency of Medicines, Department of Biologicals within the structure of the agency. |
| 5.1.2. If yes, please specify staffing (how many inspectors). | 3 in the Department of Biologicals (all multi-functional) and also 1 from another department of the agency (department for supervision over medicinal products; support to tissue establishment inspections). |
| 5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible) | Yes |

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| 5.2.1. If yes, please specify. (more than 1 answer possible) | Blood<br>Organs<br>Advanced therapies<br>Others |
| Please specify other. | General inspection process has been established on the level of the State Agency of Medicines, the agency supervises tissues and cells and pharmaceuticals. |
| 5.3. How many routine inspections of tissue establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011)? | 4 |
| 5.3.1. How many inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) following serious adverse events or reactions, or suspicion thereof ? | 0 |
| 5.3.2. How many other type of inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | 0 |
| 5.3.3. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | 0 |
| 5.3.4. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where minor shortcomings were noted? | 3 |
| 5.3.5. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where major shortcomings were noted? | 1 |
| 5.3.6. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by suspension of authorisation? | 0 |
| 5.3.7. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by closure? | 0 |
| 5.3.8. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of other inspections carried out? Please specify. | 4 |
| 5.4. How many routine inspections were conducted in ART establishments (from 1/1/2011 to 31/12/2011)? | 2 |
| 5.4.1. How many inspections were conducted in ART establishments following serious adverse events or reactions, or suspicion thereof (from 1/1/2011 to 31/12/2011)? | 0 |
| 5.4.2. How many other type of inspections were conducted on ART establishments (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | 1 - Inspection of premises and conditions prior to first authorisation (new ART site). |
| 5.4.3. Outcome of inspections of ART tissue establishments carried out in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | 0 |
| 5.4.4. What was the number of inspections carried out in ART establishments where minor shortcomings were noted? | 0 |
| 5.4.5. What was the number of inspections carried out in ART establishments where major shortcomings were noted? | 2 |
| 5.4.6. What was the number of inspections carried out in ART establishments followed by suspension of authorisation? | 0 |
| 5.4.7. What was the number of inspections carried out in ART establishments followed by closure of respective establishements? | 0 |
| 5.4.8. What was the number of other inspections of ART | 0 |

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| establishments? Please specify. | |
| 5.5. Which type of routine inspections do you conduct? (more than 1 answer possible) | General system-oriented inspections<br>Thematic inspections |
| 5.6. How do you decide which type of routine inspection to conduct? | Depends on the results of the last inspection and/or changes in the facilities and handling practices in the tissue establishment. |
| 5.7. Until 2011, did you implement the requirement concerning the time interval between two inspections (Art. 7.3.)? | Yes |
| 5.8. How many TEs were inspected at least twice between 2008-2011 (01/01/2008-31/12/2011)? | 6 - including inspections prior to first authorisations. |
| 5.9. Did you perform/conduct inspections of procurement sites outside tissue establishments? | No |
| 5.9.2. If no, why not? | Authorised tissue establishments in Estonia are themselves responsible for fulfilling the conditions for procurement. |
| 5.10. Did you carry out inspections of third parties? | No |
| 5.10.2. If no, why not? | State Agency of Medicines is not obligated to inspect third parties on routine basis. Also, laboratories performing the donor testing are accredited by Estonian Accreditation Centre. |
| 5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)? | Yes |
| 5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)? | Yes |
| 5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)? | 4 |
| 5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))? | No |
| 5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))? | No |
| 5.15. Did you organise any inspections of procurement centres or tissue establishments in third countries from which tissues and/or cells were imported in your country (as recorded by 31/12/2011)? | No |
| 5.16. Have you asked another MS, or have you been requested by any other MS, on the results and control measures of your inspections, as part of an enquiry/investigation? | No |
| 5.17. Would you be interested in developing joint inspections? Joint inspections should be understood as inspections of tissue establishments conducted jointly by two or more Member States' Competent Authorities on their territory or in third countries. | Yes |
| 5.18. Do you have any additional comments on inspections? | |
| **6. Import/export (Article 9 Directive 2004/23/EC)** | |
| 6.1. Do you have a register of authorised tissue establishments that are explicitly authorised to perform import/export of tissues and celles from/to third countries? | Yes |
| 6.2. Please specify the number of tissue establishments authorised to import tissues and cells from third countries (recorded by 31/12/2011). | 6. Only authorized tissue establishments are allowed to import/export tissues from/to third countries. |
| 6.3. Please specify the number of tissue establishments authorised to export tissues and cells from third countries (recorded by 31/12/2011). | 6 |
| 6.4. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of skin from third countries. | There are currently no tissue establishments authorized to handle skin in Estonia. |
| 6.5. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of musculo-skeletal (bone, tendons, fascia etc.) tissues from third | Only authorized tissue establishments are allowed to import tissues from third countries. |

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| countries. | |
| 6.6. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of ophtalmic (cornea, sclera, etc) tissues from third countries. | Only authorized tissue establishments are allowed to import tissues from third countries. |
| 6.7. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cardio vascular tissues from third countries. | Only authorized tissue establishments are allowed to import tissues from third countries. |
| 6.8. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) (other than cord blood) from third countries. | Only authorized tissue establishments are allowed to import tissues from third countries. |
| 6.9. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cord blood from third countries. | There are currently no tissue establishments authorized to handle cord blood in Estonia. |
| 6.10. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of reproductive cells (sperm, egg cells) from third countries. | Only authorized tissue establishments are allowed to import tissues from third countries. |
| 6.11. Did you import tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | Yes |
| 6.11.1. If yes, please provide the data concerning the number/volume of imported tissues and cells by country of origin. | 19 unrelated bags of HPC. Countries of origin: 15 from Germany, 2 from Finland, 2 from Israel. 249 sperm straws. Country of origin: Denmark. |
| 6.12. Did you export tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | Yes |
| 6.12.1. If yes, please provide the data concerning the number/volume of exported tissues and cells by country of destination. | 26 units of cord blood. Countries of destination: 25 to Lithuania, 1 to United Kingdom. |
| 6.13. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on imports/exports of tissues/cells between your country and other third countries? | No |
| 6.14. What is the relation between import/export of tissues and cells and self-sufficiency? (more than 1 answer possible) | C. Export of tissues/cells is authorised irrespective of national needs<br>F. Other |
| Please specify 'other': | Import of tissues/cells is authorised irrespective of national needs. |
| 6.15. Did you authorise direct imports of tissues/cells to hospitals/clinics in your country? | No |
| 6.16. Do you have any additional comments on import/export? | |
| **7. Distribution/intra community exchanges (Article 23 Directive 2004/23/EC)** | |
| 7.1. Do you have intra-community exchanges of tissues and cells? | Yes |
| 7.1.1. If yes, how do you address the possible more stringent quality and safety measures established by other Member States? Please specify. | Tissue establishments themselves are responsible for meeting the quality and safety measures established by Member States they want to export to. |
| 7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States? | No |
| 7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify. | The conditions of transport are in the responsibility of the tissue establishment and the means of establishing the proper conditions are controlled during routine inspections. |
| 7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible). | Yes, but only via an authorised TE in my MS |
| 7.4. Have you authorised direct distribution to the recipient of specific tissues and cells (Art. 6, Directive 2006/17/EC)? | No |
| 7.5. Do you collect data regarding the cross-border exchange of tissue/cells between your country and other EU MS? | Yes |
| 7.5.1. Please provide us with data (country of destination, type of tissue/cell and number of units distributed) concerning distribution to other MS in 2011 (01/01/2011-31/12/2011). | 26 units of cord blood. Countries of destination: 25 to Lithuania, 1 to United Kingdom. |
| 7.5.2. Please provide us with data (country of origin, type of tissue/cell and number of units distributed) concerning distribution to other MS in 2011 (01/01/2011-31/12/2011) | 19 unrelated bags of HPC. Countries of origin: 15 from Germany, 2 from Finland, 2 from Israel. 249 sperm straws. Country of origin: Denmark. |
| 7.6. Are you aware of any significant changes in 2012 which may | No |

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| invalidate the 2011 data on cross-border exchanges of tissues/cells between your country and other EU MS? | |
| 7.7. Do you allow brokerage companies for either distribution in EU and/or import/export of tissues/cells? In this context, a brokerage company means a body that arranges transactions between a supplier (tissue establishment/company selling tissues or cells) and a buyer (a tissue establishment/a hospital or clinic/an individual) without undertaking activities of processing, preservation or storage. | No |
| 7.8. Are brokers actively supplying health professionals/establishments in your country? | No |
| 7.9. Do you have any additional comments on distribution? | |
| **8. Register of tissue establishments and reporting obligations (Article 10, Directive 2004/23/EC)** | |
| 8.1. Do you have an annual report model/template on the activities of tissue establishments in your Member State? (Article 10(1)). If yes, please upload the template. | Yes |
| 8.2. How many tissue establishments submitted annual reports of their activities during 2011. Please provide an estimation. (1 answer possible) | 100% (all) |
| 8.3. Are these reports publicly available? (Article 10(1)) | No |
| 8.4. Do you publish a national annual report of the consolidated activities of all tissue establishments in your country? | Yes |
| 8.4.1. Please insert the link to the published national annual report. | http://www.ravimiamet.ee/rakkude-kudede-ja-elundite-2012-aasta-k%C3%A4itlemisandmete-kokkuv%C3%B5te |
| 8.5. Is there a publicly accessible register of authorised tissue establishements in place? (Article 10(2)) | Yes |
| 8.5.1. If yes, please provide us with the link to the register's web site. | http://www.ravimiamet.ee/en/list-licensed-handlers-cells-tissues-and-organs-tissue-establishments |
| 8.6. Do you provide data regarding tissues and cells activities to the EUROCET registry (non-mandatory reporting)? | Yes |
| 8.6.1. If yes, what data are provided to EUROCET? Please specify. | State Agency of Medicine completes forms for tissues, HPC and ART. |
| 8.7. Do you have any additional comments on reporting? | |
| **9. Traceability (Article 8, Directive 2004/23/EC; and Directive 2006/86/EC)** | |
| 9.1. Was the donor identification system (Art. 8(2)) implemented in your country? | Yes |
| 9.2. Who assigns the unique code for each donation? (only 1 answer possible) | Tissue establishment |
| 9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible) | Both paper records and electronic forms |
| 9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify. | Tissue establishments have a legal obligation to store the data and they will have to demonstrate a reasonable storage/backup system for the documents during inspections. |
| 9.5. Do you have any additional comments on traceability? | |
| **10. Notification of serious adverse events and reactions (Article 11 Directive 2004/23, Article 6 Directive 2006/76)** | |
| 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))? | Yes |
| 10.1.1. If yes, which CA/institution is responsible? | State Agency of Medicines |
| 10.1.2. If yes, please provide a short description of its organisation. | State Agency of Medicines is a governmental body under the Ministry of Social Affairs. Its main responsibility is the protection and promotion of public and animal health, through the supervision of medicines for human and veterinary use. Among other goals State Agency of Medicines aims to ensure that cells, tissues and organs used in the treatment of humans in Estonia are proven to be safe and of high quality. |
| 10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use the SAR/E (to the CA (2006/76 art 6.4)) templates developed to the Annual reporting ot the EC also at national level? | Yes |
| 10.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level? | Yes |
| 10.4. Do you have a dedicated vigilance officer in charge of | Yes |

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| collecting SAR/E from all TEs? | |
| 10.5. How many tissue establishments provided in 2011 the SAR/SAE data as requested (please provide the % from the total number of TEs authorised in your country). | 100% |
| 10.6. Do you have a mandatory procedure for the transplantation centres when reporting SAR/SAE to the TEs which distributed the tissues/cells (Art 11.2)? | No |
| 10.6.2. If no, how do you ensure that SAR/SAE are reported to the TEs? | There is no mandatory procedure but the transplantation centre is required by the law to report SAR/SAE to the TE concerned. |
| 10.7. Do you give feedback to the TEs regarding SAR/SAE recorded at national level? | Yes |
| 10.7.1. Please specify. | Vigilance activities are reported biannually on the website of State Agency of Medicines. |
| 10.8. Do you give feedback to the TEs regarding SAR/SAE recorded at EU level? | Yes |
| 10.8.1. Please specify. | EU level serious adverse reactions and adverse events will be included in the biannual overview, if Estonia was directly concerned. |
| 10.9. Do you require your TEs to have a recall procedure? | Yes |
| 10.10. How many recalls related to safety and quality of tissues/cells were issued in your country in 2011? Please specify the number and which tissues were recalled and why (e.g. missing consent, quality defects etc). | Four cases of hyperviscosity of apheresis product (HPC). |
| 10.11. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites in case of a national rapid alert? | Yes |
| 10.11.1. If yes, please give a short description of the system/procedure. | Tissue establishments concerned will be informed by e-mail and over the phone. |
| 10.12. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites when a rapid alert is issued via the EU RATC platform? | Yes |
| 10.12.1. If yes, please give a short description of the system/procedure. | Tissue establishments concerned will be informed by e-mail and over the phone. |
| 10.13. Do you provide data regarding SAR/SAE to the EUROCET registry (non-mandatory reporting)? | No |
| 10.13.2. If no, please specify why not. | We complete the SANCO “Serious Adverse Reaction(s) and Event(s)“ questtionnaire. |
| 10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems? | No |
| 10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S? | Yes |
| 10.15.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (insufficient) - 2 (sufficient) 3 (good) - 4 (very good) to 5 (essential)? | 4 |
| 10.16. Do you have any additional comments on SARE reporting? | |
| **11. Consent and personal data protection (Article 13 and 14, Directive 2004/23/EC)** | |
| 11.1. What consent system for living tissue/cell donation do you have in place within your Member State? | Explicit consent (opt-in) |
| 11.1.1. Please specify your choice of consent system for living tissue/cell donation. | Donor has to explicitly agree to donate. This is separate for each donation. |
| 11.2. What consent system for deceased tissue/cell donation do you have in place within your Member State? | Explicit consent (opt-in) |
| 11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible) | No further authorisation is needed |
| 11.4. Is the consent system for deceased tissue donation the same as for organs? | Yes |
| 11.5. How is this consent verified during inspections? (more than 1 answer possible) | Analysis of documentation |

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| 11.6. What measures are in place to ensure that donors/relatives/authorising persons on behalf of donors are provided with the appropriate information, as requested by Art. 13(2)? (more than 1 answer possible) | Only trained personnel is allowed to provide such information |
| 11.7. What measures are in place to ensure that both donors and recipients remain unidentifiable when access is given to third parties (Art. 14(1)). Please specify. | Handling of the documentation is based on the data protection act and only authorized persons are allowed to access the data. |
| 11.8. Please specify what measures are in place to ensure that the identity of the receipient is not disclosed to the donor and vice versa. | Handling of the documentation is based on the data protection act. |
| 11.9. Does your national legislation allows disclosure of donor data in case of gametes donation? | Yes |
| 11.10. Do you have any additional comments on consent and data protection? | The personal data of a donor shall not be disclosed upon artificial insemination, except in the case where the ovum donor is a relative of the woman who wishes to undergo artificial insemination. |
| **12. Selection, evaluation and procurement (Article 15 Directive 2004/23; Annexes I-IV Directive 2006/17)** | |
| 12.1. How do you ensure that all requirements related to the evaluation and selection of donors (except donors of reproductive cells) are respected in your country (Art. 15(1), Annex I Directive 2006/17/EC)? (more than 1 answer possible) | Inspections of TEs and procurement sites |
| 12.2. How do you ensure that all requirements related to the evaluation and selection of donors of reproductive cells are respected in your country (Art 15 (1), Annex III of Directive 2006/17/EC)? (more than 1 answer possible) | Inspections of ART centres |
| 12.3. Do you have more stringent criteria for donor selection than those listed in Annex I of the Directive 2006/17/EC? | No |
| 12.4. What sources are required in your MS for the evaluation of a deceased donor of tissues/cells? (more than 1 answer possible) | Interview with the donor's family or a person who knew the donor well<br>Medical records of the donor<br>Autopsy report<br>Other |
| Please specify 'other'. | Any other relevant tests. |
| 12.5. Do you have more stringent criteria for selection of donors of reproductive cells than those listed in Annex III of the Directive 2006/17/EC? | No |
| 12.6. Do you have more stringent criteria for autologous donation than those listed in Annex I of the Directive 2006/17/EC? | No |
| 12.7. Do you require more information on the donation of tissues/cells than the mandatory one as laid down in the Annex of Directive 2004/23/EC (Art 15(3)? | No |
| 12.8. How do you ensure that all requirements regarding tissues and cells' procurement, packaging and transport are complied with by tissue establishments in your country (Art 15(1), Annex IV of Directive 2006/17/EC? (more than 1 answer possible)(For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)) | Inspection of tissue establishment |
| 12.9. Do you have any additional comments on selection, evaluation and procurement? | |
| **13. Quality management, responsible person, personnel (Article 16, 17, 18 Directive 2004/23/EC)** | |
| 13.1. How do you ensure that tissue establishments in your country have in place a quality system respecting the provisions of the Directive 2004/23/EC Art 16.1? (more than 1 answer possible). (For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)). | Authorisation requirement<br>Inspections |

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| 13.2. How do you ensure that tissue establishments have a responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible) | Authorisation requirement<br>Inspections |
| 13.3. How do you ensure an appropriate training for the personnel directly involved in the activities of tissue establishments? (more than 1 answer possible) | Authorisation requirement<br>Inspections |
| 13.4. Do you have national/regional/local training programmes for the personnel of tissue establishments? | Yes |
| 13.4.1. If yes, please specify. | A competent person shall have the following qualifications: 1) an academic degree in medicine or biology or specialities relating to biology acquired in a university or a foreign qualification equal thereto; 2) at least two years of practical work experience in the field of handling cells, tissues and organs. |
| 13.5. Any additional comments on quality management, responsible person, personnel? | |
| **14. Reception, processing, storage, labelling and packaging (Art 19-22 Directive 2004/23/EC)** | |
| 14.1. How do you ensure that tissue establishments in your country fulfill the requirments of the Art. 19 (Tissue and cell reception) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | National regulation/policy for reception of tissues/cells<br>Inspections of tissue establishments |
| 14.2. How do you ensure that tissue establishments in your country fulfill the requirements of the Art. 20 (Tissue and cell processing) of Directive 2004/23/EC? (more than 1 answer possible) | SOPs for all processes affecting quality and safety are mandatory for authorisation<br>Inspections of tissue establishments |
| 14.3. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 21 (tissue and cell storage conditions) of Directive 2004/23/EC? (more than 1 answer possible) | Inspections of tissue establishments<br>Other |
| Please specify 'other'. | Short description of storage conditions is mandatory for authorisation. |
| 14.4. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | Inspections of tissue establishments<br>Other |
| Please specify 'other'. | Short description of labelling and packaging procedures is mandatory for authorisation. |
| 14.5. Any additional comments on reception, processing, storage, labelling and packaging? | |
| **15. Third party agreements (Art. 24 Directive 2004/23/EC)** | |
| 15.1. Are third party agreements foreseen/allowed in your national legislation? | Yes |
| 15.1.1. If yes, have tissue establishments in your Member State notified third party agreements? | Yes |
| 15.1.1.1. Under which circumstances and for which responsibilities? | This corresponds to the article 24 in 2004/23/EC - e.g. donor testing, transport of the material etc. |
| 15.1.1.2. How are third party agreements controlled (Art 6.2) by the Competent Auhtority(ies) in your MS? Please specify. | During inspections of tissue establishments. List of third parties performing the contractual services related to the tissue handling and the nature of these services is added to the application for authorisation. |
| 15.2. Any additional comments on third party agreements? | |
| **16. General comments - implementation** | |
| 16.1. Do you have at national level more stringent quality and safety requirements than those requested by the EU legislation in this field (e.g. restrictions concerning the donation/use of certain tissues/cells, mandatory unpaid donation etc.)? | No |
| 16.2. Has your Member State encountered any difficulties in implementing the requirements in the EU Tissues and Cells Directives? Please choose from the options below. | No difficulties |
| 16.2.1. For all selected options in question 16.2., please provide a short description. | No difficulties. |
| 16.3. In your opinion, in which of the following Directives are there shortcomings (if any)? (more than 1 answer possible) | No shortcomings |

## *A.1.9. Survey response Finland*

| **1. Public information** | |
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| 1.1. Name of National Competent Authority (NCA) 1: | Finnish Medicines Agency |
| 1.1.2. Address of NCA 1: | P.O. Box 55, FI-00034 FIMEA, FINLAND |
| 1.1.3. Telephone (central access point): | +358 29 522 3341 |
| 1.1.4. E-mail (central access point): | registry@fimea.fi / personal addresses: firstname.lastname@fimea.fi |
| 1.1.5. Website: | www.fimea.fi |
| 1.1.6. The NCA is responsible for? (more than 1 answer possible) | Non-reproductive tissues and cells<br>Reproductive tissues and cells<br>Blood and blood components<br>Human organs<br>Pharmaceuticals |
| 1.1.7. What are the role/tasks of the NCA? (more than 1 answer possible) | Accreditation, authorisation, licensing of TEs<br>Inspection<br>Vigilance |
| 1.2. National Competent Authority 2? | No |
| 1.5. Please give a short description of the legal status and organisation of the National Competent Authority(ies) (e.g. departments, staffing, number of senior and junior inspectors, staff working on EU affairs and legal matters, vigilance officers, budget, independence from government etc.). | The Finnish Medicines Agency (Fimea) is the national competent authority for regulating pharmaceuticals. As a central administrative agency operating under the Ministry of Social Affairs and Health it promotes the health and safety of the population by regulating medicinal, blood and tissue products, and by developing the pharmaceuticals sector. Fimea's organisation is structured around three core processes: Supervision and licenses, Assessment of medicinal products, and Assessment of pharmacotherapies. The Supervision and licenses -process includes Inspectorate unit and Laboratory unit. The Inspectorate is responsible for authorisation and inspection of tissue establishments, and for vigilance functions. About 20 inspectors/experts are working in the Inspectorate. Two senior inspector are responsible for the authorisation and inspection of tissue establishments, and for vigilance actions. In addition, the Assessment of medicinal products -process provides medical expertise at need (mostly in vigilance). Legal expertise is provided by the process of internal services. |
| 1.6. In case of MS with federal or decentralised systems, please indicate the roles/tasks of the Regional Competent Authority(ies). (more than 1 answer possible) | Not applicable |
| 1.7. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies) for tissues and cells: | No decentralised systems nor regional competent authorities for tissues and cells. |
| **2. Procurement (Article 5 Directive 2004/23/EC)** | |
| 2.1. Do you authorise the "conditions of procurement"? | Yes |
| 2.1.1. How do you authorise the "conditions of procurement"? (more than 1 answer possible) | By inspecting all procurement centres<br>Other |
| Please specify 'other': | Procurement sites are listed on each TE license and inspected as a part of routine TE inspection. |
| 2.1.2. How many such authorisations were granted in 2011 (01/01-31/12/2011)? | None. Almost all Finnish TEs and their procurement sites were authorized year 2007-2008. |
| 2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011). | 5 |
| 2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011). | 5 |
| 2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues | No separate procurement sites for gametes and embryos. All 23 fertility clinics (TEs) are responsible also for procurement of |

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| were carried out in 2011 (01/01-31/12/2011). | gametes and embryos. |
| 2.2.4. Please provide the number of procurement centers in which procurement of tissues/cells for ATMP manufacturing were carried out in 2011 (01/01-31/12/2011). | 1 |
| 2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC and its implementing Directive 2006/17/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) ? (more than 1 answer possible) | Inspections of the site/centre |
| 2.4. Are you also responsible for the accreditation, designation, authorisation or licensing of laboratories performing donor testing? | No |
| 2.4.2. Which National Authority is in charge of this activity? | Regional authorities and The National Institute for Health and Welfare (THL) are responsible for licensing of all clinical microbiology laboratories in Finland. THL keeps the registry of laboratories. |
| 2.5. How do you ensure, as CA for T&C, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art. 5(2))? (more than 1 answer possible) | Analysis of the mandatory documentation requested from the tissue establishment |
| 2.6. Please provide data on qualified laboratories accredited, authorised or licensed in your country (e.g. number, year of accreditation/authorisation/license, which donor tests are performed etc.). | In Finland any licensed clinical microbiology laboratory can perform donor testing. THL is a national registration authority and keeps the registry. Exact number of donor testing laboratories was not available during survey. The estimate is 20-30 laboratories (clinical laboratories of university hospitals and central hospitals as well as some private laboratories). |
| 2.7. Do you have any additional comments on procurement? | |
| **3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)** | |
| 3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>Ag HIV<br>NAT HIV 1<br>HBs AG<br>Anti HBc<br>NAT HBV<br>Anti HCV-Ab<br>NAT HCV<br>Treponema Pallidum |
| 3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>Ag HIV<br>NAT HIV 1<br>HBs AG<br>Anti HBc<br>NAT HBV<br>Anti HCV-Ab<br>NAT HCV<br>NAT Chlamydia<br>Treponema Pallidum |
| 3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to encourage its use? Please specify why or why not (e.g. number of additional cases detected, cost-benefit etc.). | The Finnish Medicines Agency will update the Administrative Regulation 3/2012 in 2013. The Finnish Medicines Agency is introducing more stringent protective testing requirements: viral PCR tests required for living and deceased donors -except donors of reproductive cells). The more stringent national requirements are being notified (Commission Directive 98/34/EC; the notification identification is 2013/0349/FIN). |
| 3.4. Do you have concerns on accuracy of the available tests and test procedures for deceased donors? | Yes |
| 3.4.1. Please specify why: | All allogenic donors (both living and deceased) should be tested as carefully (both serology and PCR). |
| 3.5. Are any other laboratory tests required for donors of non-reproductive tissues and cells in your Member State? | Yes |

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| 3.5.1. Please specify. | Risk groups (HTLV, malaria, etc) |
| 3.6. Are any other laboratory tests required for donors of reproductive tissues and cells in your Member State? | Yes |
| 3.6.1. Please specify. | Risk groups (HTLV, malaria, etc) |
| 3.7. Do you request/use international accreditation systems for testing laboratories? | No |
| 3.8. Do you have any additional comments on testing? | |
| **4. Accreditation, designation, authorisation or licensing of tissue establishments (Article 6, Directive 2004/23/EC)** | |
| 4.1. Do you have a system of designation, authorisation, accreditation or licensing for all types of tissue establishments under your responsability? | Yes |
| 4.2. Is inspection a prerequisite for the designation, authorisation, accreditation or licensing of tissue establishments? | Yes |
| 4.2.1. How many inspections were performed in 2011 for authorising/accrediting/licensing/designating TEs? | 2 |
| 4.3. Are preparation processes authorised? | Yes |
| 4.3.1. How are they authorised? (more than 1 answer possible) | During routine inspections |
| 4.4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were suspended in 2011? | 0 |
| 4.5. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011? | 0 |
| 4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)? | No |
| **4bis. Overview of tissue/cells establishments authorised by the NCA** | |
| 4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible): | Musculo-skeletal tissue establishments<br>Other tissue establishments |
| 4.7.2. How many musculo-skeletal tissue establishments? | 1 |
| 4.7.9. Please specify the type of tissues/cells and how many. | mesenchymal stem cells (ATMP) |
| 4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible): | Other tissue establishments |
| 4.8.9. Please specify the type of tissues/cells and how many. | All TEs were authorised by 31.12.2011 |
| 4.9. Tissue establishments first time authorised between 01/01/2011 and 31/12/2011 (more than 1 answer possible): | Musculo-skeletal tissue establishments<br>Other tissue establishments |
| 4.9.2. How many musculo-skeletal tissue establishments? | 1 |
| 4.9.9. Please specify the type of tissues/cells and how many. | mesenchymal stem cells |
| 4.10. All tissue establishments authorised by 31/12/2011 (more than 1 answer possible): | Skin tissue establishments<br>Musculo-skeletal tissue establishments<br>Ocular tissue establishments<br>Cardiovascular tissue establishments<br>HSC tissue establishments<br>Cord blood tissue establishments<br>ART tissue establishments<br>Multi-tissue establishments<br>Other tissue establishments |
| 4.10.1.1. How many public skin tissue establishments? | 1 |
| 4.10.1.2. How many private skin tissue establishments? | 0 |
| 4.10.2.1. How many public musculo-skeletal tissue establishments? | 22 |
| 4.10.2.2. How many private musculo-skeletal tissue establishments? | 1 |
| 4.10.3.1. How many public ocular tissue establishments? | 2 |
| 4.10.3.2. How many private ocular tissue establishments? | 0 |
| 4.10.4.1. How many public cardiovascular tissue establishments? | 1 |
| 4.10.4.2. How many private cardiovascular tissue establishments? | 0 |
| 4.10.5.1. How many public HSC tissue establishments? | 11 |
| 4.10.5.2. How many private HSC tissue establishments? | 0 |
| 4.10.6.1. How many public cord blood tissue establishments? | 1 |
| 4.10.6.2. How many private cord blood tissue establishments? | 0 |
| 4.10.7.1. How many public ART tissue establishments? | 10 |
| 4.10.7.2. How many private ART tissue establishments? | 13 |

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| 4.10.8.1. How many public multi-tissue establishments? | 1 |
| 4.10.8.2. How many private multi-tissue establishments? | 0 |
| 4.10.9.1. Please specify the type of 'other' public tissues/cells establishements and how many. | 1: mesenchymal stem cells (for ATMP) |
| 4.10.9.2. Please specify the type of 'other' private tissues/cells establishements and how many. | 0 |
| 4.11. How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Art. 6(5) during 2011? Please provide number(s) per type tissues/cells. | 0 |
| **4ter. Sanctions** | |
| 4.16. Have penalties for infringements of the national provisions pursuant to the Directive been defined (Article 27)? | Yes |
| 4.16.1. Have penalties already been imposed? | No |
| 4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing? | |
| **5. Inspections (Article 7, Directive 2004/23/EC)** | |
| 5.1. Is a system in place for organising inspections and control measures of tissue establishments? | Yes |
| 5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections. | Fimea's organisation is structured around three core processes: Supervision and licenses, Assessment of medicinal products, and Assessment of pharmacotherapies. The Supervision and licenses - process includes Inspectorate unit and Laboratory unit.The Inspectorate is responsible for authorisation and inspection of tissue establishments, and for vigilance functions. |
| 5.1.2. If yes, please specify staffing (how many inspectors). | 2 |
| 5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible) | Yes |
| 5.2.1. If yes, please specify. (more than 1 answer possible) | Blood<br>Advanced therapies |
| 5.3. How many routine inspections of tissue establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011)? | 17 |
| 5.3.1. How many inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) following serious adverse events or reactions, or suspicion thereof ? | 0 |
| 5.3.2. How many other type of inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | 0 |
| 5.3.3. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | 0 |
| 5.3.4. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where minor shortcomings were noted? | 17 |
| 5.3.5. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where major shortcomings were noted? | 0 |
| 5.3.6. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by suspension of authorisation? | 0 |
| 5.3.7. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What | 0 |

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| was the number of inspections carried out that were followed by closure? | |
| 5.3.8. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of other inspections carried out? Please specify. | 0 |
| 5.4. How many routine inspections were conducted in ART establishments (from 1/1/2011 to 31/12/2011)? | 8 |
| 5.4.1. How many inspections were conducted in ART establishments following serious adverse events or reactions, or suspicion thereof (from 1/1/2011 to 31/12/2011)? | 0 |
| 5.4.2. How many other type of inspections were conducted on ART establishments (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | 0 |
| 5.4.3. Outcome of inspections of ART tissue establishments carried out in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | 0 |
| 5.4.4. What was the number of inspections carried out in ART establishments where minor shortcomings were noted? | 8 |
| 5.4.5. What was the number of inspections carried out in ART establishments where major shortcomings were noted? | 0 |
| 5.4.6. What was the number of inspections carried out in ART establishments followed by suspension of authorisation? | 0 |
| 5.4.7. What was the number of inspections carried out in ART establishments followed by closure of respective establishements? | 0 |
| 5.4.8. What was the number of other inspections of ART establishments? Please specify. | 0 |
| 5.5. Which type of routine inspections do you conduct? (more than 1 answer possible) | General system-oriented inspections<br>Desk based reviews |
| 5.6. How do you decide which type of routine inspection to conduct? | On-site inspections are carried out at least every four years. Desk-based inspections can be used at the time of an intermediate evaluation between on-site inspections, if there have been no significant changes in TE. |
| 5.7. Until 2011, did you implement the requirement concerning the time interval between two inspections (Art. 7.3.)? | Yes |
| 5.8. How many TEs were inspected at least twice between 2008-2011 (01/01/2008-31/12/2011)? | 59 |
| 5.9. Did you perform/conduct inspections of procurement sites outside tissue establishments? | Yes |
| 5.9.1. If yes, how many? | 11 |
| 5.10. Did you carry out inspections of third parties? | No |
| 5.10.2. If no, why not? | In Finland there are quite a few third parties which act as suppliers of critical services to TEs. So far inspections of the TE have indicated no non-compliance with the written agreement by a third party. |
| 5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)? | Yes |
| 5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)? | Yes |
| 5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)? | 4 |
| 5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))? | No |
| 5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))? | No |

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| 5.15. Did you organise any inspections of procurement centres or tissue establishments in third countries from which tissues and/or cells were imported in your country (as recorded by 31/12/2011)? | No |
| 5.16. Have you asked another MS, or have you been requested by any other MS, on the results and control measures of your inspections, as part of an enquiry/investigation? | No |
| 5.17. Would you be interested in developing joint inspections? Joint inspections should be understood as inspections of tissue establishments conducted jointly by two or more Member States' Competent Authorities on their territory or in third countries. | No |
| 5.17.1. Could you please explain why not? | Limited HR |
| 5.18. Do you have any additional comments on inspections? | |
| **6. Import/export (Article 9 Directive 2004/23/EC)** | |
| 6.1. Do you have a register of authorised tissue establishments that are explicitly authorised to perform import/export of tissues and celles from/to third countries? | Yes |
| 6.2. Please specify the number of tissue establishments authorised to import tissues and cells from third countries (recorded by 31/12/2011). | 16 |
| 6.3. Please specify the number of tissue establishments authorised to export tissues and cells from third countries (recorded by 31/12/2011). | 16 |
| 6.4. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of skin from third countries. | No importation of skin |
| 6.5. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of musculo-skeletal (bone, tendons, fascia etc.) tissues from third countries. | Authorised TE is responsible for import procedures. Procedures are inspected douring routine TE inspection. TEs report number of import/export tissues and cells annually. |
| 6.6. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of ophtalmic (cornea, sclera, etc) tissues from third countries. | Authorised TE is responsible for import procedures. Procedures are inspected douring routine TE inspection. TEs report number of import/export tissues and cells annually. |
| 6.7. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cardio vascular tissues from third countries. | No importation of cardio vascular tissues |
| 6.8. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) (other than cord blood) from third countries. | Authorised TE is responsible for import procedures. Procedures are inspected douring routine TE inspection. TEs report number of import/export tissues and cells annually. |
| 6.9. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cord blood from third countries. | Authorised TE is responsible for import procedures. Procedures are inspected douring routine TE inspection. TEs report number of import/export tissues and cells annually. |
| 6.10. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of reproductive cells (sperm, egg cells) from third countries. | Authorised TE is responsible for import procedures. Procedures are inspected douring routine TE inspection. TEs report number of import/export tissues and cells annually. |
| 6.11. Did you import tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | Yes |
| 6.11.1. If yes, please provide the data concerning the number/volume of imported tissues and cells by country of origin. | HSC: 7 grafts from USA, 1 graft from Israel. |
| 6.12. Did you export tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | No |
| 6.13. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on imports/exports of tissues/cells between your country and other third countries? | No |
| 6.14. What is the relation between import/export of tissues and cells and self-sufficiency? (more than 1 answer possible) | F. Other |
| Please specify 'other': | HSC: HLA match criteria |
| 6.15. Did you authorise direct imports of tissues/cells to hospitals/clinics in your country? | No |

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| 6.16. Do you have any additional comments on import/export? | |
| **7. Distribution/intra community exchanges (Article 23 Directive 2004/23/EC)** | |
| 7.1. Do you have intra-community exchanges of tissues and cells? | Yes |
| 7.1.1. If yes, how do you address the possible more stringent quality and safety measures established by other Member States? Please specify. | All grafts must fulfill minimum requirements. In exceptional cases, Fimea can grant permission to import/export graft nor fulfilling the requirements (health reasons, benefits outwigjt the risks). |
| 7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States? | No |
| 7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify. | Authorised TE is responsible for ensuring that the other TE fulfill the requirements. |
| 7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible). | Yes, but only via an authorised TE in my MS |
| 7.4. Have you authorised direct distribution to the recipient of specific tissues and cells (Art. 6, Directive 2006/17/EC)? | No |
| 7.5. Do you collect data regarding the cross-border exchange of tissue/cells between your country and other EU MS? | Yes |
| 7.5.1. Please provide us with data (country of destination, type of tissue/cell and number of units distributed) concerning distribution to other MS in 2011 (01/01/2011-31/12/2011). | HSC: 4 grafts to Germany and Sweden Amniotic membrane: 14 grafts to Ireland |
| 7.5.2. Please provide us with data (country of origin, type of tissue/cell and number of units distributed) concerning distribution to other MS in 2011 (01/01/2011-31/12/2011) | HSC: 79 grafts from Germany, 1 from UK, 1 from Portugese, 1 from France Sclera: 15 from Netherlands Tendons: 63 from Netherlands Sperms: Denmark |
| 7.6. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on cross-border exchanges of tissues/cells between your country and other EU MS? | No |
| 7.7. Do you allow brokerage companies for either distribution in EU and/or import/export of tissues/cells? In this context, a brokerage company means a body that arranges transactions between a supplier (tissue establishment/company selling tissues or cells) and a buyer (a tissue establishment/a hospital or clinic/an individual) without undertaking activities of processing, preservation or storage. | No |
| 7.8. Are brokers actively supplying health professionals/establishments in your country? | No |
| 7.9. Do you have any additional comments on distribution? | |
| **8. Register of tissue establishments and reporting obligations (Article 10, Directive 2004/23/EC)** | |
| 8.1. Do you have an annual report model/template on the activities of tissue establishments in your Member State? (Article 10(1)). If yes, please upload the template. | Yes |
| 8.2. How many tissue establishments submitted annual reports of their activities during 2011. Please provide an estimation. (1 answer possible) | 100% (all) |
| 8.3. Are these reports publicly available? (Article 10(1)) | No |
| 8.4. Do you publish a national annual report of the consolidated activities of all tissue establishments in your country? | Yes |
| 8.4.1. Please insert the link to the published national annual report. | http://www.fimea.fi/download/21482_Kudoslaitostoiminta_Suomessa_vuonna_2011.pdf |
| 8.5. Is there a publicly accessible register of authorised tissue establishements in place? (Article 10(2)) | Yes |
| 8.5.1. If yes, please provide us with the link to the register's web site. | http://www.fimea.fi/download/23600_FI_Lista_Suomessa_toimivista_kudoslaitoksista_10-7-2013.pdf |
| 8.6. Do you provide data regarding tissues and cells activities to the EUROCET registry (non-mandatory reporting)? | Yes |
| 8.6.1. If yes, what data are provided to EUROCET? Please specify. | All |
| 8.7. Do you have any additional comments on reporting? | The role of EUROCET should be clarify (mandatory or non-mandatory reporting). |
| **9. Traceability (Article 8, Directive 2004/23/EC; and Directive 2006/86/EC)** | |
| 9.1. Was the donor identification system (Art. 8(2)) implemented in your country? | Yes |
| 9.2. Who assigns the unique code for each donation? (only 1 answer | Tissue establishment |

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| possible) | |
| 9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible) | Both paper records and electronic forms |
| 9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify. | During inpections particular attention is paid to the identification systems, traceability and registries (IT systems and paper documentation). |
| 9.5. Do you have any additional comments on traceability? | |
| **10. Notification of serious adverse events and reactions (Article 11 Directive 2004/23, Article 6 Directive 2006/76)** | |
| 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))? | Yes |
| 10.1.1. If yes, which CA/institution is responsible? | Fimea |
| 10.1.2. If yes, please provide a short description of its organisation. | Fimea's organisation is structured around three core processes: Supervision and licenses, Assessment of medicinal products, and Assessment of pharmacotherapies. The Supervision and licenses - process includes Inspectorate unit and Laboratory unit. |
| 10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use the SAR/E (to the CA (2006/76 art 6.4)) templates developed to the Annual reporting ot the EC also at national level? | Yes |
| 10.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level? | Yes |
| 10.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all TEs? | Yes |
| 10.5. How many tissue establishments provided in 2011 the SAR/SAE data as requested (please provide the % from the total number of TEs authorised in your country). | 100% |
| 10.6. Do you have a mandatory procedure for the transplantation centres when reporting SAR/SAE to the TEs which distributed the tissues/cells (Art 11.2)? | No |
| 10.6.2. If no, how do you ensure that SAR/SAE are reported to the TEs? | TEs give instructions to the transplantaion centers. |
| 10.7. Do you give feedback to the TEs regarding SAR/SAE recorded at national level? | Yes |
| 10.7.1. Please specify. | Annual summary is published. |
| 10.8. Do you give feedback to the TEs regarding SAR/SAE recorded at EU level? | Yes |
| 10.8.1. Please specify. | We give feedback to those TEs which are involved in particular event. |
| 10.9. Do you require your TEs to have a recall procedure? | Yes |
| 10.10. How many recalls related to safety and quality of tissues/cells were issued in your country in 2011? Please specify the number and which tissues were recalled and why (e.g. missing consent, quality defects etc). | 0 |
| 10.11. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites in case of a national rapid alert? | Yes |
| 10.11.1. If yes, please give a short description of the system/procedure. | We notify TEs by phone or e-mails. |
| 10.12. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites when a rapid alert is issued via the EU RATC platform? | Yes |
| 10.12.1. If yes, please give a short description of the system/procedure. | We notify TEs by phone or e-mails. |
| 10.13. Do you provide data regarding SAR/SAE to the EUROCET registry (non-mandatory reporting)? | No |
| 10.13.2. If no, please specify why not. | We already provide data regarding SAR/SAE to the Comission. |
| 10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems? | Yes |
| 10.14.1. If yes, please specify which of the following systems are usually contacted. (more than 1 answer possible) | Haemovigilance<br>Pharmacovilance |

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| | Medical devices |
| 10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S? | Yes |
| 10.15.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (insufficient) - 2 (sufficient) 3 (good) - 4 (very good) to 5 (essential)? | 4 |
| 10.16. Do you have any additional comments on SARE reporting? | |
| **11. Consent and personal data protection (Article 13 and 14, Directive 2004/23/EC)** | |
| 11.1. What consent system for living tissue/cell donation do you have in place within your Member State? | Explicit consent (opt-in) |
| 11.1.1. Please specify your choice of consent system for living tissue/cell donation. | Donors must give informed written consent to the removal of an organ or tissue. Before giving written consent, donors must be provided with an explanation of the significance of the procedure for themselves and the recipients, and be informed that their consent can be withdrawn. |
| 11.2. What consent system for deceased tissue/cell donation do you have in place within your Member State? | Presumed consent (opt-out) |
| 11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible) | First degree relatives (including spouse)<br>Other relatives<br>Non-marital partners |
| 11.4. Is the consent system for deceased tissue donation the same as for organs? | Yes |
| 11.5. How is this consent verified during inspections? (more than 1 answer possible) | Analysis of documentation<br>Interviews with personnel |
| 11.6. What measures are in place to ensure that donors/relatives/authorising persons on behalf of donors are provided with the appropriate information, as requested by Art. 13(2)? (more than 1 answer possible) | Only trained personnel is allowed to provide such information |
| 11.7. What measures are in place to ensure that both donors and recipients remain unidentifiable when access is given to third parties (Art. 14(1)). Please specify. | Coding systems for donors. Restrict access to registries. |
| 11.8. Please specify what measures are in place to ensure that the identity of the receipient is not disclosed to the donor and vice versa. | Coding systems for donors. Restrict access to registries. |
| 11.9. Does your national legislation allows disclosure of donor data in case of gametes donation? | Yes |
| 11.10. Do you have any additional comments on consent and data protection? | |
| **12. Selection, evaluation and procurement (Article 15 Directive 2004/23; Annexes I-IV Directive 2006/17)** | |
| 12.1. How do you ensure that all requirements related to the evaluation and selection of donors (except donors of reproductive cells) are respected in your country (Art. 15(1), Annex I Directive 2006/17/EC)? (more than 1 answer possible) | Inspections of TEs and procurement sites |
| 12.2. How do you ensure that all requirements related to the evaluation and selection of donors of reproductive cells are respected in your country (Art 15 (1), Annex III of Directive 2006/17/EC)? (more than 1 answer possible) | Inspections of ART centres |
| 12.3. Do you have more stringent criteria for donor selection than those listed in Annex I of the Directive 2006/17/EC? | No |
| 12.4. What sources are required in your MS for the evaluation of a deceased donor of tissues/cells? (more than 1 answer possible) | Interview with the donor's family or a person who knew the donor well<br>Medical records of the donor<br>Interview with the treating physician<br>Autopsy report |
| 12.5. Do you have more stringent criteria for selection of donors of reproductive cells than those listed in Annex III of the Directive 2006/17/EC? | No |
| 12.6. Do you have more stringent criteria for autologous donation than those listed in Annex I of the Directive 2006/17/EC? | No |
| 12.7. Do you require more information on the donation of tissues/cells than the mandatory one as laid down in the Annex of | No |

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| Directive 2004/23/EC (Art 15(3)? | |
| 12.8. How do you ensure that all requirements regarding tissues and cells' procurement, packaging and transport are complied with by tissue establishments in your country (Art 15(1), Annex IV of Directive 2006/17/EC? (more than 1 answer possible)(For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)) | Inspection of tissue establishment<br>Inspection of the centre of human application (e.g. transplantation centre, ART centre) |
| 12.9. Do you have any additional comments on selection, evaluation and procurement? | |
| **13. Quality management, responsible person, personnel (Article 16, 17, 18 Directive 2004/23/EC)** | |
| 13.1. How do you ensure that tissue establishments in your country have in place a quality system respecting the provisions of the Directive 2004/23/EC Art 16.1? (more than 1 answer possible). (For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)). | Authorisation requirement<br>Inspections<br>Internal audits |
| 13.2. How do you ensure that tissue establishments have a responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible) | Authorisation requirement<br>Inspections<br>Regular evaluation of personnel |
| 13.3. How do you ensure an appropriate training for the personnel directly involved in the activities of tissue establishments? (more than 1 answer possible) | Authorisation requirement<br>Inspections<br>Regular evaluation of personnel |
| 13.4. Do you have national/regional/local training programmes for the personnel of tissue establishments? | No |
| 13.4.2. If no, in which country(ies) is your personnel trained? | EU countries |
| 13.4.2.1. Please specify EU-countries. | ESHRE EATB etc. |
| 13.5. Any additional comments on quality management, responsible person, personnel? | |
| **14. Reception, processing, storage, labelling and packaging (Art 19-22 Directive 2004/23/EC)** | |
| 14.1. How do you ensure that tissue establishments in your country fulfill the requirments of the Art. 19 (Tissue and cell reception) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | National regulation/policy for reception of tissues/cells<br>Inspections of tissue establishments<br>Internal audits of tissue establishments |
| 14.2. How do you ensure that tissue establishments in your country fulfill the requirements of the Art. 20 (Tissue and cell processing) of Directive 2004/23/EC? (more than 1 answer possible) | SOPs for all processes affecting quality and safety are mandatory for authorisation<br>Inspections of tissue establishments<br>Internal audits of tissue establishments |
| 14.3. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 21 (tissue and cell storage conditions) of Directive 2004/23/EC? (more than 1 answer possible) | SOPs for procedures associated with storage of tissues and cells are mandatory for authorisation<br>Inspections of tissue establishments<br>Internal audits of tissue establishments |
| 14.4. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | SOPs for procedures associated with labelling and packaging are mandatory for authorisation<br>Inspections of tissue establishments<br>Internal audits of tissue establishments |
| 14.5. Any additional comments on reception, processing, storage, labelling and packaging? | |
| **15. Third party agreements (Art. 24 Directive 2004/23/EC)** | |
| 15.1. Are third party agreements foreseen/allowed in your national legislation? | Yes |
| 15.1.1. If yes, have tissue establishments in your Member State notified third party agreements? | No |
| 15.2. Any additional comments on third party agreements? | |

| **16. General comments - implementation** | |
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| 16.1. Do you have at national level more stringent quality and safety requirements than those requested by the EU legislation in this field (e.g. restrictions concerning the donation/use of certain tissues/cells, mandatory unpaid donation etc.)? | Yes |
| 16.1.1. Please specify. | Tissue Act 101/2001: No donor or assignee of a donor may be promised or paid a fee for the removal and use of an organ or tissue as laid down in this Act, or for the donation of a cadaver. |
| 16.2. Has your Member State encountered any difficulties in implementing the requirements in the EU Tissues and Cells Directives? Please choose from the options below. | No difficulties |
| 16.2.1. For all selected options in question 16.2., please provide a short description. | No difficulties. |
| 16.3. In your opinion, in which of the following Directives are there shortcomings (if any)? (more than 1 answer possible) | Directive 2006/17/EC |
| 16.3.2. How would you suggest to solve these issues in Directive 2006/17/EC? | All allogenic donors (both living and deceased) should be tested as carefully (both serology and PCR). Oocyte and sperm donors (non-partner) should have same test requirements (if there is no quarantine: PCR-tests for HIV, HBV, HCV and Chlmaydia) |

### *A.1.10. Survey response France*

| **1. Public information** | |
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| 1.1. Name of National Competent Authority (NCA) 1: | Ministry of health |
| 1.1.2. Address of NCA 1: | 14, avenue duquesne 75700 PARIS France |
| 1.1.3. Telephone (central access point): | 00 33 1 40 56 50 61 |
| 1.1.4. E-mail (central access point): | genevieve.liffran@sante.gouv.fr |
| 1.1.5. Website: | www.sante.gouv.fr |
| 1.1.6. The NCA is responsible for? (more than 1 answer possible) | Non-reproductive tissues and cells<br>Reproductive tissues and cells<br>Blood and blood components<br>Human organs<br>Pharmaceuticals<br>Medical devices<br>Other |
| Please specify 'other': | cosmetic products, tatoo ink, biocides, ancillary products, milk breast, medicinal products, medicinal products (human , paediatric, veterinary medicinal products) |
| 1.1.7. What are the role/tasks of the NCA? (more than 1 answer possible) | Other |
| Please specify 'other': | The ministry of health draws rules and regulations according to the law applying to the activities on organs, tissues and cells. It designs the strategic orientations of these areas.It manages the health alerts. |
| 1.2. National Competent Authority 2? | Yes |
| 1.2.1. Name of National Competent Authority 2: | Agence nationale de sécurité du médicament et des produits de santé (ANSM) |
| 1.2.2. Address of NCA 2: | 143/147, Boulevard Anatole France 93285 SAINT DENIS CEDEX 3 FRANCE |
| 1.2.3. Telephone (central access point): | 00 33 1 55 87 40 41 |
| 1.2.4. E-mail (central access point): | fewzi.teskrat@ansm.sante.fr |
| 1.2.5. Website: | www.ansm.sante.fr |
| 1.2.6. The NCA is responsible for? (more than 1 answer possible) | Non-reproductive tissues and cells<br>Reproductive tissues and cells<br>Blood and blood components<br>Human organs<br>Pharmaceuticals<br>Medical devices<br>Other |
| Please specify 'other': | cosmetic products, tatoo ink, breast milk, microorganisms and toxins,biocide products, all kinds of medicinal products (including ATMPs), cellular products,contraceptive products,contact lenses |
| 1.2.7. What are the role/tasks of the NCA? (more than 1 answer possible) | Accreditation, authorisation, licensing of TEs<br>Inspection<br>Vigilance<br>Other |
| Please specify 'other': | drawing decisions , recall of products, suspension of authorization, revok of the authorisation, managing rapid alert system,regulatory discussion at national and european level under the supervision of the health Ministry . |
| 1.3. National Competent Authority 3? | Yes |
| 1.3.1. Name of National Competent Authority 3: | Agence de la biomédecine (ABM) |
| 1.3.2. Address of NCA 3: | 1, avenue du stade de france 93212 LA PLAINE SAINT DENIS FRANCE |
| 1.3.3. Telephone (central access point): | 00 33 1 55 93 65 09 |
| 1.3.4. E-mail (central access point): | francoise.merlet@biomedecine.fr |
| 1.3.5. Website: | www.agence-biomedecine.fr |
| 1.3.6. The NCA is responsible for? (more than 1 answer possible) | Reproductive tissues and cells<br>Human organs |
| 1.3.7. What are the role/tasks of the NCA? (more than 1 answer possible) | Inspection<br>Vigilance<br>Other |
| Please specify 'other': | The Agence de la biomedecine is under the authority of the Ministry of health. In the reproductive tissues and cells it has inspection and vigilance missions . It also provides the ministry of health with expertise in order to improve the quality and |

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| | safety in the fields of organs, tissues, reproductive and non reproductive cells procurement, donation and use. It plays an essential role in the promotion and the development of these activities .It has an operational task in allocation of appropriate organs or cells in the purpose of transplantation. |
| 1.4. National Competent Authority 4? | No |
| 1.5. Please give a short description of the legal status and organisation of the National Competent Authority(ies) (e.g. departments, staffing, number of senior and junior inspectors, staff working on EU affairs and legal matters, vigilance officers, budget, independence from government etc.). | The Health Ministry is in charge of drafting the general policy of public health according to the legal framework applying to the activities on organs, tissues and cells (ethical, medical and legal aspects). It also defines the main orientations for the development of these activities .It implements policies for improving the quality and the health security regarding health cares, health products and medical trials. The "Agence nationale de sécurité du médicament et des produits de santé (ANSM)" is responsible for the evaluation, authorisation, inspection and control of whole health products and establishments which process them (for more information: http://www.ansm.fr) The Agence de la biomedecine (ABM) provides expertise in order to improve the quality and safety in four fields : organ procurement, assisted reproduction, embryology and genetics, and haematopoietic stem cells. It plays an essential role in the promotion and the development of these activities. It also has operational tasks in allocation of organs and HSC to the matched recipient in vue of transplantation. Given its expertise in these fields, the ABM is the CA for all medical and scientific aspects relating to these issues. It should be pointed out that in the vigilance field, ANSM is the competent authority for biovigilance and materio vigilance in relation with the Agence de la biomédecine whereas ABM is fully competent for ART vigilance. |
| 1.6. In case of MS with federal or decentralised systems, please indicate the roles/tasks of the Regional Competent Authority(ies). (more than 1 answer possible) | Accreditation, authorisation, licensing of TEs<br>Inspection |
| 1.7. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies) for tissues and cells: | The regional competent authorities (Agences régionales de santé : ARS) are in charge of authorization and inspection of procurement and transplantation of organs, tissues and cells establishments, including hematopoietic stem cells (HSC) and Assisted Reproductive Techniques (ART) centres. ABM provides the regional agencies with an expertise advice in the process of the authorisation. |
| **2. Procurement (Article 5 Directive 2004/23/EC)** | |
| 2.1. Do you authorise the "conditions of procurement"? | Yes |
| 2.1.1. How do you authorise the "conditions of procurement"? (more than 1 answer possible) | Other |
| Please specify 'other': | These conditions are evaluated during the product evaluation where procurement conditions are described in the dossier. |
| 2.1.2. How many such authorisations were granted in 2011 (01/01-31/12/2011)? | 4 |
| 2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011). | 168 authorized procurement centers (among these 168, 22 authorized procurement centers don't perform this procurement activity) |
| 2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011). | 32 bone marrow collection and apheresis centres and 9 cord blood banks. |
| 2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues were carried out in 2011 (01/01-31/12/2011). | In France, in 2011, 104 IVF centres (composed of a biological unit and a clinical unit in an unique site in an establishment for health) and 95 labs for insemination (just a biological site) have performed ART activities. |
| 2.2.4. Please provide the number of procurement centers in which procurement of tissues/cells for ATMP manufacturing were carried out in 2011 (01/01-31/12/2011). | Data not available because the procurement site authorizations are not linked to the regulatory status of the final product. (cell/tissues/ATMP) |
| 2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 | Inspections of the site/centre<br>Analysis of the mandatory documentation |

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| of Directive 2004/23/EC and its implementing Directive 2006/17/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) ? (more than 1 answer possible) | |
| 2.4. Are you also responsible for the accreditation, designation, authorisation or licensing of laboratories performing donor testing? | No |
| 2.4.2. Which National Authority is in charge of this activity? | In 2020, all the French laboratories must be fully accredited by the comité français d'accréditation (COFRAC), designed as the national accreditation body in France (2008 decree). |
| 2.5. How do you ensure, as CA for T&C, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art. 5(2))? (more than 1 answer possible) | Analysis of the mandatory documentation requested from the tissue establishment<br>Other |
| Please specify 'other': | Only medical laboratories authorized by regional health competent authorities realize the donor qualification . |
| 2.6. Please provide data on qualified laboratories accredited, authorised or licensed in your country (e.g. number, year of accreditation/authorisation/license, which donor tests are performed etc.). | We have about 200 accredited qualified laboratories but It's impossible to provide precise data about the ones which perform donor testing : there are private or public laboratories : some of them depend on hospitals (private and public), Some of them depend on blood transfusion establishments. Sometimes these establishments have agreements with private accredited laboratories which carry out the donor tests |
| 2.7. Do you have any additional comments on procurement? | HSC donors procurement centres associated to the national registry are accredited by the WMDA. HLA labs performing HLA typing on donors and CB units are EFI accredited. Regarding ART, there are two separate processes : the first one is the legal framework of authorisation and inspection by the regional competent authorities for both clinical and biological activities, the second one is the legal accreditation process required for all the French laboratories and validated by Cofrac on all their activities including biological ART activities. About testing of gametes donors, the tests are not performed in the reproductive lab where the donors are recruited but by medical labs wich all are in the process of accreditation. |
| **3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)** | |
| 3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>Ag HIV<br>NAT HIV 1<br>HBs AG<br>Anti HBc<br>NAT HBV<br>Anti HCV-Ab<br>NAT HCV<br>Treponema Pallidum<br>HTLV-2 |
| 3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>Ag HIV<br>HBs AG<br>Anti HBc<br>Anti HCV-Ab<br>NAT Chlamydia<br>Treponema Pallidum |
| 3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to encourage its use? Please specify why or why not (e.g. number of additional cases detected, cost-benefit etc.). | Nat testing is not mandatory for ART patients ; it is performed according to the medical context and the general recommendations. However for egg donation, NAT HIV is mandatory immediately before the collection of eggs as a second determination of the viral status of the donor. |
| 3.4. Do you have concerns on accuracy of the available tests and test procedures for deceased donors? | No |
| 3.5. Are any other laboratory tests required for donors of non-reproductive tissues and cells in | Yes |

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| your Member State? | |
| 3.5.1. Please specify. | For cells qualification : -cytomegalovirus virus '-Epstein -Barr -Toxoplasma gondii |
| 3.6. Are any other laboratory tests required for donors of reproductive tissues and cells in your Member State? | Yes |
| 3.6.1. Please specify. | Actually, required testing differs between ART couples or non partner donor. For ART couples (both male and female partners, even if gametes from donors are used) : Anti HIV1 and 2, Anti HCV, anti HBS, Anti HBC, Ag HBV and treponema pallidum. If necessary : Nat HCV, Nat HIV, or HTLV depending on the context and for women, Rubella and toxo For gamete donors, the same and in addition : Anti CMV and Nat HIV |
| 3.7. Do you request/use international accreditation systems for testing laboratories? | No |
| 3.8. Do you have any additional comments on testing? | no |
| **4. Accreditation, designation, authorisation or licensing of tissue establishments (Article 6, Directive 2004/23/EC)** | |
| 4.1. Do you have a system of designation, authorisation, accreditation or licensing for all types of tissue establishments under your responsability? | Yes |
| 4.2. Is inspection a prerequisite for the designation, authorisation, accreditation or licensing of tissue establishments? | No |
| 4.3. Are preparation processes authorised? | Yes |
| 4.3.1. How are they authorised? (more than 1 answer possible) | During inspections organised for this purpose<br>By review of a submitted application with supporting documentation |
| 4.4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were suspended in 2011? | 0 |
| 4.5. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011? | 1 |
| 4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)? | Yes |
| 4.6.1. What is the relation between the indpendent certification(s) (e.g. ISO, JACIE, FACT) and the CA authorisation of the tissue establishments? (more than 1 answer possible) | Optional, but TEs are encouraged to get a certification<br>Other |
| Please specify 'other': | Cord blood unit must be USA IND qualified for the shipment (NMDP sponsor) |
| **4bis. Overview of tissue/cells establishments authorised by the NCA** | |
| 4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible): | Musculo-skeletal tissue establishments |
| 4.7.2. How many musculo-skeletal tissue establishments? | 2 |
| 4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible): | Musculo-skeletal tissue establishments |
| 4.8.2. How many musculo-skeletal tissue establishments? | 1 |
| 4.9. Tissue establishments first time authorised between 01/01/2011 and 31/12/2011 (more than 1 answer possible): | Musculo-skeletal tissue establishments |
| 4.9.2. How many musculo-skeletal tissue establishments? | 1 |
| 4.10. All tissue establishments authorised by 31/12/2011 (more than 1 answer possible): | Skin tissue establishments<br>Musculo-skeletal tissue establishments |

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| | Ocular tissue establishments<br>Cardiovascular tissue establishments<br>HSC tissue establishments<br>Cord blood tissue establishments<br>ART tissue establishments<br>Multi-tissue establishments |
| 4.10.1.1. How many public skin tissue establishments? | 10 |
| 4.10.1.2. How many private skin tissue establishments? | 0 |
| 4.10.2.1. How many public musculo-skeletal tissue establishments? | 17 |
| 4.10.2.2. How many private musculo-skeletal tissue establishments? | 7 |
| 4.10.3.1. How many public ocular tissue establishments? | 16 |
| 4.10.3.2. How many private ocular tissue establishments? | 1 |
| 4.10.4.1. How many public cardiovascular tissue establishments? | 12 |
| 4.10.4.2. How many private cardiovascular tissue establishments? | 1 |
| 4.10.5.1. How many public HSC tissue establishments? | 36 |
| 4.10.5.2. How many private HSC tissue establishments? | 2 |
| 4.10.6.1. How many public cord blood tissue establishments? | 9 |
| 4.10.6.2. How many private cord blood tissue establishments? | 0 |
| 4.10.7.1. How many public ART tissue establishments? | 42 IVF centres |
| 4.10.7.2. How many private ART tissue establishments? | 62 IVF centres and 92 IUI labs |
| 4.10.8.1. How many public multi-tissue establishments? | 16 |
| 4.10.8.2. How many private multi-tissue establishments? | 0 |
| 4.11. How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Art. 6(5) during 2011? Please provide number(s) per type tissues/cells. | 1402 (bone marrow + PBSC + cord blood + lymphocytes) |
| **4ter. Sanctions** | |
| 4.16. Have penalties for infringements of the national provisions pursuant to the Directive been defined (Article 27)? | Yes |
| 4.16.1. Have penalties already been imposed? | No |
| 4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing? | Actually, in the field of reproductive cells, 104 IVF centres and 92 IUI labs are authorised and had an ART activity in 2011. Among the IUI labs, near 100% are private. Among the IVF centres, it is about 40% which have a public status. Some of them have both status private and public (different status between the clinical unit and the biological unit). A legal provision set that only the public or if private, non profit establishments, are authorised to manage non parner donors. |
| **5. Inspections (Article 7, Directive 2004/23/EC)** | |
| 5.1. Is a system in place for organising inspections and control measures of tissue establishments? | Yes |
| 5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections. | The CA in charge of inspection of TE (non reproductive tissues and cells) is ANSM. The division in charge of inspections is "INSBIO" (inspection of biological products). For ART, the regional agencies are in charge of inspection. The ABM must publish a mandatory annual report on inspections performed by the regional agencies, according |

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| | to their inspection reports they send to ABM. |
| 5.1.2. If yes, please specify staffing (how many inspectors). | 4 inspectors in ANSM. Regarding ART, there are 22 regional agencies with at least 2 inspectors trained in ART per agency in order to inspect every two years all the ART centres. |
| 5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible) | Yes |
| 5.2.1. If yes, please specify. (more than 1 answer possible) | Others |
| Please specify other. | Common trainings about the general inspection practises, the frame of the inspection report , the common inspection procedures ,the graduation of the shortcomings based on a risk approach etc.... |
| 5.3. How many routine inspections of tissue establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011)? | 27 |
| 5.3.1. How many inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) following serious adverse events or reactions, or suspicion thereof ? | 0 |
| 5.3.2. How many other type of inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | 0 |
| 5.3.3. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | 0 |
| 5.3.4. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where minor shortcomings were noted? | 27 |
| 5.3.5. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where major shortcomings were noted? | 8 |
| 5.3.6. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by suspension of authorisation? | 0 |
| 5.3.7. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by closure? | 0 |
| 5.3.8. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of other inspections carried out? Please specify. | 0 |
| 5.4. How many routine inspections were conducted in ART establishments (from 1/1/2011 to 31/12/2011)? | 32 |

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| 5.4.1. How many inspections were conducted in ART establishments following serious adverse events or reactions, or suspicion thereof (from 1/1/2011 to 31/12/2011)? | 1 |
| 5.4.2. How many other type of inspections were conducted on ART establishments (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | 0 |
| 5.4.3. Outcome of inspections of ART tissue establishments carried out in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | 0 |
| 5.4.4. What was the number of inspections carried out in ART establishments where minor shortcomings were noted? | 32 |
| 5.4.5. What was the number of inspections carried out in ART establishments where major shortcomings were noted? | 32 |
| 5.4.6. What was the number of inspections carried out in ART establishments followed by suspension of authorisation? | 0 |
| 5.4.7. What was the number of inspections carried out in ART establishments followed by closure of respective establishements? | 0 |
| 5.4.8. What was the number of other inspections of ART establishments? Please specify. | 0 |
| 5.5. Which type of routine inspections do you conduct? (more than 1 answer possible) | General system-oriented inspections<br>Thematic inspections<br>Desk based reviews |
| 5.6. How do you decide which type of routine inspection to conduct? | The type of routine inspection is decided according a risk based inspection programme. Regarding ART, routine inspections are planned every two years according to a national inspection programm. However the lack of ressources leads to real difficulties to respect the interval of two years between two inspections. |
| 5.7. Until 2011, did you implement the requirement concerning the time interval between two inspections (Art. 7.3.)? | Yes |
| 5.8. How many TEs were inspected at least twice between 2008-2011 (01/01/2008-31/12/2011)? | In the field of reproductive cells the TEs inspected twice were TEs with major shortcomings. 14 TEs were inspected twice. The total number of inspections was 163. |
| 5.9. Did you perform/conduct inspections of procurement sites outside tissue establishments? | No |
| 5.9.2. If no, why not? | The agences régionales de santé (ARS) are in charge of the inspection of the procurement establishments. ANSM, time to time, inspect procurement establishments when there is doubt about the quality and safety of the products. Regarding ART, centers carry out both procurement and clinical applications of gametes and embryos. The regional agencies must inspect the ART centres for both clinical and biological activities. |
| 5.10. Did you carry out inspections of third parties? | Yes |
| 5.10.1. If yes, how many? | It depends on the kind of implemented process of tissues and cells |
| 5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)? | No |
| 5.11.1. If no, which guidelines/regulations are used for inspections at national level? | For inspections ,we use the national good tissues and cells practices (the 27th october 2010 ANSM decision), ISO norms, GMP, aide memoire , decree and ministerial orders. Regarding ART, routine inspections are based on the control of the compliance with the regulations in force in France and particularly with the rules of ART good practices in ART (published by decree in 2010). A large place is given to traceability.A national guide is available for inspection in ART. |
| 5.11.2. If no, please provide a hyperlink to these | http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000023086655. |

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| guidelines/inspections. | Good practices in ART : http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000022809674&dateTexte=&categorieLien=id National guide for ART centres inspection : http:/www.agence-biomedecine.fr/Referentiel-inspection-AMP |
| 5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)? | Yes |
| 5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)? | 5 |
| 5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))? | Yes |
| 5.13.1. Could you please explain why? | In some cases , French national CAs needs to know the accuracy of the data provided by the MS, suppliers (distributors) of tissues and cells. |
| 5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))? | No |
| 5.15. Did you organise any inspections of procurement centres or tissue establishments in third countries from which tissues and/or cells were imported in your country (as recorded by 31/12/2011)? | Yes |
| 5.15.1. If yes, please specify why. | In some cases , the French national CAs needs to know the accuracy of the data provided by the procurement establishment or provided by the tissue establishments, importer of tissues and cells |
| 5.16. Have you asked another MS, or have you been requested by any other MS, on the results and control measures of your inspections, as part of an enquiry/investigation? | Yes |
| 5.16.1. If yes, please specify. | Some European member states (poland, Danemark, Portugal, Estonia, etc) |
| 5.17. Would you be interested in developing joint inspections? Joint inspections should be understood as inspections of tissue establishments conducted jointly by two or more Member States' Competent Authorities on their territory or in third countries. | Yes |
| 5.18. Do you have any additional comments on inspections? | There is a need of organizing a legal framework in the field of joint inspections especially when tissues and cells are imported within EU countries. |
| **6. Import/export (Article 9 Directive 2004/23/EC)** | |
| 6.1. Do you have a register of authorised tissue establishments that are explicitly authorised to perform import/export of tissues and celles from/to third countries? | Yes |
| 6.2. Please specify the number of tissue establishments authorised to import tissues and cells from third countries (recorded by 31/12/2011). | tissues:1 ; HSC: all the 36 HSC centers |
| 6.3. Please specify the number of tissue establishments authorised to export tissues and cells from third countries (recorded by 31/12/2011). | tissues :5; HSC :all the 36 centres, |
| 6.4. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of skin from third countries. | 1. through the import/export authorisation procedure where the CA authorizes the product based on the assessment of the data provided by the importer in the dossier submitted to the CA 2. through the documents accompanying each import and sent to the importing TE ; 3. through inspections of the supliers of tissues and cells in third countries. Currently no product authorization has been granted for this type of tissues imported from a third country . |
| 6.5. Please specify which procedures you have in | the same as 6.4 Currently no product authorization has been granted for this type of |

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| place for verifying the equivalent standards of quality and safety for importation of musculo-skeletal (bone, tendons, fascia etc.) tissues from third countries. | tissues imported from a third country . |
| 6.6. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of ophtalmic (cornea, sclera, etc) tissues from third countries. | the same as 6.4 Currently no product authorization has been granted for this type of tissues imported from a third country . |
| 6.7. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cardio vascular tissues from third countries. | the same as 6.4 Currently no product authorization has been granted for this type of tissues imported from a third country . |
| 6.8. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) (other than cord blood) from third countries. | through the import/export authorization procedure where the CA authorizes the product based on the assessment of the data provided by the importer in the dossier submitted to the CA. An authorization is granted on a case by case basis for this type of cells.. |
| 6.9. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cord blood from third countries. | the same as 6.8 |
| 6.10. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of reproductive cells (sperm, egg cells) from third countries. | Import of reproductive cells in France from third country or EU MS must be individually authorised by the ABM. A specific file with available data on the conditions of the procurement, donation, testing,etc is submitted to ABM by the French ART centre requesting an authorization. ABM makes its decision on a case by case basis depending on the data provided and the respect of French legal and ethical principles during the whole process. |
| 6.11. Did you import tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | Yes |
| 6.11.1. If yes, please provide the data concerning the number/volume of imported tissues and cells by country of origin. | tissue : 0 ; HSC = 283 ; Reproductive cells = 4. the data per country of origin are not available. |
| 6.12. Did you export tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | Yes |
| 6.12.1. If yes, please provide the data concerning the number/volume of exported tissues and cells by country of destination. | tissues = 0 ; HSC = 64 Reproductive cells = 7 ( the data per countries of destination are not available) |
| 6.13. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on imports/exports of tissues/cells between your country and other third countries? | No |
| 6.14. What is the relation between import/export of tissues and cells and self-sufficiency? (more than 1 answer possible) | F. Other |
| Please specify 'other': | No tissues are imported from a third country - imported cells are based on HLA compatibility. |
| 6.15. Did you authorise direct imports of tissues/cells to hospitals/clinics in your country? | No |
| 6.16. Do you have any additional comments on import/export? | In the field of HSC, import and export are necessary to comply with the medical need for matching between donor and recipient. 75% of HSC are imported in France. Direct import by hospital or clinics are not allowed in France. |
| **7. Distribution/intra community exchanges (Article 23 Directive 2004/23/EC)** | |
| 7.1. Do you have intra-community exchanges of tissues and cells? | Yes |
| 7.1.1. If yes, how do you address the possible more stringent quality and safety measures established by other Member States? Please specify. | The problem is that when a 6.2 authorisation is granted by another Member-state we don't know how they have performed their assessment ,which were their safety criteria..... In the field of HSC, international registries follow WMDA standards. |
| 7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States? | Yes |
| 7.1.2.1. How do you address this difference for tissues and cells coming from a MS with minimum | Based on the european directive, member states need to recognize authorization granted by the other member states. |

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| quality requirements? Please specify. | |
| 7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify. | -through the evaluation of the file of the TE authorization submitted to the NCAs and which contains data about distribution such as the requirements to provide a description of the organization set up to ensure the distribution ; - also through inspections on site carried out on the basis of the good tissues and cell practices. |
| 7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible). | No |
| 7.4. Have you authorised direct distribution to the recipient of specific tissues and cells (Art. 6, Directive 2006/17/EC)? | Yes |
| 7.4.1. If yes, how many authorisations were given in 2011 (01/01/2011 to 31/12/2011)? | For HSC = 607 ; For reproductive cells = 49 |
| 7.4.2. If yes, for which tissues/cells? | HSC = Bone marrow, PBSC, cord blood and lympho ; Reproductive cells = gametes, embryos. |
| 7.5. Do you collect data regarding the cross-border exchange of tissue/cells between your country and other EU MS? | Yes |
| 7.5.1. Please provide us with data (country of destination, type of tissue/cell and number of units distributed) concerning distribution to other MS in 2011 (01/01/2011-31/12/2011). | - for tissues (skin ,bones ,vessels etc...) : 1643 distributions to others MS. - For HSC, see EBMT: exchanges within the UE or the world according to the needs of matching. - For reproductive cells, the main part of exchange is represented by export of cryopreserved sperm to Spain, in order to obtain an ART with donated eggs. We know that this represents a very small part of the patients who travel abroad for egg donation. |
| 7.5.2. Please provide us with data (country of origin, type of tissue/cell and number of units distributed) concerning distribution to other MS in 2011 (01/01/2011-31/12/2011) | - For tissues (skin ,bones ,vessels etc...) : 4480 distributions from others MS - For HSC, see EBMT. Exchanges within the UE or the world according to the needs of matching. - in 9 cases, autorizations are given by ABM for import gametes from a EU MS, probably because of the legal restrictions about embryo transfers in Switzerland and Germany. In other few cases, authorisations are given because patients intend to move while gametes or embryos are cryopreserved. |
| 7.6. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on cross-border exchanges of tissues/cells between your country and other EU MS? | No |
| 7.7. Do you allow brokerage companies for either distribution in EU and/or import/export of tissues/cells? In this context, a brokerage company means a body that arranges transactions between a supplier (tissue establishment/company selling tissues or cells) and a buyer (a tissue establishment/a hospital or clinic/an individual) without undertaking activities of processing, preservation or storage. | No |
| 7.8. Are brokers actively supplying health professionals/establishments in your country? | No |
| 7.9. Do you have any additional comments on distribution? | |
| **8. Register of tissue establishments and reporting obligations (Article 10, Directive 2004/23/EC)** | |
| 8.1. Do you have an annual report model/template on the activities of tissue establishments in your Member State? (Article 10(1)). If yes, please upload the template. | No |
| 8.1.1. If no, why not? | in progress. |
| 8.2. How many tissue establishments submitted annual reports of their activities during 2011. Please provide an estimation. (1 answer possible) | 100% (all) |
| 8.3. Are these reports publicly available? (Article 10(1)) | No |
| 8.4. Do you publish a national annual report of the consolidated activities of all tissue establishments in your country? | Yes |

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| 8.4.1. Please insert the link to the published national annual report. | http://ansm.sante.fr/var/ansm_site/storage/original/application/79a989c66ec609a6c7a60db3464f9636.pd ; http : //www.agence.biomedecine.fr/AMP ; http : //www.agence.biomedecine.fr/CSH |
| 8.5. Is there a publicly accessible register of authorised tissue establishements in place? (Article 10(2)) | Yes |
| 8.5.1. If yes, please provide us with the link to the register's web site. | http://ansm.sante.fr/var/ansm_site/storage/original/application/b9b896c06d8367834865273951775d4b.pdf ; http : //www.agence.biomedecine.fr/Autorisation-des-centres ; http : //www.agence.biomedecine.fr/Les-etablissements-autorises.73 |
| 8.6. Do you provide data regarding tissues and cells activities to the EUROCET registry (non-mandatory reporting)? | Yes |
| 8.6.1. If yes, what data are provided to EUROCET? Please specify. | Data about tissues and cells establishment activities, about the processed products and about the authorised ART centers and activities performed, activities and results (pregnancies, children...) in partner and non partner donation. |
| 8.7. Do you have any additional comments on reporting? | |
| **9. Traceability (Article 8, Directive 2004/23/EC; and Directive 2006/86/EC)** | |
| 9.1. Was the donor identification system (Art. 8(2)) implemented in your country? | Yes |
| 9.2. Who assigns the unique code for each donation? (only 1 answer possible) | Tissue establishment |
| 9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible) | Both paper records and electronic forms |
| 9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify. | by inspections Only electronic files in HSC centres and national registry in ABM |
| 9.5. Do you have any additional comments on traceability? | |
| **10. Notification of serious adverse events and reactions (Article 11 Directive 2004/23, Article 6 Directive 2006/76)** | |
| 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))? | Yes |
| 10.1.1. If yes, which CA/institution is responsible? | ABM is leading the Assisted Reproductive Techniques (ART) vigilance system, in relation with ANSM - ANSM for biovigilance (including organs, tissues and cells) in relation with ABM |
| 10.1.2. If yes, please provide a short description of its organisation. | In tissues and cells field other than reproductive At the top of the system there's the ANSM which coordinates the actions of the stakeholders who play a part in the biovigilance system. ANSM receives all the notifications of adverse events/reactions and takes the adequate safety measures. Then, in each public or private tissues or cells establishment, there is a local biovigilant correspondent who sends the dedicated form of adverse events/reactions to the ANSM.An assessment is performed for each report by the local biovigilant,the ANSM assessors in link with the Agence de la biomedecine.Based on the findings,corrective actions are implemented locally or nationally. The ART VS is organised according to 2 levels : - National level : Agence de la biomedecine × Leads the national ART VS × Designs methods and tools (documents, grading scale, I.S. etc.) × Collects adverse event and reactions (AER) × Analyses AER × Coordinates investigation and monitor corrective measures × Implements national guidelines × Reports to Ministry of Health and professionals × Coordinates nationally with other VS - Local level : ART clinical centers and lab × Identify a local correspondent for ART VS (mandatory) × ART professionals inform the CLA of AER × The CLAs notify the ABM and coordinates locally with other VS |
| 10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use the SAR/E (to the CA (2006/76 art 6.4)) templates developed to the Annual reporting ot the EC also at national level? | No |
| 10.2.1. If no, what template do you use? You are welcome to upload the template if you wish. | The principles included in the common Approach Document developed for the Annual reporting to the EC were already in place in the french proceedings. No, ABM does not use the SAR/E templates developped by EC since it is not really appropriate for reproductive cells and embryos |

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| 10.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level? | Yes |
| 10.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all TEs? | Yes |
| 10.5. How many tissue establishments provided in 2011 the SAR/SAE data as requested (please provide the % from the total number of TEs authorised in your country). | 100% |
| 10.6. Do you have a mandatory procedure for the transplantation centres when reporting SAR/SAE to the TEs which distributed the tissues/cells (Art 11.2)? | Yes |
| 10.6.1. If yes, please provide a brief description. | http://ansm.sante.fr/var/ansm site/storage/original/application/bcef203df79ae53c65ff2277f9bc52f5.pdf In each ART center, the local ART vigilance correspondant notifies the SARE using a specific form. Information related to SARE collected are defined by law. |
| 10.7. Do you give feedback to the TEs regarding SAR/SAE recorded at national level? | Yes |
| 10.7.1. Please specify. | Only if the SAR/SAE could impact their own activities. |
| 10.8. Do you give feedback to the TEs regarding SAR/SAE recorded at EU level? | Yes |
| 10.8.1. Please specify. | Only if the SAR/SAE could impact their own activities. |
| 10.9. Do you require your TEs to have a recall procedure? | Yes |
| 10.10. How many recalls related to safety and quality of tissues/cells were issued in your country in 2011? Please specify the number and which tissues were recalled and why (e.g. missing consent, quality defects etc). | see annual biovigilance report (www.ansm.sante.fr) |
| 10.11. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites in case of a national rapid alert? | Yes |
| 10.11.1. If yes, please give a short description of the system/procedure. | All procurements sites and TE must designate a local biovigilance correspondant and both state their coordinates (mail and fax). In case of alert, one is sent by mailing list and depending on its severity, coupled with a fax. In the field of ART, any alert could be communicated through a specific and secure I.S. |
| 10.12. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites when a rapid alert is issued via the EU RATC platform? | Yes |
| 10.12.1. If yes, please give a short description of the system/procedure. | All procurements sites and TE must designate a local biovigilance correspondant and both state their coordinates (mail and fax). In case of alert, one is sent by mailing list and depending on its severity, coupled with a fax. In the field of ART, any alert could be communicated through a specific and secure I.S. |
| 10.13. Do you provide data regarding SAR/SAE to the EUROCET registry (non-mandatory reporting)? | No |
| 10.13.2. If no, please specify why not. | .. |
| 10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems? | Yes |
| 10.14.1. If yes, please specify which of the following systems are usually contacted. (more than 1 answer possible) | Haemovigilance<br>Pharmacovilance<br>Medical devices<br>Other |
| Please specify 'other'. | nosocomial infection surveillance |
| 10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S? | Yes |
| 10.15.1. If yes, how would you rate the usefulness | 4 |

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| and efficacy of these trainings on a scale from 1 (insufficient) - 2 (sufficient) 3 (good) - 4 (very good) to 5 (essential)? | |
| 10.16. Do you have any additional comments on SARE reporting? | In France not only severe SARE are collected but also SARE. The national ART VS requires also to notify all AR related to ART activities not only those related to the quality of reproductive cells. We consider the notification templates presented in the tools I the 2006/86 EUTCD is not appropriate for ART |
| **11. Consent and personal data protection (Article 13 and 14, Directive 2004/23/EC)** | |
| 11.1. What consent system for living tissue/cell donation do you have in place within your Member State? | Explicit consent (opt-in) |
| 11.1.1. Please specify your choice of consent system for living tissue/cell donation. | It is a legal requirement for donation of soho. We think that it's the best way to guarantee the donor's freedom and will because the condition of this consent is a clear information provided to the donor,particualrly regarding all the medical consequences of his donation. |
| 11.2. What consent system for deceased tissue/cell donation do you have in place within your Member State? | Presumed consent (opt-out) |
| 11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible) | No further authorisation is needed |
| 11.4. Is the consent system for deceased tissue donation the same as for organs? | Yes |
| 11.5. How is this consent verified during inspections? (more than 1 answer possible) | Analysis of documentation<br>Interviews with personnel<br>Interviews with relatives of deceased donors |
| 11.6. What measures are in place to ensure that donors/relatives/authorising persons on behalf of donors are provided with the appropriate information, as requested by Art. 13(2)? (more than 1 answer possible) | Only trained personnel is allowed to provide such information |
| 11.7. What measures are in place to ensure that both donors and recipients remain unidentifiable when access is given to third parties (Art. 14(1)). Please specify. | It's a principle set in the French bioethical Law: the article L.1211-5 (code de la santé publique) lays down that "no information allowing to identify at the same time the one who donated an element or a product of his body and the one who received it cannot be revealed". |
| 11.8. Please specify what measures are in place to ensure that the identity of the receipient is not disclosed to the donor and vice versa. | there are two measures : 1) the first one mentionned above lays down that no information allowing to identify at the same time the one who donated an element or a product of its body and the one who received it cannot be revealed". 2) the second one is mentionned in the article R.1211-19 of the french health code (code de la santé publique) which states that "traceability is ensured by a codification which is also uses to guarantee the anonymity of the two persons involved in a procurement and a transplantation. |
| 11.9. Does your national legislation allows disclosure of donor data in case of gametes donation? | No |
| 11.9.1. If no, please specify the circumstances and measures in place. | An anonymous code is allocated as the donor is recruited at the ART center level and this code will be kept during the whole procedure untill gametes are distributed. No information concerning the donor (position, hobbies etc...) is given to the recipients in order to avoid to reveal potentially identifying data. Staff dealing with recruitement of donors are specifically trained. Registries of donors and donations are strictly kept at a local level and have validated protection against intrusion and are controlled by the CNIL and during inspections. |
| 11.10. Do you have any additional comments on consent and data protection? | |
| **12. Selection, evaluation and procurement (Article 15 Directive 2004/23; Annexes I-IV Directive 2006/17)** | |
| 12.1. How do you ensure that all requirements related to the evaluation and selection of donors (except donors of reproductive cells) are respected in your country (Art. 15(1), Annex I Directive 2006/17/EC)? (more than 1 answer possible) | Stadardised questionnaires at national levels<br>Inspections of TEs and procurement sites |

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| 12.2. How do you ensure that all requirements related to the evaluation and selection of donors of reproductive cells are respected in your country (Art 15 (1), Annex III of Directive 2006/17/EC)? (more than 1 answer possible) | Standardised questionnaires at national level<br>Inspections of ART centres<br>Audit documentation |
| 12.3. Do you have more stringent criteria for donor selection than those listed in Annex I of the Directive 2006/17/EC? | No |
| 12.4. What sources are required in your MS for the evaluation of a deceased donor of tissues/cells? (more than 1 answer possible) | Interview with the donor's family or a person who knew the donor well<br>Medical records of the donor<br>Interview with the treating physician<br>Interview with the general practitioner<br>Autopsy report |
| 12.5. Do you have more stringent criteria for selection of donors of reproductive cells than those listed in Annex III of the Directive 2006/17/EC? | No |
| 12.6. Do you have more stringent criteria for autologous donation than those listed in Annex I of the Directive 2006/17/EC? | No |
| 12.7. Do you require more information on the donation of tissues/cells than the mandatory one as laid down in the Annex of Directive 2004/23/EC (Art 15(3)? | No |
| 12.8. How do you ensure that all requirements regarding tissues and cells' procurement, packaging and transport are complied with by tissue establishments in your country (Art 15(1), Annex IV of Directive 2006/17/EC? (more than 1 answer possible)(For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)) | Inspection of tissue establishment<br>Audit of tissue establishment<br>Inspection of the centre of human application (e.g. transplantation centre, ART centre)<br>Audit of the centre of human application |
| 12.9. Do you have any additional comments on selection, evaluation and procurement? | |
| **13. Quality management, responsible person, personnel (Article 16, 17, 18 Directive 2004/23/EC)** | |
| 13.1. How do you ensure that tissue establishments in your country have in place a quality system respecting the provisions of the Directive 2004/23/EC Art 16.1? (more than 1 answer possible). (For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)). | Authorisation requirement<br>Inspections<br>Internal audits<br>External audits |
| 13.2. How do you ensure that tissue establishments have a responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible) | Authorisation requirement<br>Inspections<br>Regular evaluation of personnel<br>Mandatory trainings |
| 13.3. How do you ensure an appropriate training for the personnel directly involved in the activities of tissue establishments? (more than 1 answer possible) | Authorisation requirement<br>Inspections<br>Regular evaluation of personnel<br>Mandatory trainings |

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| 13.4. Do you have national/regional/local training programmes for the personnel of tissue establishments? | Yes |
| 13.4.1. If yes, please specify. | ABM organizes different trainings for health professionals working in the fields of organs, tissues and HSC procurement and transplantation .It has experimented this year a learning management system. It also organises different trainings on quality management, legal and ethical aspects in ART or also for midwives involved in ART activities. The programs are available on the website of ABM. Moreover ABM proposes several annual meetings for the different kinds of health professionals working in organs, tissues and HSC procurement and transplantation and in ART(for example the annual meeting of the correspondents in ART vigilance during the national congress in ART). |
| 13.5. Any additional comments on quality management, responsible person, personnel? | |
| **14. Reception, processing, storage, labelling and packaging (Art 19-22 Directive 2004/23/EC)** | |
| 14.1. How do you ensure that tissue establishments in your country fulfill the requirments of the Art. 19 (Tissue and cell reception) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | National regulation/policy for reception of tissues/cells<br>Inspections of tissue establishments<br>Internal audits of tissue establishments<br>External audits of tissue establishments (e.g. ISO) |
| 14.2. How do you ensure that tissue establishments in your country fulfill the requirements of the Art. 20 (Tissue and cell processing) of Directive 2004/23/EC? (more than 1 answer possible) | SOPs for all processes affecting quality and safety are mandatory for authorisation<br>Inspections of tissue establishments<br>Internal audits of tissue establishments<br>External audits of tissue establishments (e.g. ISO) |
| 14.3. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 21 (tissue and cell storage conditions) of Directive 2004/23/EC? (more than 1 answer possible) | SOPs for procedures associated with storage of tissues and cells are mandatory for authorisation<br>Inspections of tissue establishments<br>Internal audits of tissue establishments<br>External audits of tissue establishments (e.g. ISO) |
| 14.4. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | SOPs for procedures associated with labelling and packaging are mandatory for authorisation<br>Inspections of tissue establishments<br>Internal audits of tissue establishments<br>External audits of tissue establishments(e.g. ISO) |
| 14.5. Any additional comments on reception, processing, storage, labelling and packaging? | All the questions are related to the presence of procedures and not on their contents, what is assessed regarding the quality of the tissues and cells procured, processed and controlled. |
| **15. Third party agreements (Art. 24 Directive 2004/23/EC)** | |
| 15.1. Are third party agreements foreseen/allowed in your national legislation? | Yes |
| 15.1.1. If yes, have tissue establishments in your Member State notified third party agreements? | Yes |
| 15.1.1.1. Under which circumstances and for which responsibilities? | When third parties provide good or services which might have an impact on the quality and safety of the products.The agreement clearely states the responsabilities of each part of the agreement and particularly it describes the tasks entrusted with the third party and the way it has to carry out them . |
| 15.1.1.2. How are third party agreements controlled (Art 6.2) by the Competent Auhtority(ies) in your MS? Please specify. | At the beginning through the dossier submitted for the authorization of tissue establishment and after that through inspections. |
| 15.2. Any additional comments on third party agreements? | HSC centres have an agreement with FDA. ABM has an agreement with a transport company for CB unit shipments. |
| **16. General comments - implementation** | |
| 16.1. Do you have at national level more stringent quality and safety requirements than those requested by the EU legislation in this field (e.g. restrictions concerning the donation/use of certain tissues/cells, mandatory unpaid donation etc.)? | Yes |
| 16.1.1. Please specify. | Because quality and safety are directly linked with the conditions of recrutment of donors, the French law set ethical provisions. Among them : - the recruitment of donors must be managed through a non profit organisation which can evaluate the |

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| | needs at a national level and organize on a non-profit basis the promotion and the evaluation of the donors; - payment of donors for donation is totally forbidden. - except in the cases of duly justified therapeutic interest, donation is anonymus and it's done for all the patients who need a transpalntation : for this reason the private autologous cord blood banks are not authorized in France Key principles should be reasserted at the UE level: the products of the human body should not be a source of financial gain. Some compensation practices relate to payment and leads to ethical abuses. |
| 16.2. Has your Member State encountered any difficulties in implementing the requirements in the EU Tissues and Cells Directives? Please choose from the options below. | ART provisions<br>Testing provisions<br>Import-export<br>Vigilance<br>Inspections |
| 16.2.1. For all selected options in question 16.2., please provide a short description. | Terminology not appropriate for the field of reproductive cells. Difficulties to strictly apply the periodicity of two years between two inspections of the same ART center. The French system of ART vigilance takes care of women exposed to complications of ovarian hyperstimulation and surgical collection of eggs which are not taken into account in the European system as they don't have consequences on the quality of reproductives cells. D.2006-17 : the requirements for testing have to be revised for both partner and non partner donations (genetics and virological testing) D 2006-86 : the requirements about quality of air in the facilities should be discussed in the context of ART (class D classification cannot be applied for ART field due to some processes contrainst) |
| 16.3. In your opinion, in which of the following Directives are there shortcomings (if any)? (more than 1 answer possible) | Directive 2004/23/EC<br>Directive 2006/17/EC<br>Directive 2006/86/EC |
| 16.3.1. How would you suggest to solve these issues in Directive 2004/23/EC? | 1) In the tissues and cells field There is a need : - to extend the scope of the directive to the tissues and cells collected and transplanted back to the same patient, within the same surgical procedure, after being subject to a manipulation at the surgical unit or in the patient's room so that the cells or tissues are not intended to be used for the same essential function; -to clarify the legal status of the dehydrated human placenta and the status of certain products for which it's difficult to determine which is the relevant legal field ( directive 2004/23 ; medical device directives ; ATMP regulation ) -to extend the scope of the inspection organized, at the request of the competent authorities of another member-state whenever there are grounds for suspecting non compliance with the principles of the directive; - to add a provision which excludes a competent authority which is as the same time a tissue establishment ; -to change the frequency of the inspection of tissue establishment (between two inspections the intervall should not exceed 3 years (instead of two years) -to harmonize the process assesment for tissues and cells to avoid as much as possible the differences on the quality of the tissues and cells prepared in the different meember-states via a standardized format of dossier and via guidelines -to develop rules and guidelines applying to ATMP with hospital exemptions -to apply the international santards (FACT,JACIE,AABB) in all cord blood banks (private/public,autologous/allogenic) 2) In the field of ART threis a need to foresee a specific technical directive for reproductive tissues and cells . |
| 16.3.2. How would you suggest to solve these issues in Directive 2006/17/EC? | - the requirements for testing have to be revised for both partner and non partner donations (genetics and virological testing) |
| 16.3.3. How would you suggest to solve these issues in Directive 2006/86/EC? | - In order to guarantee the harmfulness and the therapeutic efficiency of the tissues and cells ,by providing that in certain cases the CA can require the implementation of clinicals trials for new tissues and cells products results. - the requirements about quality of air in the facilities should be discussed in the context of ART (class D classification cannot be applied for ART field due to some processes contrainst) - to harmonize the process assesment for tissues and cells to avoid as much as possible the differences on the quality of the tissues and cells prepared in the different meember-states via a standardized format of dossier and via guidelines |

### *A.1.11. Survey response Germany*

| **1. Public information** | |
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| 1.1. Name of National Competent Authority (NCA) 1: | Paul-Ehrlich-Institut, Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel |
| 1.1.2. Address of NCA 1: | Paul-Ehrlich-Straße 51-59, 63225 Langen, Germany |
| 1.1.3. Telephone (central access point): | +49 6103 77 0 |
| 1.1.4. E-mail (central access point): | pei@pei.de |
| 1.1.5. Website: | www.pei.de |
| 1.1.6. The NCA is responsible for? (more than 1 answer possible) | Non-reproductive tissues and cells<br>Blood and blood components<br>Pharmaceuticals<br>Other |
| Please specify 'other': | Other biomedicinal products such as sera, vaccines, allergens, advanced therapy medicinal products and xenogenic medicinal products |
| 1.1.7. What are the role/tasks of the NCA? (more than 1 answer possible) | Inspection<br>Vigilance<br>Other |
| Please specify 'other': | Marketing authorisation of tissue products and their vigilance including tissue vigilance inspections |
| 1.2. National Competent Authority 2? | No |
| 1.5. Please give a short description of the legal status and organisation of the National Competent Authority(ies) (e.g. departments, staffing, number of senior and junior inspectors, staff working on EU affairs and legal matters, vigilance officers, budget, independence from government etc.). | The Paul-Ehrlich-Institut is the "Federal Institute for Vaccines and Biomedicines", thus a higher competent authority of the Federal Republic of Germany. It reports to the "Bundesministerium für Gesundheit" (Federal Ministry of Health). The Paul-Ehrlich-Institut is the National Competent Authority for Tissues and Cells. Most of its activities relate to the various duties laid down in German and European medicinal product legislation, such as for example the approval of clinical trials and the marketing authorization of particular groups of medicinal products. The legal responsibilities of the Paul-Ehrlich-Institut relate to biological medicinal products such as vaccines for humans and animals, medicinal products containing antibodies, allergens used for therapy and in diagnostics, plasma-derived medicinal products and medicinal products for gene therapy, somatic cell therapy and xenogeneic cell therapy, i.e. for processes in the latest forms of biomedical treatment. Product responsibilities extend to blood and blood products for transfusion medicine and as well as tissue and cell products. The Paul-Ehrlich-Institut´s organization entails 7 product-related divisions performing research and regulatory activities. The division "Safety of Medicinal Products and Medical Devices" performs tasks related to pharmacovigialnce, hemovigilance and tissue vigilance. The sections "EU-Cooperation/Biological Medicinal Products", "Legal Affairs", "Clinical Trials", "Microbial Safety", "Viral Safety" and "Biostatistics", for example, provide support for assessment and regulation of all vaccines and biomedicines. The division "Administration" provides administrative support. For further details see the Annual Report of the Paul-Ehrlich-Institut (http://www.pei.de/DE/institut/jahresberichte/jahresberichte-node.html). As a public body, the Paul-Ehrlich-Institut is subject to the principles of national budget law (laid down mainly in the Constitution), a number of other relevant laws, and the Annual Budget Act. The Paul-Ehrlich-Institut receives an annual budget from the government that is not affected by the amount of collected fees. The Paul-Ehrlich-Institut´s budget and finance plan are divided into types of expenditure for personnel expenses, tangible expenses (including expenses for consumables, facility management, staff training, travels etc.) and investment expenses. For further details |

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| | see the Annual Report of the Paul-Ehrlich-Institut (http://www.pei.de/DE/institut/jahresberichte/jahresberichte-node.html). |
| 1.6. In case of MS with federal or decentralised systems, please indicate the roles/tasks of the Regional Competent Authority(ies). (more than 1 answer possible) | Accreditation, authorisation, licensing of TEs<br>Inspection<br>Vigilance<br>Other |
| Please specify 'other': | The Regional Competent Authorities in the German Länder are basically entrusted with the task of supervising and continuously monitoring the compliance with legal provisions. For this purpose, they grant authorisations. |
| 1.7. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies) for tissues and cells: | There is a splitted competence between the National Competent Authority (PEI) and the Regional Competent Authorities of the Länder. Generally spoken, the Regional Competent Authorities are responsible for activities in matters of Article 5 and 6 of the Directive 2004/23/EC well as for granting import authorizations, Article 9 of the Directive 2004/23/EC. Furthermore, it is their regional responsibility to continuously monitor the compliance with legal provisions. In case of noncompliance, they also have the power to impose penalties/sanctions. The PEI is responsible for the marketing authorisation of tissue products as well as for the fulfilment of pharmacovigilance duties . Both, the Regional Competent Authorities and the PEI work together, e.g. in the field of inspections. The German Federal Government as well as the Paul-Ehrlich-Institut have no authority to issue directives opposite the Länder. For further information regarding the Regional Competent Authorities of the Länder see annex. |
| **2. Procurement (Article 5 Directive 2004/23/EC)** | |
| 2.1. Do you authorise the "conditions of procurement"? | Yes |
| 2.1.1. How do you authorise the "conditions of procurement"? (more than 1 answer possible) | By inspecting all procurement centres<br>By inspecting the documentation associated with procurement that is available in the tissue establishment working with procurement centres |
| 2.1.2. How many such authorisations were granted in 2011 (01/01-31/12/2011)? | 226 |
| 2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011). | 345 |
| 2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011). | 983 |
| 2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues were carried out in 2011 (01/01-31/12/2011). | 208 |
| 2.2.4. Please provide the number of procurement centers in which procurement of tissues/cells for ATMP manufacturing were carried out in 2011 (01/01-31/12/2011). | 234 |
| 2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC and its implementing Directive 2006/17/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) ? (more than 1 answer possible) | Inspections of the site/centre<br>Analysis of the mandatory documentation |
| 2.4. Are you also responsible for the accreditation, designation, authorisation or licensing of laboratories performing donor testing? | Yes |
| 2.4.1. Please provide the number of the laboratories performing donor testing. | 207 In Germany, the Regional Competent Authorities are responsible for this authorisation. |
| 2.5. How do you ensure, as CA for T&C, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art. 5(2))? (more than 1 answer | Inspections of the laboratories<br>Analysis of the mandatory documentation requested from the tissue establishment |

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| possible) | Other |
| Please specify 'other': | Authorisation of the laboratories by inspection of the laboratories and analysis of the mandatory documentation in the laboratories. |
| 2.6. Please provide data on qualified laboratories accredited, authorised or licensed in your country (e.g. number, year of accreditation/authorisation/license, which donor tests are performed etc.). | 173 The performed donor tests in the qualified laboratories depend on the scope of the authorisation. Most of the laboratories provide the following tests: HIV1, HIV2 (including NAT-tests), Hepatitis B, Hepatitis C (including NAT-tests), HTLV-1/2, Treponema pallidum, Chlamydien. Laboratories also provide the subsequent mentioned tests: - Hepatitis A - CMV (including NAT-test) - Epstein-Barr-Virus - Toxoplasma - Malaria - Rubella - Trypanosoma cruzi - Parvovirus B 19 (including NAT-test) - Gonorrhoea (including NAT-test) - RV - VZV - HSV (including NAT-test) - Measles (including NAT-test) - RhD - HLA-typing - blood-typing |
| 2.7. Do you have any additional comments on procurement? | No. |
| **3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)** | |
| 3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>HBs AG<br>Anti HBc<br>Anti HCV-Ab<br>Treponema Pallidum |
| 3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>HBs AG<br>Anti HBc<br>Anti HCV-Ab<br>NAT Chlamydia<br>Treponema Pallidum |
| 3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to encourage its use? Please specify why or why not (e.g. number of additional cases detected, cost-benefit etc.). | NAT testing is not mandatory by German law, however, it is an additional requirement imposed by the national competent authority. According to current scientific knowledge viruses can be transmitted by cardiovascular and highly blood supplied tissues (e.g. HBV and HCV). Therefore, the competent authority PEI requires in addition to serological testing and as a further safety measure HIV-, HBV-, and HCV-NAT for deceased donors (exceptions for cornea and skin) . Since for cardiovascular and highly blood contaminated tissues effective virus inactivation is not possible (preservation of tissue morphology necessary) the advantage of NAT is apparent (reduction of diagnostic window period). |
| 3.4. Do you have concerns on accuracy of the available tests and test procedures for deceased donors? | Yes |
| 3.4.1. Please specify why: | All assay systems intended to be used for the detection of infections with HIV, HCV and HBV used in the European Union have to comply with the requirements of Directive 98/79/EC and with the Common Technical Specifications (CTS). The CTS require investigations on the sensitivity and specificity of the assays which are fulfilled for all devices bearing the CE-mark. These investigations are to be carried out using serum and plasma. In general, the CE-marked assays are not validated for the use of cadaveric specimens. After death, rapid changes due to autolysis, haemolysis, bacterial growths etc. occur in the blood specimens. The latter complicate the determination of infection markers and may eventually lead to unspecific reactions and, as a consequence, to false-positive results or to loss of reactivity and false-negative results. In addition, the pre-mortal administration of blood and blood products may lead to significant dilution effects of the blood which could also diminish sensitivity. Therefore, the Paul-Ehrlich-Institut as competent authority recommends validating the assay systems before use on cadaveric samples. |
| 3.5. Are any other laboratory tests required for donors of non-reproductive tissues and cells in your Member State? | No |

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| 3.6. Are any other laboratory tests required for donors of reproductive tissues and cells in your Member State? | No |
| 3.7. Do you request/use international accreditation systems for testing laboratories? | No |
| 3.8. Do you have any additional comments on testing? | Commission Directive 2006/17/EC requires HTLV-I antibody testing for donors living in, or originating from, high-incidence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas. Since it is very difficult to determine what a HTLV-I high-incidence area is and more data on prevalence are available than data on incidence, the Commission Directive should be amended in regard of replacing the references "high-incidence" to references "high-prevalence". The competent authority completely agrees with this science-based specification. Additional testing referred to medical directives or guidelines (e.g. of the German Federal Medical Association / "Bundesärztekammer"), e.g. aminotransferase for bone tissue banks as state of the scientific and technical knowledge. |
| **4. Accreditation, designation, authorisation or licensing of tissue establishments (Article 6, Directive 2004/23/EC)** | |
| 4.1. Do you have a system of designation, authorisation, accreditation or licensing for all types of tissue establishments under your responsability? | Yes |
| 4.2. Is inspection a prerequisite for the designation, authorisation, accreditation or licensing of tissue establishments? | Yes |
| 4.2.1. How many inspections were performed in 2011 for authorising/accrediting/licensing/designating TEs? | 98 |
| 4.3. Are preparation processes authorised? | Yes |
| 4.3.1. How are they authorised? (more than 1 answer possible) | During routine inspections<br>During inspections organised for this purpose<br>By review of a submitted application with supporting documentation |
| 4.4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were suspended in 2011? | 3 |
| 4.5. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011? | 0 |
| 4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)? | No |
| **4bis. Overview of tissue/cells establishments authorised by the NCA** | |
| 4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible): | Skin tissue establishments<br>Musculo-skeletal tissue establishments<br>Ocular tissue establishments<br>Cardiovascular tissue establishments<br>HSC tissue establishments<br>ART tissue establishments<br>Other tissue establishments |
| 4.7.1. How many skin tissue establishments? | 1 |
| 4.7.2. How many musculo-skeletal tissue establishments? | 58 |
| 4.7.3. How many ocular tissue establishments? | 19 |
| 4.7.4. How many cardiovascular tissue establishments? | 2 |
| 4.7.5. How many HSC tissue establishments? | 12 |
| 4.7.7. How many ART tissue establishments? | 113 |
| 4.7.9. Please specify the type of tissues/cells and how many. | 16 (e.g. chondrozytes, reproductive tissue, fetal tissue, amnion) |
| 4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible): | Skin tissue establishments<br>Musculo-skeletal tissue establishments<br>Ocular tissue establishments<br>Cardiovascular tissue establishments<br>HSC tissue establishments<br>ART tissue establishments<br>Multi-tissue establishments<br>Other tissue establishments |

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| 4.8.1. How many skin tissue establishments? | 1 |
| 4.8.2. How many musculo-skeletal tissue establishments? | 39 |
| 4.8.3. How many ocular tissue establishments? | 14 |
| 4.8.4. How many cardiovascular tissue establishments? | 2 |
| 4.8.5. How many HSC tissue establishments? | 9 |
| 4.8.7. How many ART tissue establishments? | 87 |
| 4.8.8. How many multi-tissue establishments? | 0 |
| 4.8.9. Please specify the type of tissues/cells and how many. | 10 (e.g. chondrocytes, reproductive tissue, fetal tissue, amnion) |
| 4.9. Tissue establishments first time authorised between 01/01/2011 and 31/12/2011 (more than 1 answer possible): | Musculo-skeletal tissue establishments<br>Ocular tissue establishments<br>Cardiovascular tissue establishments<br>HSC tissue establishments<br>ART tissue establishments<br>Multi-tissue establishments<br>Other tissue establishments |
| 4.9.2. How many musculo-skeletal tissue establishments? | 17 |
| 4.9.3. How many ocular tissue establishments? | 5 |
| 4.9.4. How many cardiovascular tissue establishments? | 2 |
| 4.9.5. How many HSC tissue establishments? | 4 |
| 4.9.7. How many ART tissue establishments? | 37 |
| 4.9.8. How many multi-tissue establishments? | 2 |
| 4.9.9. Please specify the type of tissues/cells and how many. | 34 (e.g. arms, hands, amnion) |
| 4.10. All tissue establishments authorised by 31/12/2011 (more than 1 answer possible): | Skin tissue establishments<br>Musculo-skeletal tissue establishments<br>Ocular tissue establishments<br>Cardiovascular tissue establishments<br>HSC tissue establishments<br>Cord blood tissue establishments<br>ART tissue establishments<br>Multi-tissue establishments<br>Other tissue establishments |
| 4.10.1.1. How many public skin tissue establishments? | 2 |
| 4.10.1.2. How many private skin tissue establishments? | 9 |
| 4.10.2.1. How many public musculo-skeletal tissue establishments? | 23 |
| 4.10.2.2. How many private musculo-skeletal tissue establishments? | 96 |
| 4.10.3.1. How many public ocular tissue establishments? | 8 |
| 4.10.3.2. How many private ocular tissue establishments? | 6 |
| 4.10.4.1. How many public cardiovascular tissue establishments? | 3 |
| 4.10.4.2. How many private cardiovascular tissue establishments? | 3 |
| 4.10.5.1. How many public HSC tissue establishments? | 22 |
| 4.10.5.2. How many private HSC tissue establishments? | 29 |
| 4.10.6.1. How many public cord blood tissue establishments? | 2 |
| 4.10.6.2. How many private cord blood tissue establishments? | 11 |
| 4.10.7.1. How many public ART tissue establishments? | 14 |
| 4.10.7.2. How many private ART tissue establishments? | 105 |
| 4.10.8.1. How many public multi-tissue establishments? | 2 |
| 4.10.8.2. How many private multi-tissue establishments? | 8 |
| 4.10.9.1. Please specify the type of 'other' public tissues/cells establishements and how many. | 1 |
| 4.10.9.2. Please specify the type of 'other' private tissues/cells establishements and how many. | 2 |
| 4.11. How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Art. 6(5) during 2011? Please provide number(s) per type tissues/cells. | 4 |
| **4ter. Sanctions** | |
| 4.16. Have penalties for infringements of the national provisions pursuant to the Directive been defined (Article 27)? | Yes |
| 4.16.1. Have penalties already been imposed? | Yes |
| 4.16.1.1. How many penalties have been imposed in 2011 (from 01/01/2011-31/12/2011)? | In 2011 there has been one penalty imposed under the Transplantation Act. |

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| 4.16.1.2. What were the reasons for imposing the penalties? Please describe. | The statistics do not specify the infringement. It cannot be said, whether the infringement was in relation to organs or tissues and cells. Beside, there are no specific statistical data available relating to infringements against tissue regulation. |
| 4.16.1.3. What kind of penalties were imposed? Please describe (e.g. suspension of authorisation, criminal penalty etc.) | The penalty imposed was a financial penalty. |
| 4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing? | No. |
| **5. Inspections (Article 7, Directive 2004/23/EC)** | |
| 5.1. Is a system in place for organising inspections and control measures of tissue establishments? | Yes |
| 5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections. | The Regional Competent Authorities in the German Länder are entrusted with the task of inspections; they are supported by the Paul-Ehrlich-Institute. For further information see answer 1.7. |
| 5.1.2. If yes, please specify staffing (how many inspectors). | No further data available. |
| 5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible) | Yes |
| 5.2.1. If yes, please specify. (more than 1 answer possible) | Blood<br>Pharmaceuticals<br>Advanced therapies<br>Medical devices<br>Others |
| Please specify other. | Whole salers, brokers, pharmacies and GCP/GLP-Surveillance/License |
| 5.3. How many routine inspections of tissue establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011)? | 56 |
| 5.3.1. How many inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) following serious adverse events or reactions, or suspicion thereof ? | 0 |
| 5.3.2. How many other type of inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | 8 |
| 5.3.3. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | 16 |
| 5.3.4. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where minor shortcomings were noted? | 46 |
| 5.3.5. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where major shortcomings were noted? | 9 |
| 5.3.6. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by suspension of authorisation? | 1 |
| 5.3.7. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by closure? | 0 |
| 5.3.8. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of other inspections carried out? Please specify. | 4 |
| 5.4. How many routine inspections were conducted in ART | 32 |

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| establishments (from 1/1/2011 to 31/12/2011)? | |
| 5.4.1. How many inspections were conducted in ART establishments following serious adverse events or reactions, or suspicion thereof (from 1/1/2011 to 31/12/2011)? | 1 |
| 5.4.2. How many other type of inspections were conducted on ART establishments (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | 8 |
| 5.4.3. Outcome of inspections of ART tissue establishments carried out in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | 0 |
| 5.4.4. What was the number of inspections carried out in ART establishments where minor shortcomings were noted? | 34 |
| 5.4.5. What was the number of inspections carried out in ART establishments where major shortcomings were noted? | 13 |
| 5.4.6. What was the number of inspections carried out in ART establishments followed by suspension of authorisation? | 0 |
| 5.4.7. What was the number of inspections carried out in ART establishments followed by closure of respective establishements? | 0 |
| 5.4.8. What was the number of other inspections of ART establishments? Please specify. | 4 |
| 5.5. Which type of routine inspections do you conduct? (more than 1 answer possible) | General system-oriented inspections<br>Thematic inspections |
| 5.6. How do you decide which type of routine inspection to conduct? | Risk-based approach referred to the outcome of the last inspection. |
| 5.7. Until 2011, did you implement the requirement concerning the time interval between two inspections (Art. 7.3.)? | Yes |
| 5.8. How many TEs were inspected at least twice between 2008-2011 (01/01/2008-31/12/2011)? | 62 |
| 5.9. Did you perform/conduct inspections of procurement sites outside tissue establishments? | Yes |
| 5.9.1. If yes, how many? | 50 |
| 5.10. Did you carry out inspections of third parties? | Yes |
| 5.10.1. If yes, how many? | 63 |
| 5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)? | No |
| 5.11.1. If no, which guidelines/regulations are used for inspections at national level? | Not mandatory, but recommended as a guideline, additional guideline as aide memoire. |
| 5.11.2. If no, please provide a hyperlink to these guidelines/inspections. | Aide memoire «Surveillance of procurement establishments and laboratories » (No. 07122501), https://www.zlg.de/arzneimittel/deutschland/qualitaetssystem.html (no open resource) |
| 5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)? | Yes |
| 5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)? | 4 |
| 5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))? | No |
| 5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))? | No |
| 5.15. Did you organise any inspections of procurement centres or tissue establishments in third countries from which tissues and/or cells were imported in your country (as recorded by 31/12/2011)? | Yes |
| 5.15.1. If yes, please specify why. | Required pursuant sec. 72b of the German Medicinal Products Act. |
| 5.16. Have you asked another MS, or have you been requested by any other MS, on the results and control measures of your | Yes |

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| inspections, as part of an enquiry/investigation? | |
| 5.16.1. If yes, please specify. | Requirements, conditions and data basis of an import licence granted by HTA (UK) for a tissue preparation of a US tissue. Information to other MS because of tissue import from the Ukraine and USA conducted by a German holder of import license. |
| 5.17. Would you be interested in developing joint inspections? Joint inspections should be understood as inspections of tissue establishments conducted jointly by two or more Member States' Competent Authorities on their territory or in third countries. | Yes |
| 5.18. Do you have any additional comments on inspections? | No. |
| **6. Import/export (Article 9 Directive 2004/23/EC)** | |
| 6.1. Do you have a register of authorised tissue establishments that are explicitly authorised to perform import/export of tissues and celles from/to third countries? | Yes |
| 6.2. Please specify the number of tissue establishments authorised to import tissues and cells from third countries (recorded by 31/12/2011). | 37 |
| 6.3. Please specify the number of tissue establishments authorised to export tissues and cells from third countries (recorded by 31/12/2011). | Ocular, limbal 1 Cardiovascular, pericardium 1 Musculoskeletal, bone, femoral 17 Musculoskeletal, soft tissue 2 Musculoskeletal, bone, preparation 2 Musculoskeletal, cartilage 32 Skin 3 Reproductive, sperm 13 Note: In Germany, there is no authorisation for export of tissues and cells, but the export of tissue and cells has to be notifed annually by the tissue establishments. |
| 6.4. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of skin from third countries. | Import authorisation and certification pursuant sec. 72b of the German Medicinal Products Act, granted by the Regional Competent Authorities, product-related marketing authorisation pursuant sec. 21a or sec. 21 of the German Medicinal Products Act, granted by the Paul-Ehrlich-Institut. |
| 6.5. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of musculo-skeletal (bone, tendons, fascia etc.) tissues from third countries. | See answer 6.4. |
| 6.6. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of ophtalmic (cornea, sclera, etc) tissues from third countries. | See answer 6.4. |
| 6.7. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cardio vascular tissues from third countries. | See answer 6.4. |
| 6.8. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) (other than cord blood) from third countries. | See answer 6.4. |
| 6.9. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cord blood from third countries. | See answer 6.4. |
| 6.10. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of reproductive cells (sperm, egg cells) from third countries. | Import authorisation and certification pursuant sec. 72b of the German Medicinal Products Act, granted by the Regional Competent Authorities. |
| 6.11. Did you import tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | Yes |
| 6.11.1. If yes, please provide the data concerning the number/volume of imported tissues and cells by country of origin. | The notification requirement according to section 8d of the German Transplantation Act (TPG) does not distinguish between import from third countries and import from member states of the European Union. The following table contains all tissues which were notified to the Paul-Ehrlich-Institut as being “imported” to Germany during 2011: Ocular, corneal 550 Cardiovascular, heart valves 128 Cardiovascular, vessels 12 Cardiovascular, membrane, pericardium 2410 Musculoskeletal, bone, complete 7914 Musculoskeletal, bone, femoral 1680 Musculoskeletal, bone, preparation 14056 Musculoskeletal, soft tissues 17822 Musculoskeletal, cartilage 176 |

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| | Skin (area in square centimeter) 3436004 Skin (number of pieces) 2 Reproductive, sperm 325 |
| 6.12. Did you export tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | Yes |
| 6.12.1. If yes, please provide the data concerning the number/volume of exported tissues and cells by country of destination. | The notification requirement according to section 8d of the German Transplantation Act (TPG) does not distinguish between export to third countries and export to member states of the European Union. The following table contains all tissues which were notified to the Paul-Ehrlich-Institut as being "exported" from Germany during 2011: Ocular, corneal 185 Ocular, limbal 3 Cardiovascular, membrane, pericardium 2131 Musculoskeletal, bone, complete 8985 Musculoskeletal, bone, femoral 2850 Musculoskeletal, bone, preparation 119407 Musculoskeletal, soft tissues 12951 Musculoskeletal, cartilage 180 Membrane, amniotic 130 Skin (area in square centimeter) 2825092 Reproductive, sperm 1463 |
| 6.13. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on imports/exports of tissues/cells between your country and other third countries? | No |
| 6.14. What is the relation between import/export of tissues and cells and self-sufficiency? (more than 1 answer possible) | F. Other |
| Please specify 'other': | There is no information about this issue. |
| 6.15. Did you authorise direct imports of tissues/cells to hospitals/clinics in your country? | Yes |
| 6.15.1. If yes, please specify the number of cases and for which type of tissues/cells. | 31 (e.g. bone marrow stem cells, peripheral blood stem cells, coord blood, cardiac valves) |
| 6.16. Do you have any additional comments on import/export? | No. |
| **7. Distribution/intra community exchanges (Article 23 Directive 2004/23/EC)** | |
| 7.1. Do you have intra-community exchanges of tissues and cells? | Yes |
| 7.1.1. If yes, how do you address the possible more stringent quality and safety measures established by other Member States? Please specify. | Certification by the Paul-Ehrlich-Institut before the first placing on the market pursuant to sec. 21a para. 9 of the German Medicinal Products Act: Before issuing the certificate, the PEI examines whether the processing of the tissue preparations meet the requirements with respect to the removal and processing procedures including the donor selection procedures and the laboratory test methods, and whether the quantitative and qualitative criteria for the tissue preparations meet the requirements of the German Medicinal Products Act and its ordinances. The competent higher federal authority issues the certificate if the authorisation certificate or another certificate from the competent authority of the country of origin demonstrates the equivalence of the requirements pursuant to the German regulation and the proof of authorisation in the Member State of the European Union or in another State Party to the Agreement on the European Economic Area is submitted. |
| 7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States? | Yes |
| 7.1.2.1. How do you address this difference for tissues and cells coming from a MS with minimum quality requirements? Please specify. | In Germany human tissue preparations are regarded as medicinal products (according to section 4 number 30 of the Medicinal Products Act; German Medicinal Product Act; AMG). Accordingly, authorizations for the manufacturing and placing on the market of tissue preparations are required. Industrially produced tissue preparations are regulated as pharmaceutical medicinal products, tissue preparations not produced using industrial processes, produced with methods well established and known in the EU, having functions or being associated with adverse reactions known from public literature are regulated according to the framework of Directive 2004/23/EC. Therefore, in Germany there are two different marketing authorizations depending on the classification of the product based on the AMG: 1.) authorization for "classical" human tissue preparations (regulated as medicinal products) according to section 21a AMG and 2.) marketing authorization according to section 21 AMG (regulated as medicinal products according to |

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| | Directive 2001/83/EC). "Classical" human tissue preparations subject to authorization according to section 21a AMG which are intended to be placed on the market in a member state of the European Union shall require a certificate according to section 21a sub-section 9 AMG prior to the first placing on the market in Germany. Before issuing the certificate, the competent higher federal authority, Paul-Ehrlich-Institut, shall examine whether the processing of the tissue preparations meets the requirements with respect to the removal and processing procedures including the donor selection procedures and the laboratory examinations, and whether the quantitative and qualitative criteria for the tissue preparations meet the requirements of the AMG and its ordinances. Without the above mentioned marketing authorisation, authorisation or certification , respectively, the placing of human tissue preparations on the German market is not permitted. |
| 7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify. | Authorisation pursuant sec. 20c of the German Medicinal Products Act and inspections, granted by the Regional Competent Authorities. The tissue establishments are supervised by the Regional Competent Authorities of the Länder. Technical requirements for processing, storage and distribution must be defined in the quality management system which is checked during the supervision. |
| 7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible). | Other |
| Please specify 'other'. | Before the first placing on the market a certificate, which is issued by the Paul-Ehrlich-Institut, is required (section 21a sub-section 9 AMG). The certificate shall ensure that only equivalent products are introduced into the purview of the AMG (see answer 7.1.1.). Otherwise, in the case of non-equivalence, a "full marketing authorization" (authorization for tissue preparations regarding Section 21a AMG) must be obtained. |
| 7.4. Have you authorised direct distribution to the recipient of specific tissues and cells (Art. 6, Directive 2006/17/EC)? | No |
| 7.5. Do you collect data regarding the cross-border exchange of tissue/cells between your country and other EU MS? | Yes |
| 7.5.1. Please provide us with data (country of destination, type of tissue/cell and number of units distributed) concerning distribution to other MS in 2011 (01/01/2011-31/12/2011). | Ocular, limbal 3 Cardiovascular, pericadium 2.410 Cardiovascular, heart valves 110 Cardiovascular, vessels 12 Musculoskeletal, bone, complete 7.914 Musculoskeletal, bone, femoral 1.647 Musculoskeletal,, soft tissues 17.822 Musculoskeletal, bone, preparation 14.059 Musculoskeletal, cartilage 208 Skin (area in square centimetre) 3.287.339 Skin (number of pieces) 61.511 Reproductive, sperm 325 Note: In Germany, the country of destination has not to be notifed by the tissue establishments. |
| 7.5.2. Please provide us with data (country of origin, type of tissue/cell and number of units distributed) concerning distribution to other MS in 2011 (01/01/2011-31/12/2011) | Ocular, corneal 1 Cardiovascular, pericadium 2.131 Musculoskeletal, bone, complete 8.985 Musculoskeletal, bone, femoral 2.844 Musculoskeletal,, soft tissues 12.951 Musculoskeletal, bone, preparation 128.392 Musculoskeletal, cartilage 177 Skin (area in square centimetre) 2.825.092 Skin (number of pieces) 967 Reproductive, sperm 1.007 Note: In Germany, the country of origin has not to be notifed by the tissue establishments. |
| 7.6. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on cross-border exchanges of tissues/cells between your country and other EU MS? | No |
| 7.7. Do you allow brokerage companies for either distribution in EU and/or import/export of tissues/cells? In this context, a brokerage company means a body that arranges transactions between a supplier (tissue establishment/company selling tissues or cells) and a buyer (a tissue establishment/a hospital or clinic/an individual) without undertaking activities of processing, preservation or storage. | Yes |
| 7.7.1. Please describe the legal requirements and your role (if any) as a Competent Authority, in their authorisation/monitoring or inspection. | New definition "brokering of medicinal products" (sec. 4 para. 22a German Medicinal Products Act), notification of trade activities without conducting wholesale distribution to the Regional |

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| | Competent Authorities acc. to sec. 52c of the German Medicinal Product Act. No experiences in implementing these regulations with regard to "classical tissues". Interdiction of commerce for "classical" tissues acc. to sec. 17 of the German Transplantation Act (Transplantationsgesetz – TPG), no commerce for germ cells due to the German Embryo Protection Law (Embryonenschutzgesetz - ESchG). |
| 7.8. Are brokers actively supplying health professionals/establishments in your country? | No |
| 7.9. Do you have any additional comments on distribution? | No. |
| **8. Register of tissue establishments and reporting obligations (Article 10, Directive 2004/23/EC)** | |
| 8.1. Do you have an annual report model/template on the activities of tissue establishments in your Member State? (Article 10(1)). If yes, please upload the template. | Yes |
| 8.2. How many tissue establishments submitted annual reports of their activities during 2011. Please provide an estimation. (1 answer possible) | 60-99% |
| 8.3. Are these reports publicly available? (Article 10(1)) | No |
| 8.4. Do you publish a national annual report of the consolidated activities of all tissue establishments in your country? | Yes |
| 8.4.1. Please insert the link to the published national annual report. | http://www.pei.de/DE/infos/meldepflichtige/meldung-gewebe-8d-transplantationsgesetz/berichte-pei/berichte-meldung-8d-transplantationsgesetz-tpg-node.html |
| 8.5. Is there a publicly accessible register of authorised tissue establishements in place? (Article 10(2)) | Yes |
| 8.5.1. If yes, please provide us with the link to the register's web site. | www.pharmnet-bund.de |
| 8.6. Do you provide data regarding tissues and cells activities to the EUROCET registry (non-mandatory reporting)? | Yes |
| 8.6.1. If yes, what data are provided to EUROCET? Please specify. | 1. Donation of ocular tissues, skin, heart valves, blood vessels, musculoskeletal tissues and placenta. 2. Procurement of $cm^2$ of skin retrieved. 3. Storage at 01/01/ 00:00, procession, discarding, distribution and storage at 31/12 24:00 of the above tissues (no. 1) completed by ovarian and testicular tissues (units).The musculoskeletal tissues are subdivided in whole or part of supporting bone (units), tendons / ligaments (units), cartilage (units), bone filling material (units) and other musculoskeletal (units) (i.e. ear ossicles). 4. Import- and Export of the above mentioned tissues (no.3) |
| 8.7. Do you have any additional comments on reporting? | The Register of tissue establishments is based on the German Transplantation Act (sec. 8f TPG) and was established in 2011 at the German Institut for Medicinal Documentation and Information (Deutsches Institut für Medizinische Dokumentation und Information – DIMDI). It is a publicly accessible register of tissue establishments specifying the acitivities for which they have been authorised by the Regional Competent Authority; it contains also the contact details of the tissue establishments. Due to the fact that DIMDI hosts this register since end of 2011, the data in the registry do not yet contain the whole dataset of tissue establishments that existed in Germany in the implied period of time. Final transplantation data cannot be provided because this is not part of the notification requirement according to section 8d para. 3 of the German Transplantation Act (TPG). Beside, there is no obligation pursuant to Article 10 of the Directive 2004/23/EC. |
| **9. Traceability (Article 8, Directive 2004/23/EC; and Directive 2006/86/EC)** | |
| 9.1. Was the donor identification system (Art. 8(2)) implemented in your country? | Yes |
| 9.2. Who assigns the unique code for each donation? (only 1 answer possible) | Procurement centre |
| 9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible) | Both paper records and electronic forms |

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| 9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify. | Tissue establishments and organisations responsible for human application are required by law to retain the data for 30 years, in an appropriate and readable storage medium (sec. 41 AMWHV, sec. 15 para. 2 German Transplantation Act). The tissue establishments have to provide a solution for the case of closing the establishment in respect to storage of remained tissues as well as the data for purposes of traceability (e.g. by contract with another tissue establishment) (sec. 20c para. 7 German Medicinal Products Act, sec. 41 AMWHV). These aspects are part of the surveillance of inspections by the Regional Competent Authorities. |
| 9.5. Do you have any additional comments on traceability? | No. |
| **10. Notification of serious adverse events and reactions (Article 11 Directive 2004/23, Article 6 Directive 2006/76)** | |
| 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))? | Yes |
| 10.1.1. If yes, which CA/institution is responsible? | The vigilance of tissue products is in the competence of the National Competent Authority (PEI) insofar tissue products require a marketing authorisation pursuant to sec. 21a or sec. 21 of the German Medicinal Products Act. The surveillance of the vigilance system of the procurement and tissue establishments (SOPs, reporting channels) is in the responsibility of the Regional Competent Authorities. |
| 10.1.2. If yes, please provide a short description of its organisation. | Section 63i of the German Medicinal Products Act / documentation and notification obligations in respect of tissue preparations and tissues: (1) The holder of a marketing authorisation or authorisation for tissue preparations pursuant to section 21a, shall keep documents on all suspected serious incidents or serious adverse reactions in the Member States of the European Union or in the States party to the Agreement on the European Economic Area or in a third country, as well as on the number of recalls. (2) The holder of a marketing authorisation or authorisation for tissue preparations pursuant to sub-section 1 shall, furthermore, document every suspected serious incident and every suspected serious adverse reaction and shall report them to the competent higher federal authority immediately, or at the latest within 15 days of acquiring this knowledge. The report shall contain all necessary information, especially the name or firm and address of the pharmaceutical entrepreneur, name and number or code of the tissue preparation, date and documentation of the emergence of the suspicion of the serious incident or the serious adverse reaction, date and place where the removal of the tissue took place, enterprises or facilities supplied as well as information on the donor. The incidents or reactions reported pursuant to sentence 1 are to be examined with respect to their causes and effects and subsequently evaluated and the results together with the measures to trace and protect both the donor and the recipient reported immediately to the competent higher federal authority. (3) In the case of tissue preparations and tissues which are not subject to marketing authorisation or authorisation, the tissue facilities shall notify the competent authority, immediately, of every suspected serious incident and every suspected serious adverse reaction. The notification shall contain all necessary information such as the name or firm and address of the donation or tissue facility, name and number or code of tissue preparation, date and documentation of the emergence of the suspected serious incident or the serious adverse reaction, date on which the tissue preparation was manufactured as well as information on the donor. Sub-section 2 sentence 3 shall apply mutatis mutandis. The competent authority shall transmit the notifications pursuant to sentences 1 and 2 as well as the notifications pursuant to sentence 3 to the competent higher federal authority. (4) The holder of a marketing authorisation or authorisation for tissue preparations within the meaning of sub-section 1 shall submit, to the competent higher federal authority, on |

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| | the basis of the obligations contained in sub-section 1, an updated report on the safety of the medicinal product immediately upon request or, where recalls, confirmed or suspected serious incidents or serious adverse reactions are involved, at least once a year. Sentence 1 shall not apply to parallel importers. (5) Section 62 sub-section 6 shall apply mutatis mutandis to tissue facilities; Section 63b sub-section 3 shall apply mutatis mutandis to the holder of an authorisation for tissue preparations. (6) A serious incident within the meaning of the foregoing provisions is any undesired event in connection with the procurement, testing, processing, preserving, storage or supply of tissues preparations which could lead to the transmission of an infectious disease, the death of a patient, a life-threatening state, disability or invalidity of patients, the need for or prolongation of hospitalisation or disease. A serious incident is also any incorrect identification or confusion of germ cells or impregnated egg cells within the framework of medically-assisted insemination measures. (7) A serious adverse reaction within the meaning of the foregoing provisions is an unintended reaction, including an infectious disease in the donor or recipient in connection with the procurement of tissues or the transplanting of tissue preparations, which is fatal or life-threatening or leads to disability or invalidity or requires hospitalisation or the prolongation of existing hospitalisation or causes or prolongs a disease. |
| 10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use the SAR/E (to the CA (2006/76 art 6.4)) templates developed to the Annual reporting ot the EC also at national level? | Yes |
| 10.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level? | No |
| 10.3.1. If no, please specify what guidelines you use. | The tissue establishments are requested to use the notification form, which is available on the PEI homepage. |
| 10.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all TEs? | Yes |
| 10.5. How many tissue establishments provided in 2011 the SAR/SAE data as requested (please provide the % from the total number of TEs authorised in your country). | <50% |
| 10.6. Do you have a mandatory procedure for the transplantation centres when reporting SAR/SAE to the TEs which distributed the tissues/cells (Art 11.2)? | Yes |
| 10.6.1. If yes, please provide a brief description. | According to the German Transplantation Act (TPG) there is an obligation for transplantation centers/ transplant doctors to report SARs to the Regional or National Competent Authority. They are asked to use the notification form available on the PEI homepage. |
| 10.7. Do you give feedback to the TEs regarding SAR/SAE recorded at national level? | No |
| 10.7.2. Please specify why not. | At present there is no established feedback, but the PEI is planning to publish an annual tissue vigilance report. |
| 10.8. Do you give feedback to the TEs regarding SAR/SAE recorded at EU level? | No |
| 10.8.2. Please specify why not. | At present there is no established feedback, but the PEI is planning to include this issue in an annual tissue vigilance report. |
| 10.9. Do you require your TEs to have a recall procedure? | Yes |
| 10.10. How many recalls related to safety and quality of tissues/cells were issued in your country in 2011? Please specify the number and which tissues were recalled and why (e.g. missing consent, quality defects etc). | 0 |
| 10.11. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites in case of a national rapid alert? | Yes |
| 10.11.1. If yes, please give a short description of the system/procedure. | The German competent authorities established a reporting system to inform the qualified person in each tissue establishment responsible for quality and safety of the medicinal products. |

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| 10.12. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites when a rapid alert is issued via the EU RATC platform? | Yes |
| 10.12.1. If yes, please give a short description of the system/procedure. | The German competent authorities established a reporting system to inform the qualified person in each tissue establishment responsible for quality and safety of the medicinal products. |
| 10.13. Do you provide data regarding SAR/SAE to the EUROCET registry (non-mandatory reporting)? | No |
| 10.13.2. If no, please specify why not. | There is no obligation and no benefit for this procedure. |
| 10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems? | Yes |
| 10.14.1. If yes, please specify which of the following systems are usually contacted. (more than 1 answer possible) | Haemovigilance<br>Medical devices |
| 10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S? | Yes |
| 10.15.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (insufficient) - 2 (sufficient) 3 (good) - 4 (very good) to 5 (essential)? | 4 |
| 10.16. Do you have any additional comments on SARE reporting? | Cooperation with relevant third countries with regard to SARE reporting (e.g. USA, case Cryolife), Establishment of an interface for SARE reporting to other product areas, e.g. industrial tissue products in terms of the Directive 2001/83/EG or ATMP in terms of the Regulation (EC) 1394/2007 SOHO V&S Vigilance Guidance for Competent Authorities is helpful and should be updated if necessary. |
| **11. Consent and personal data protection (Article 13 and 14, Directive 2004/23/EC)** | |
| 11.1. What consent system for living tissue/cell donation do you have in place within your Member State? | Explicit consent (opt-in) |
| 11.1.1. Please specify your choice of consent system for living tissue/cell donation. | In the case of living donation the explicit consent of the donor is mandatory. |
| 11.2. What consent system for deceased tissue/cell donation do you have in place within your Member State? | Explicit consent (opt-in) |
| 11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible) | First degree relatives (including spouse)<br>Other relatives<br>Non-marital partners<br>Friends<br>Other |
| Please specify 'other'. | Section 4 of the Transplantation Act regulates the removal of organs with the consent of persons other than the donor: In cases where the physician who is supposed to remove the organ has neither written evidence of consent nor written evidence of objection by the potential donor, the latter's next-of-kin shall be asked whether he or she is aware of a declaration of donation on the part of the potential donor. If the next-of-kin has no knowledge of such a declaration either, removal under the provisions set forth in Section 3, paragraph 1 numbers 2 and 3 as well as paragraph 2 shall only be admissible if a physician has informed the next-of-kin about a possible organ removal and has obtained his or her consent. In making the decision, the next-of-kin shall respect the presumed wishes of the potential donor. The physician shall inform the next-of-kin of this requirement. The latter may agree with the physician that his or her consent may be withdrawn within a specific, agreed deadline. Within the meaning of this Act, next-of-kin are, in the following order of priority: 1. the spouse, 2. children of full age, 3. the parents or, in so far as the potential donor was a minor at the time of death and the custody for his or her person was exercised at that time by only one parent, by a guardian or curator, then the person exercising this custody, 4. sisters and brothers of full age, 5. grand-parents. Next-of-kin are only authorised to make a decision pursuant to paragraph 1 if personal contact between the former and the potential donor existed in the two years preceding the potential donor's death. |

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| | The physician shall determine this fact by questioning the next-of-kin. In the case of several next-of-kin of equal rank, it is sufficient for one of them to be consulted under the terms of paragraph 1 and take a decision; however, an objection on the part of any of them is noteworthy. If a prior-ranking next-of-kin cannot be reached within an appropriate period of time, the consultation and decision of the next-of-kin of lower rank who can be reached next shall be sufficient. A person of full age who has evidently had an especially intimate personal relationship with the potential donor until the latter's death shall be of equal rank to the next-of-kin; such a person shall be on a par with the next-of-kin. In the event that the potential donor had delegated the decision regarding organ removal to a specific person, this person shall take the place of the next-of-kin. |
| 11.4. Is the consent system for deceased tissue donation the same as for organs? | Yes |
| 11.5. How is this consent verified during inspections? (more than 1 answer possible) | Analysis of documentation<br>Interviews with personnel<br>Other |
| Please specify 'other'. | Surveillance of SOPs, contracts between procurement and tissue establishments. |
| 11.6. What measures are in place to ensure that donors/relatives/authorising persons on behalf of donors are provided with the appropriate information, as requested by Art. 13(2)? (more than 1 answer possible) | Only trained personnel is allowed to provide such information<br>Information for donors are standardised at national/regional level<br>Other |
| Please specify 'other'. | General information is also available within the national schemes on public awareness as well as information made available by medical associations. |
| 11.7. What measures are in place to ensure that both donors and recipients remain unidentifiable when access is given to third parties (Art. 14(1)). Please specify. | According to Section 14 of the Transplantation Act are those persons involved in the disclosure or passing on of information pursuant to relevant sections of the Transplantations Act are not authorised to disclose the personal data of either the organ donor or the organ recipient. The personal data compiled within the framework of the Transplantation Act may not be processed or utilised for any purpose other than those stipulated in the Act. They may be processed and utilised for court proceedings the subject matter of which is the violation of any prohibition to disclose data pursuant to sentence 1 or 2. These provisions shall, in the case of the donation of semen, be without prejudice to the right of the child to have access to knowledge about his or her own parentage. In the case of a bone narrow transplantation, by way of derogation from sub-section 2, the identity of the tissue donor and that of the tissue recipient or of the relative in question may be mutually revealed if the tissue donor and the recipient or his or her legal representative have explicitly agreed to do so. |
| 11.8. Please specify what measures are in place to ensure that the identity of the receipient is not disclosed to the donor and vice versa. | See answer to question 11.7. |
| 11.9. Does your national legislation allows disclosure of donor data in case of gametes donation? | Yes |
| 11.10. Do you have any additional comments on consent and data protection? | No. |
| **12. Selection, evaluation and procurement (Article 15 Directive 2004/23; Annexes I-IV Directive 2006/17)** | |
| 12.1. How do you ensure that all requirements related to the evaluation and selection of donors (except donors of reproductive cells) are respected in your country (Art. 15(1), Annex I Directive 2006/17/EC)? (more than 1 answer possible) | Inspections of TEs and procurement sites<br>Audit of documentation<br>Other |
| Please specify 'other'. | Authorisation of procurement establishments pursuant sec. 20b of the German Medicinal Products Act, surveillance of SOPs, quality management system and the training of the personnal (see sec. 33, 34 und 35 Arzneimittel- und Wirkstoffherstellungsverordnung / AMWHV, TPG-GewV). The determination of donor eligibility and the data from laboratory tests are carried out according to pre- |

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| | established SOPs in accordance with good professional practice (sec. 33 AMWHV). |
| 12.2. How do you ensure that all requirements related to the evaluation and selection of donors of reproductive cells are respected in your country (Art 15 (1), Annex III of Directive 2006/17/EC)? (more than 1 answer possible) | Inspections of ART centres<br>Audit documentation<br>Other |
| Please specify 'other'. | See question 12.1. (other) |
| 12.3. Do you have more stringent criteria for donor selection than those listed in Annex I of the Directive 2006/17/EC? | Yes |
| 12.3.1. If yes, please specify. | Donor selection: The exclusion criteria are adapted to the donor of a specific tissue (for example donor for heart valves or vessels or cornea). Therefore, the donor selection criteria are sometimes more specific or stringent, respectively. As criteria for donor selection, the medical history of bacterial and protozoic diseases which can lead to chronically persistent infections, including tuberculosis, brucellosis, leprosis, melioidosis, Q fever, chlamydiosis, salmonellosis and tularaemia, should be considered by manufacturers. In this connection, specific attention should be paid on tick / arthropode borne diseases such as borreliosis, bartonellosis, rickettsiosis, trypanosomiasis, leishmaniasis, babesiosis and ehrlichiosis. The risk to transmit these infectious agents with specific tissues has to be assessed and negative effects for the recipient have to be excluded. Manufacturers are advised to refer to the German Guidelines on Hemotherapy, as published by the Federal Medical Association (Bundesärztekammer) in order to revise the donor questionnaire and to consider restrictions for specific tissue preparations.<br>Procurement: Manufacturers are asked to provide a detailed procedure for the preparation and disinfection of the donor's skin. So far, in many cases this is not possible due to a multitude of different procurement sites with non-supervised disinfection procedures. Manufacturers are asked to revise all applied procedures. A standardized procedure for skin disinfection should be provided to all procurement sites by the tissue organisation or establishment in future. They should follow the recommended standards of practice used for surgical patients and should account for the elimination of bacterial spores as well as vegetative microorganisms and therefore include suitable disinfectants, their concentration and duration of exposure. |
| 12.4. What sources are required in your MS for the evaluation of a deceased donor of tissues/cells? (more than 1 answer possible) | Interview with the donor's family or a person who knew the donor well<br>Medical records of the donor<br>Interview with the treating physician<br>Interview with the general practitioner<br>Autopsy report<br>Other |
| Please specify 'other'. | Post mortem physical examination as well as the results of the laboratory tests required according to Annex II of Directive 2004/23/EC. |
| 12.5. Do you have more stringent criteria for selection of donors of reproductive cells than those listed in Annex III of the Directive 2006/17/EC? | No |
| 12.6. Do you have more stringent criteria for autologous donation than those listed in Annex I of the Directive 2006/17/EC? | No |
| 12.7. Do you require more information on the donation of tissues/cells than the mandatory one as laid down in the Annex of Directive 2004/23/EC (Art 15(3)? | No |
| 12.8. How do you ensure that all requirements regarding tissues and cells' procurement, packaging and transport are complied with by tissue establishments in your country (Art 15(1), Annex IV of Directive 2006/17/EC? (more than 1 answer possible)(For this question "audit" means a documented review of procedures, records, | Inspection of tissue establishment<br>Other |

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| personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)) | |
| 12.8.1. Please specify. | Authorisation of procurement establishments pursuant sec. 20b of the German Medicinal Products Act. |
| 12.9. Do you have any additional comments on selection, evaluation and procurement? | No. |
| **13. Quality management, responsible person, personnel (Article 16, 17, 18 Directive 2004/23/EC)** | |
| 13.1. How do you ensure that tissue establishments in your country have in place a quality system respecting the provisions of the Directive 2004/23/EC Art 16.1? (more than 1 answer possible). (For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)). | Authorisation requirement<br>Inspections<br>Internal audits |
| 13.2. How do you ensure that tissue establishments have a responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible) | Authorisation requirement<br>Inspections<br>Other |
| Please specify 'other'. | Notification of changes, reservation of authorisation |
| 13.3. How do you ensure an appropriate training for the personnel directly involved in the activities of tissue establishments? (more than 1 answer possible) | Authorisation requirement<br>Inspections |
| 13.4. Do you have national/regional/local training programmes for the personnel of tissue establishments? | Yes |
| 13.4.1. If yes, please specify. | Local training of the personnel by the tissue establishment or other providers. |
| 13.5. Any additional comments on quality management, responsible person, personnel? | No. |
| **14. Reception, processing, storage, labelling and packaging (Art 19-22 Directive 2004/23/EC)** | |
| 14.1. How do you ensure that tissue establishments in your country fulfill the requirments of the Art. 19 (Tissue and cell reception) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | National regulation/policy for reception of tissues/cells<br>Inspections of tissue establishments<br>Internal audits of tissue establishments |
| 14.2. How do you ensure that tissue establishments in your country fulfill the requirements of the Art. 20 (Tissue and cell processing) of Directive 2004/23/EC? (more than 1 answer possible) | SOPs for all processes affecting quality and safety are mandatory for authorisation<br>Inspections of tissue establishments<br>Internal audits of tissue establishments |
| 14.3. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 21 (tissue and cell storage conditions) of Directive 2004/23/EC? (more than 1 answer possible) | SOPs for procedures associated with storage of tissues and cells are mandatory for authorisation<br>Inspections of tissue establishments<br>Internal audits of tissue establishments |
| 14.4. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | SOPs for procedures associated with labelling and packaging are mandatory for authorisation<br>Inspections of tissue establishments<br>Internal audits of tissue establishments |
| 14.5. Any additional comments on reception, processing, storage, labelling and packaging? | The requirements for microbiological testing of the source materials as well as of the final tissue product should be included: Microbiological testing for bacteria and fungi must be performed on the starting or incoming tissue itself, where possible; otherwise testing of a substitute like tissue or cell material closely related to the procured tissue or rinsing / transport solution has to be performed. Testing methods should be able to detect relevant aerobic and anaerobic bacteria, as well as fungi, and have to take into account possible specific contaminations of the tissue, for instance with fastidious microorganisms such as Neisseria sp. or Mycobacterium sp. Preferably, a representative sample of the tissue itself should be tested using appropriate media, incubation conditions and |

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| | temperatures. Other suitable samples may be taken from transport or washing solutions. In-process microbiological testing should be performed at relevant manufacturing steps, for instance after a stage of decontamination or inactivation, after washing or change of storage solution. For in-process control tests large amounts of spent storage solutions or cell culturing medium, or other suitable sample material should be used. Suitable microbiological control tests have to be applied on each batch of a final tissue or cell preparation. Whenever possible, a tissue or cell sample should be tested after final packaging, otherwise immediately prior to this step. In addition or in exceptional cases as an exclusive sample, spent storage or culturing medium or final washing solutions may be used for final testing. Every effort should be made to take representative samples. Tests for the detection of mycoplasmas should be performed as late as possible during the manufacturing process. If risk factors are present, it is desirable to perform additional tests for the detection of specific infectious agents. The need for endotoxin/pyrogen testing should be evaluated for each type of tissue or cell preparation. It depends on the intended route of administration, the usual endotoxin content of a preparation and the possible impact on the recipient. Sampling and testing methods have to be validated to show the representativeness of the sample and the suitability of the selected methods. Microbiological safety of tissues and cells should follow the concept of a risk-based approach. It is based on donor selection, the absence of initial contamination or surveillance of incoming bioburden in combination with the absence of specific microorganisms, respectively, and the therapeutic use of the preparation. This is supplemented by control and monitoring of the manufacturing process and the final preparation, and validated methods of disinfection, decontamination or inactivation of microorganisms during processing of tissues and cells. Treatment of tissues with antibiotics and antimycotics cannot be regarded as a safe procedure for elimination of viable microorganisms in cells and tissue preparations. Some microorganisms may survive the antibiotic treatment, but may be inhibited in growth and not detected by microbiological testing due to the sampling error, and can recover when conditions change. Therefore, if possible due to the nature of the starting material, a treatment with antimicrobial substances should not be performed, or should at least be restricted to a validated time as short as possible with subsequent processing steps without the use of such substances. |
| **15. Third party agreements (Art. 24 Directive 2004/23/EC)** | |
| 15.1. Are third party agreements foreseen/allowed in your national legislation? | Yes |
| 15.1.1. If yes, have tissue establishments in your Member State notified third party agreements? | Yes |
| 15.1.1.1. Under which circumstances and for which responsibilities? | On the authority of the tissue establishments. |
| 15.1.1.2. How are third party agreements controlled (Art 6.2) by the Competent Auhtority(ies) in your MS? Please specify. | They are controlled in the context of the authorisation of the tissue establishment and the regular inspections. |
| 15.2. Any additional comments on third party agreements? | No. |
| **16. General comments - implementation** | |
| 16.1. Do you have at national level more stringent quality and safety requirements than those requested by the EU legislation in this field (e.g. restrictions concerning the donation/use of certain tissues/cells, mandatory unpaid donation etc.)? | Yes |
| 16.1.1. Please specify. | The German legislation has restrictions on the certain use of gametes and embryotic stem cells which fall under Article 4 para. 3 of Directive 2004/23/EC and are not covered by the scope of Art. 168 para. 4 letter a of the Treaty. |
| 16.2. Has your Member State encountered any difficulties in implementing the requirements in the EU Tissues and Cells | Testing provisions<br>Import-export |

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| Directives? Please choose from the options below. | Other |
| 16.2.1. For all selected options in question 16.2., please provide a short description. | For further details see letter from German Federal Ministry of Health from 3th June 2013. |
| 16.3. In your opinion, in which of the following Directives are there shortcomings (if any)? (more than 1 answer possible) | Directive 2004/23/EC<br>Directive 2006/17/EC<br>Directive 2006/86/EC |
| 16.3.1. How would you suggest to solve these issues in Directive 2004/23/EC? | Article 28 should be amended by requirements for an approach for microbiological testing on incoming material, in-process and final product samples. |
| 16.3.2. How would you suggest to solve these issues in Directive 2006/17/EC? | Directive 2006/17/EC should be amended by an article on microbiological testing on tissue as incoming material, in-process controls and final product testing, similar to Article 4 (laboratory tests required for donors) and corresponding annex. |
| 16.3.3. How would you suggest to solve these issues in Directive 2006/86/EC? | Directive 2006/86/EC should be amended by an article on microbiological testing on tissue as incoming material, in-process controls and final product testing, similar to Article 4 (laboratory tests required for donors) and corresponding annex. |

### *A.1.12. Survey response Greece*

| **1. Public information** | |
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| 1.1. Name of National Competent Authority (NCA) 1: | HELLENIC TRANSPLANT ORGANISATION & BONE MARROW DEPARTMENT |
| 1.1.2. Address of NCA 1: | 5, ANASTASIOU TSOHA STREET, ATHENS, 115 21 , GREECE |
| 1.1.3. Telephone (central access point): | 0030 2016471200, 0030 2132027000 |
| 1.1.4. E-mail (central access point): | eom@eom.gr |
| 1.1.5. Website: | www.eom.gr |
| 1.1.6. The NCA is responsible for? (more than 1 answer possible) | |
| Non-reproductive tissues and cells | Yes |
| Reproductive tissues and cells | |
| Blood and blood components | |
| Human organs | Yes |
| Pharmaceuticals | |
| Medical devices | |
| Other | |
| Please specify 'other': | |
| 1.1.7. What are the role/tasks of the NCA? (more than 1 answer possible) | |
| Accreditation, authorisation, licensing of TEs | Yes |
| Inspection | Yes |
| Vigilance | Yes |
| Other | |
| THE PROCESS OF IDENTIFYING A SUITABLE HEMATOPOETIC STEM CELL DONOR FOR A PATIENT IN A NEED FOR TRANSPLANT | Search |
| 1.2. National Competent Authority 2? | |
| 1.2.1. Name of National Competent Authority 2: | |
| 1.2.2. Address of NCA 2: | |
| 1.2.3. Telephone (central access point): | |
| 1.2.4. E-mail (central access point): | |
| 1.2.5. Website: | |
| 1.2.6. The NCA is responsible for? (more than 1 answer possible) | |
| Non-reproductive tissues and cells | |
| Reproductive tissues and cells | |
| Blood and blood components | |
| Human organs | |
| Pharmaceuticals | |
| Medical devices | |
| Other | |
| Please specify 'other': | |
| 1.2.7. What are the role/tasks of the NCA? (more than 1 answer possible)* | |
| Accreditation, authorisation, licensing of TEs | |
| Inspection | |
| Vigilance | |
| Other | |
| Please specify 'other': | |
| 1.3. National Competent Authority 3? | |
| Yes No | |
| 1.3.1. Name of National Competent Authority 3 | |
| 1.3.2. Address of NCA 3: | |
| 1.3.3. Telephone (central access point): | |
| 1.3.4. E-mail (central access point): | |
| 1.3.5. Website: | |
| 1.3.6. The NCA is responsible for? (more than 1 answer possible) | |
| Non-reproductive tissues and cells | |
| Reproductive tissues and cells | |

| | |
|---|---|
| Blood and blood components | |
| Human organs | |
| Pharmaceuticals | |
| Medical devices | |
| Other | |
| Please specify 'other': | |
| 1.3.7. What are the role/tasks of the NCA? (more than 1 answer possible | |
| Accreditation, authorisation, licensing of TEs | |
| Inspection | |
| Vigilance | |
| Other | |
| Please specify 'other': | |
| 1.4. National Competent Authority 4? | |
| Yes No | |
| 1.4.1. Name of National Competent Authority 4: | |
| 1.4.2. Address of NCA 4: | |
| 1.4.3. Telephone (central access point): | |
| 1.4.4. E-mail (central access point): | |
| 1.4.5. Website: | |
| 1.4.6. The NCA is responsible for? (more than 1 answer possible) | HTO is a non profit organisation granted from the Ministry of Health.<br>It has three departments: solid organs department- 5 employees<br>bone marrow department -5 employees<br>administrative economical department - 3 employees and two lawyers working on legal matters |
| Non-reproductive tissues and cells | |
| Reproductive tissues and cells | |
| Blood and blood components | |
| Human organs | |
| Pharmaceuticals | |
| Medical devices | |
| Other | |
| Please specify 'other': | |
| 1.4.7. What are the role/tasks of the NCA? (more than 1 answer possible) | |
| Accreditation, authorisation, licensing of TEs | |
| Inspection | |
| Vigilance | |
| Other | |
| Please specify 'other': | |
| 1.5. Please give a short description of the legal status and organisation of the National Competent Authority(ies) | Periodically we have inspectors from the Ministry of Health |
| (e.g. departments, staffing, number of senior and junior inspectors, staff working on EU affairs and legal matters, | |
| vigilance officers, budget, independence from government etc.). | |
| 1.6. In case of MS with federal or decentralised systems, please indicate the roles/tasks of the Regional Competent | Not applicable |
| Authority(ies). (more than 1 answer possible) | |
| Accreditation, authorisation, licensing of TEs | |
| Inspection | |
| Vigilance | |
| Other | |
| Not applicable | |
| Please specify 'other': | |
| 1.7. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation | |
| with the National Competent Authority(ies) for tissues and cells: | |
| **2. Procurement (Article 5 Directive 2004/23/EC)** | |
| 2.1. Do you authorise the "conditions of procurement"? | |

| | |
|---|---|
| Yes No | Yes |
| 2.1.1. How do you authorise the "conditions of procurement"? (more than 1 answer possible) | |
| By inspecting all procurement centres | |
| By inspecting some procurement centres | Yes |
| By inspecting the documentation associated with procurement that is available in the tissue establishment | Yes |
| working with procurement centres | |
| Other | |
| Please specify 'other': | |
| 2.1.2. How many such authorisations were granted in 2011 (01/01-31/12/2011)? | 1)University hospital of Alexandroupolis- Corneas department 2) Ofthalmiatreio of Athens |
| 2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" | 1)Biometics Dental 2)Iamex Endolysi 3) Optimum Orthopedics |
| (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, | Sceletical tissues |
| adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011). | |
| 2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone | 1) EVAGGELISMOS HOSPITAL UNIT 2) AGHIA SOFIA HOSPITAL UNIT 3) RIO HOSPITAL 4) PAPANIKOLAOU HOSPITAL 5) ATTIKON HOSPITAL 6) AGHIOS SAVVAS HOSPITAL 7) LAIKO HOSPITAL 8) HELLENIC CORD BLOOD HOSPITAL OF ATHENS 9)HELLENIC CORD BLOOD HOSPITAL OF THESSALONIKI |
| marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011). | |
| 2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other | |
| reproductive tissues were carried out in 2011 (01/01-31/12/2011). | |
| 2.2.4. Please provide the number of procurement centers in which procurement of tissues/cells for ATMP | |
| manufacturing were carried out in 2011 (01/01-31/12/2011). | |
| 2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive | |
| 2004/23/EC and its implementing Directive 2006/17/EC (e.g. trained personnel, conditions accredited, designated, | |
| authorised, licensed) ? (more than 1 answer possible) | |
| Inspections of the site/centre | |
| Analysis of the mandatory documentation | Yes |
| Other | |
| Please specify 'other': | |
| 2.4. Are you also responsible for the accreditation, designation, authorisation or licensing of laboratories performing donor | |
| testing? | |
| Yes No | Yes |
| 2.4.1. Please provide the number of the laboratories performing donor testing. | 1)G. GENNIMATAS HOSPITAL 2) ELENA VENIZELOU HOSPITAL 3) EVAGGELISMOS HOSPITAL 4) IPPOKRATEIO THESSALONIKIS HOSPITAL 5) GENERAL HOSPITAL OF LARISSA |
| 2.4.2. Which National Authority is in charge of this activity? | HTO |
| 2.5. How do you ensure, as CA for T&C, that tests required for donors are carried out only by qualified laboratories | |
| accredited, designated, authorised or licensed Art. 5(2))? (more than 1 answer possible) | |
| Inspections of the laboratories | |
| Analysis of the mandatory documentation requested from the tissue establishment | Yes |
| Other | |
| Please specify 'other': | |
| | 6 LABORATORIES (ANTI -HIV, ANTI HTLV I + II, CMV/ ANTI CMV, HBS-Ag, ANTI- HBC, ANTI HCV, TREPONEMA |

| | |
|---|---|
| | PALLIDUM) |
| year of accreditation/authorisation/license, which donor tests are performed etc.). | |
| 2.7. Do you have any additional comments on procurement? | |
| **3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)** | |
| 3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. | Yes |
| (more than 1 answer possible) | Yes |
| Anti-HIV 1 | Yes |
| Anti-HIV 2 | Yes |
| Ag HIV | Yes |
| NAT HIV 1 | Yes |
| HBs AG | Yes |
| Anti HBc | Yes |
| NAT HBV | Yes |
| Anti HCV-Ab | Yes |
| NAT HCV | Yes |
| Treponema Pallidum | Yes |
| HTLV-2 | Yes |
| NAT HTLV-2 | Yes |
| 3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. | |
| (more than 1 answer possible) | |
| Anti-HIV 1 | |
| Anti-HIV 2 | |
| Ag HIV | |
| NAT HIV 1 | |
| HBs AG | |
| Anti HBc | |
| NAT HBV | |
| Anti HCV-Ab | |
| NAT HCV | |
| HTLV-2 | |
| NAT HTLV-2 | |
| NAT Chlamydia | |
| Treponema Pallidum | |
| 3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it | NAT TESTING NOT MANDATORY. UNTIL NOW NAT TEST IS MANDATORY FOR BLOOD DONATION. WE TEND TO EXTEND THE USE OF THIS METHOD TO TISSUE & CELL DONORS. |
| mandatory or to encourage its use? Please specify why or why not (e.g. number of additional cases detected, cost-benefit etc.). | |
| 3.4. Do you have concerns on accuracy of the available tests and test procedures for deceased donors? | |
| Yes No | Yes |
| 3.4.1. Please specify why: | |
| | Safety reasons , Quality & Traceability |
| 3.5. Are any other laboratory tests required for donors of non-reproductive tissues and cells in your Member State? | |
| | |
| Yes No | No |
| 3.5.1. Please specify. | |
| 3.6. Are any other laboratory tests required for donors of reproductive tissues and cells in your Member State | |
| Yes No | |
| 3.6.1. Please specify. | |
| 3.7. Do you request/use international accreditation systems for testing laboratories? | |

| | |
|---|---|
| Yes No | Yes |
| | EUROPEAN FEDERATION FOR IMMUNOGENETICS (EFI)<br>ELOT/ EN/ ISO 15015189:2007(2012) |
| 3.8. Do you have any additional comments on testing? | |
| **4. Accreditation, designation, authorisation or licensing of tissue establishments (Article 6, Directive 2004/23/EC)** | |
| 4.1. Do you have a system of designation, authorisation, accreditation or licensing for all types of tissue | |
| establishments under your responsability? | |
| Yes No | Yes |
| 4.1.1. Why not? | |
| 4.2. Is inspection a prerequisite for the designation, authorisation, accreditation or licensing of tissue establishments? | |
| Yes No | Yes |
| 4.2.1. How many inspections were performed in 2011 for authorising/accrediting/licensing/designating TEs? | 1) BIOMETICS DENTAL 2) IAMEX ENDOLYSI 3) OPTIMUM ORTOPEDICS 4) OPTHALMIATREIO OF ATHENS 5) UNIVERSITY HOSPITAL OF ALEXANDROUPOLIS |
| 4.3. Are preparation processes authorised? | |
| | |
| Yes No | Yes |
| 4.3.1. How are they authorised? (more than 1 answer possible) | |
| During routine inspections | |
| During inspections organised for this purpose | Yes |
| By review of a submitted application with supporting documentation | Yes |
| 4.4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were suspended in 2011? | 1) OTHALMIATREIO OF ATHENS 2) UNIVERSITY HOSPITAL OF ALEXANDROUPOLIS |
| 4.5. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011? | – |
| 4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)? | |
| Yes No | No |
| 4.6.1. What is the relation between the indpendent certification(s) (e.g. ISO, JACIE, FACT) and the CA authorisation of the tissue establishments? (more than 1 answer possible) | |
| Mandatory for authorisation | |
| Optional, but TEs are encouraged to get a certification | Yes |
| Inspections are conducted jointly by the CAs and independent certifying body | |
| No relation | Yes |
| Other | |
| Please specify 'other': | |
| | |
| **4bis. Overview of tissue/cells establishments authorised by the NCA** | |
| (Establishments authorised for only one type of tissue should be included under the appropriate categories | |
| 3.6.1.-3.6.7.; establishments authorised for more than one type of tissue, should be included under "multi-tissue" | |
| establishments" - category 3.6.8.) | |
| In questions XX – XX please select the appropriate type(s) of tissue establishments in your country and then provide | |
| the requested numbers. | |
| 4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible): | |
| Skin tissue establishments | Yes |
| Musculo-skeletal tissue establishments | Yes |
| Ocular tissue establishments | Yes |

| | |
|---|---|
| Cardiovascular tissue establishments | |
| HSC tissue establishments | Yes |
| Cord blood tissue establishments | Yes |
| ART tissue establishments | |
| Multi-tissue establishments | |
| Other tissue establishments | |
| 4.7.1. How many skin tissue establishments? | 1 |
| 4.7.2. How many musculo-skeletal tissue establishments? | 1) ASKLIPIEION HOSPITAL |
| 4.7.3. How many ocular tissue establishments? | OCULAR 2 |
| 4.7.4. How many cardiovascular tissue establishments? | |
| 4.7.5. How many HSC tissue establishments? | 4 |
| 4.7.6. How many cord blood tissue establishments? | 2 |
| 4.7.7. How many ART tissue establishments? | |
| 4.7.8. How many multi-tissue establishments? | |
| 4.7.9. Please specify the type of tissues/cells and how many. | |
| 4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible): | |
| Skin tissue establishments | Yes |
| Musculo-skeletal tissue establishments | Yes |
| Ocular tissue establishments | Yes |
| Cardiovascular tissue establishments | |
| HSC tissue establishments | Yes |
| Cord blood tissue establishments | Yes |
| ART tissue establishments | |
| Multi-tissue establishments | |
| Other tissue establishments | |
| 4.8.1. How many skin tissue establishments? | 8 |
| 4.8.2. How many musculo-skeletal tissue establishments? | 17 |
| 4.8.3. How many ocular tissue establishments? | 20 |
| 4.8.4. How many cardiovascular tissue establishments? | |
| 4.8.5. How many HSC tissue establishments? | 4 |
| 4.8.6. How many cord blood tissue establishments? | 2 |
| 4.8.7. How many ART tissue establishments? | |
| 4.8.8. How many multi-tissue establishments? | |
| 4.8.9. Please specify the type of tissues/cells and how many. | |
| 4.9. Tissue establishments first time authorised between 01/01/2011 and 31/12/2011 (more than 1 answer possible): | None |
| Skin tissue establishments | |
| Musculo-skeletal tissue establishments | |
| Ocular tissue establishments | |
| Cardiovascular tissue establishments | |
| HSC tissue establishments | |
| Cord blood tissue establishments | |
| ART tissue establishments | |
| Multi-tissue establishments | |
| Other tissue establishments | |
| 4.9.1. How many skin tissue establishments? | |
| 4.9.2. How many musculo-skeletal tissue establishments? | |
| 4.9.3. How many ocular tissue establishments? | |
| 4.9.4. How many cardiovascular tissue establishments? | |
| 4.9.5. How many HSC tissue establishments? | |
| 4.9.6. How many cord blood tissue establishments? | |
| 4.9.7. How many ART tissue establishments? | |
| 4.9.8. How many multi-tissue establishments? | |
| 4.9.9. Please specify the type of tissues/cells and how many. | |
| 4.10. All tissue establishments authorised by 31/12/2011 (more than 1 answer possible): | |
| Skin tissue establishments | |
| Musculo-skeletal tissue establishments | |

| | |
|---|---|
| Ocular tissue establishments | Yes |
| Cardiovascular tissue establishments | |
| HSC tissue establishments | |
| Cord blood tissue establishments | Yes |
| ART tissue establishments | |
| Multi-tissue establishments | |
| Other tissue establishments | |
| 4.10.1.1. How many public skin tissue establishments | |
| 4.10.1.2. How many private skin tissue establishments? | NA |
| 4.10.2.1. How many public musculo-skeletal tissue establishments? | 1 |
| 4.10.2.2. How many private musculo-skeletal tissue establishments? | None |
| 4.10.3.1. How many public ocular tissue establishments? | 2 |
| 4.10.3.2. How many private ocular tissue establishments? | |
| 4.10.4.1. How many public cardiovascular tissue establishments? | |
| 4.10.4.2. How many private cardiovascular tissue establishments? | |
| 4.10.5.1. How many public HSC tissue establishments? | |
| 4.10.5.2. How many private HSC tissue establishments? | |
| 4.10.6.1. How many public cord blood tissue establishments? | One public |
| 4.10.6.2. How many private cord blood tissue establishments? | |
| 4.10.7.1. How many public ART tissue establishments? | |
| 4.10.7.2. How many private ART tissue establishments? | |
| 4.10.8.1. How many public multi-tissue establishments? | |
| 4.10.8.2. How many private multi-tissue establishments? | |
| 4.10.9.1. Please specify the type of 'other' public tissues/cells establishements and how many. | |
| 4.10.9.2. Please specify the type of 'other' private tissues/cells establishements and how many. | |
| 4.11. How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Art. 6(5) during 2011? Please provide number(s) per type tissues/cells. | CORNEAS: 345 , HEMATOPOETIC STEM CELL: 78, HELLENIC CORD BANK OF ATHENS : 2 |
| **4ter. Sanctions** | |
| 4.16. Have penalties for infringements of the national provisions pursuant to the Directive been defined (Article 27)? | |
| Yes No | Yes |
| 4.16.1. Have penalties already been imposed? | |
| Yes No | No |
| 4.16.1.1. How many penalties have been imposed in 2011 (from 01/01/2011-31/12/2011)? | |
| 4.16.1.2. What were the reasons for imposing the penalties? Please describe. | |
| 4.16.1.3. What kind of penalties were imposed? Please describe (e.g. suspension of authorisation, criminal penalty etc.) | |
| 4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing? | |
| **5. Inspections (Article 7, Directive 2004/23/EC)** | |
| 5.1. Is a system in place for organising inspections and control measures of tissue establishments? | |
| Yes No | Yes |
| 5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections. | A team fron the Ministry of Health authorized for inspections |
| 5.1.2. If yes, please specify staffing (how many inspectors). | Yes |
| 5.1.3. If no, please specify why not. | It depend upon the type of tissue |
| 5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example | |
| blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible) | |
| Yes No | No |

| | |
|---|---|
| 5.2.1. If yes, please specify. (more than 1 answer possible) | |
| Blood | |
| Organs | |
| Pharmaceuticals | |
| Advanced therapies | |
| Medical devices | |
| Hospitals | |
| Accreditation organisations (e.g. JACIE) | |
| Others | |
| Please specify other. | |
| 5.3. How many routine inspections of tissue establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011)? | Two corneas |
| 5.3.1. How many inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) following serious adverse events or reactions, or suspicion thereof ? | |
| 5.3.2. How many other type of inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | |
| 5.3.3. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | Every two years |
| 5.3.4. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where minor shortcomings were noted? | Every six months |
| 5.3.5. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where major shortcomings were noted? | Onr year |
| 5.3.6. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by suspension of authorisation? | Two inspecrions |
| 5.3.7. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by closure? | Three inspections |
| 5.3.8. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of other inspections carried out? Please specify. | |
| 5.4. How many routine inspections were conducted in ART establishments (from 1/1/2011 to 31/12/2011)? | |
| 5.4.1. How many inspections were conducted in ART establishments following serious adverse events or reactions, | |
| or suspicion thereof (from 1/1/2011 to 31/12/2011)? | |
| 5.4.2. How many other type of inspections were conducted on ART establishments (from 1/1/2011 to 31/12/2011) ( | |
| e.g. due to a whistle-blower)? Please specify. | |
| 5.4.3. Outcome of inspections of ART tissue establishments carried out in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | |
| 5.4.4. What was the number of inspections carried out in ART establishments where minor shortcomings were noted? | |
| 5.4.5. What was the number of inspections carried out in ART establishments where major shortcomings were noted? | |

| | |
|---|---|
| 5.4.6. What was the number of inspections carried out in ART establishments followed by suspension of authorisation? | |
| 5.4.7. What was the number of inspections carried out in ART establishments followed by closure of respective establishements? | |
| 5.4.8. What was the number of other inspections of ART establishments? Please specify. | |
| 5.5. Which type of routine inspections do you conduct? (more than 1 answer possible) | |
| General system-oriented inspections | |
| Thematic inspections | |
| Desk based reviews | |
| 5.6. How do you decide which type of routine inspection to conduct? | |
| 5.7. Until 2011, did you implement the requirement concerning the time interval between two inspections (Art. 7.3.)? | |
| Yes No | |
| 5.7.1. Why not? | |
| 5.7.2. How do you prioritise tissue establishments to be inspected? | According to the date of the request from the T.E |
| 5.8. How many TEs were inspected at least twice between 2008-2011 (01/01/2008-31/12/2011)? | Two corneas |
| 5.9. Did you perform/conduct inspections of procurement sites outside tissue establishments? | |
| Yes No | Yes |
| 5.9.1. If yes, how many? | Two in public tissue and none yet in private establishment |
| 5.9.2. If no, why not? | |
| 5.10. Did you carry out inspections of third parties? | |
| Yes No | No |
| 5.10.1. If yes, how many? | |
| 5.10.2. If no, why not? | Because we request a private contact between the T.E and the 3r d parties which reassures the safety and the quality system according to the Greek law |
| 5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)? | |
| Yes No | Yes |
| 5.11.1. If no, which guidelines/regulations are used for inspections at national level? | |
| 5.11.2. If no, please provide a hyperlink to these guidelines/inspections. | |
| 5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)? | |
| Yes No | Yes |
| 5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)? | 4 |
| 1 2 3 4 5 | |
| 5.12.2. Why not? | |
| 5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))? | |
| Yes No | No |
| 5.13.1. Could you please explain why? | |
| 5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))? | |
| Yes No | Yes |
| 5.14.1. Could you please explain why? | |
| 5.15. Did you organise any inspections of procurement centres or | |

| | |
|---|---|
| tissue establishments in third countries from which tissues and/or cells were imported in your country (as recorded by 31/12/2011)? | |
| Yes No | No |
| 5.15.1. If yes, please specify why. | |
| 5.16. Have you asked another MS, or have you been requested by any other MS, on the results and control | |
| measures of your inspections, as part of an enquiry/investigation? | |
| Yes No | No |
| 5.16.1. If yes, please specify. | |
| 5.17. Would you be interested in developing joint inspections? | |
| Joint inspections should be understood as inspections of tissue establishments conducted jointly by two or more | |
| Member States' Competent Authorities on their territory or in third countries. | |
| Yes No | No |
| 5.17.1. Could you please explain why not? | We are not ready yet |
| 5.18. Do you have any additional comments on inspections? | |
| **6. Import/export (Article 9 Directive 2004/23/EC)** | |
| Import/export refers to the exchange of tissue/cells with non-EU Member States | |
| 6.1. Do you have a register of authorised tissue establishments that are explicitly authorised to perform import/export of tissues and celles from/to third countries? | |
| Yes No | No |
| 6.2. Please specify the number of tissue establishments authorised to import tissues and cells from third countries (recorded by 31/12/2011). | |
| 6.3. Please specify the number of tissue establishments authorised to export tissues and cells from third countries (recorded by 31/12/2011). | |
| 6.4. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of skin from third countries. | |
| 6.5. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of musculo-skeletal (bone, tendons, fascia etc.) tissues from third countries. | |
| 6.6. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of ophtalmic (cornea, sclera, etc) tissues from third countries. | DIRECTIVE 2008 & PRESIDENTIAL LAW 26/2008 |
| 6.7. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cardio vascular tissues from third countries. | |
| 6.8. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) (other than cord blood) from third countries. | |
| 6.9. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cord blood from third countries. | DIRECTIVE 2008 & PRESIDENTIAL LAW 26/2008 |
| 6.10. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of reproductive cells (sperm, egg cells) from third countries. | |
| 6.11. Did you import tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | |
| Yes No | No |
| 6.11.1. If yes, please provide the data concerning the number/volume of imported tissues and cells by country of origin. | |

| | |
|---|---|
| 6.12. Did you export tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | |
| Yes No | No |
| 6.12.1. If yes, please provide the data concerning the number/volume of exported tissues and cells by country of destination. | |
| 6.13. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on imports/exports of | |
| tissues/cells between your country and other third countries?* | |
| Yes No | |
| 6.13.1. If yes, please specify. | |
| 6.14. What is the relation between import/export of tissues and cells and self-sufficiency? (more than 1 answer | |
| possible) | |
| A. Export of tissues/cells is authorised only after checking that local/national needs are fulfilled. | Yes |
| B. Export of tissues/cells is authorised based on estimations performed on an annual basis | Yes |
| C. Export of tissues/cells is authorised irrespective of national needs | |
| D. Import of tissues/cells is authorised only after checking that local/national needs are not fulfilled | Yes |
| E. Import of tissues/cells is authorised based on estimations showing that there is chronic deficiency of those | |
| tissues/cells | |
| F. Other | |
| Please specify 'other': | |
| 6.14.1. If A or D were selected, please explain how you quantify local/national needs. | THERE IS A WAITING LIST FOR HCC & OCULAR |
| 6.15. Did you authorise direct imports of tissues/cells to hospitals/clinics in your country? | |
| Yes No | NO |
| 6.15.1. If yes, please specify the number of cases and for which type of tissues/cells. | |
| 6.16. Do you have any additional comments on import/export? | |
| **7. Distribution/intra community exchanges (Article 23 Directive 2004/23/EC)** | |
| For this question, distribution should be understood as cross-border exchanges of tissues/cells, and not between | |
| tissue establishments and centres of human application within the same MS. | |
| 7.1. Do you have intra-community exchanges of tissues and cells? | |
| Yes No | YES |
| 7.1.1. If yes, how do you address the possible more stringent quality and safety measures established by other | WE REQUEST FROM THE OTHER MS TO FOLLOW STRICTLY THE DIRECTIVE GUIDELINES |
| Member States? Please specify. | |
| 7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States? | |
| Yes No | NO |
| 7.1.2.1. How do you address this difference for tissues and cells coming from a MS with minimum quality requirements? Please | WE INSIST TO FOLOOW THE DIRECTIVES GUIDELINES |
| specify. | |
| 7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify. | BY INSPECTIONS |
| 7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible). | |
| Yes, no restrictions | |
| apply | |
| Yes, but only via an | |

| | |
|---|---|
| authorised TE in my MS | |
| No / Other | NO |
| Please specify 'other'. | |
| 7.4. Have you authorised direct distribution to the recipient of specific tissues and cells (Art. 6, Directive 2006/17/EC)? | |
| Yes No | NO |
| 7.4.1. If yes, how many authorisations were given in 2011 (01/01/2011 to 31/12/2011)? | |
| 7.4.2. If yes, for which tissues/cells? | |
| 7.5. Do you collect data regarding the cross-border exchange of tissue/cells between your country and other EU MS? | |
| Yes No | YES |
| 7.5.1. Please provide us with data (country of destination, type of tissue/cell and number of units distributed) concerning distribution to other MS in 2011 (01/01/2011-31/12/2011). | DONATION TWO CORD BLOOD UNITS TO UK IN 2011 |
| 7.5.2. Please provide us with data (country of origin, type of tissue/cell and number of units distributed) concerning distribution to other MS in 2011 (01/01/2011-31/12/2011) | PBSC: 2011 78, CORNEAS: 345 SCELETICAL TISSUES: 519 |
| 7.6. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on cross-border exchanges of tissues/cells between your country and other EU MS? | |
| Yes No | NO |
| 7.6.1. Please specify. | |
| 7.7. Do you allow brokerage companies for either distribution in EU and/or import/export of tissues/cells? | |
| In this context, a brokerage company means a body that arranges transactions between a supplier (tissue | |
| establishment/company selling tissues or cells) and a buyer (a tissue establishment/a hospital or clinic/an individual) | |
| without undertaking activities of processing, preservation or storage. | |
| Yes No | NO |
| 7.7.1. Please describe the legal requirements and your role (if any) as a Competent Authority, in their authorisation/monitoring or inspection. | ACCORDING TO THE DIRECTIVES |
| 7.8. Are brokers actively supplying health professionals/establishments in your country? | |
| Yes No | NO |
| 7.8.1. Where are the brokers located? | |
| Your country Another country | |
| 7.8.2. If the broker is located in another country, how easy/difficult is it to ensure that safety and quality requirements are met? | |
| 7.9. Do you have any additional comments on distribution? | |
| **8. Register of tissue establishments and reporting obligations (Article 10, Directive 2004/23/EC)** | |
| 8.1. Do you have an annual report model/template on the activities of tissue establishments in your Member State? | |
| (Article 10(1)). If yes, please upload the template. | |
| Yes No | NO |
| 8.1.1. If no, why not | WE DO NOT HAVE AT THE MOMENT A TEMPLATE FOR EACH ASCTIVITY BUT WE KEEP DATA BASE IN PAPER FORM FROM THE T.E. |
| 8.2. How many tissue establishments submitted annual reports of their activities during 2011. Please provide an | |
| estimation. (1 answer possible) | |
| 100% (all) 60-99% 50-69% <50% | 50-69% |
| 8.3. Are these reports publicly available? (Article 10(1)) | |
| Yes No | YES |
| 8.3.1. If yes, please insert the link(s) to the report(s). | www.eom.gr / www.eae.gr |

| | |
|---|---|
| 8.4. Do you publish a national annual report of the consolidated activities of all tissue establishments in your country? | |
| Yes No | NO |
| 8.4.1. Please insert the link to the published national annual report. | |
| 8.4.2. If no, why not? | NO DUE TO FINANCIAL REASONS |
| 8.5. Is there a publicly accessible register of authorised tissue establishements in place? (Article 10(2)) | |
| Yes No | NO |
| 8.5.1. If yes, please provide us with the link to the register's web site. | |
| 8.5.2. If no, why not? | NO DUE TO FINANCIAL REASONS |
| 8.6. Do you provide data regarding tissues and cells activities to the EUROCET registry (non-mandatory reporting)? | |
| Yes No | YES |
| 8.6.1. If yes, what data are provided to EUROCET? Please specify. | HSC & CORNEAS DATA |
| 8.6.2. If no, why not? | |
| 8.7. Do you have any additional comments on reporting? | |
| **9. Traceability (Article 8, Directive 2004/23/EC; and Directive 2006/86/EC)** | |
| 9.1. Was the donor identification system (Art. 8(2)) implemented in your country? | |
| Yes No | YES |
| 9.1.1. If no, why not? | |
| 9.2. Who assigns the unique code for each donation? (only 1 answer possible) | |
| National Competent Authority | |
| Regional Authority | |
| Tissue establishment | YES |
| Procurement centre | |
| Other | |
| Please specify 'other'. | |
| 9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer | |
| possible) | |
| Only paper records Only electronic forms Both paper records and | BOTH PAPERS AND ELECTRONICS FORMS |
| electronic forms | |
| 9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? | WE KEEP THEM IN A SEPARATE LOCKED SPACE WITH LIMITED ACCESS |
| Please specify. | |
| 9.5. Do you have any additional comments on traceability? | |
| **10. Notification of serious adverse events and reactions (Article 11 Directive 2004/23, Article 6 Directive 2006/76)** | |
| 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions | |
| (Article 11(1))? | |
| Yes No | YES |
| 10.1.1. If yes, which CA/institution is responsible? | HTO |
| 10.1.2. If yes, please provide a short description of its organisation. | HTO IS AN NON PROFIT ORGANISATION GRANTED FROM THE MINISTRY OF HEALTH. |
| 10.1.3. If no, why not? | |
| 10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use the SAR/E (to the CA (2006/76 art 6.4)) templates | |
| developed to the Annual reporting ot the EC also at national level? | |
| Yes No | YES |
| 10.2.1. If no, what template do you use? You are welcome to upload the template if you wish. | |
| 10.3. Do you use the Common Approach Document developed | |

| | |
|---|---|
| for the Annual reporting to the EC also at national level? | |
| Yes No | YES |
| 10.3.1. If no, please specify what guidelines you use. | |
| 10.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all TEs? | |
| Yes No | NO |
| 10.4.1. Why not? | DUE TO THE STUFF LIMITATION |
| 10.5. How many tissue establishments provided in 2011 the SAR/SAE data as requested (please provide the % | |
| from the total number of TEs authorised in your country). | |
| 100% 70-99% 50-69% <50% | <50% |
| 10.6. Do you have a mandatory procedure for the transplantation centres when reporting SAR/SAE to the TEs | |
| which distributed the tissues/cells (Art 11.2)? | |
| Yes No | YES |
| 10.6.1. If yes, please provide a brief description. | WE DISTRIBUTE THE SURVEY FORMS TO BE COMPLETED BY THE T.E.'s |
| 10.6.2. If no, how do you ensure that SAR/SAE are reported to the TEs? | |
| 10.7. Do you give feedback to the TEs regarding SAR/SAE recorded at national level? | |
| Yes No | YES |
| 10.7.1. Please specify. | WE GIVE SOME DIRECTIONS FOLLOWED BY INSPECTIONS TO THE T.E.'s |
| 10.7.2. Please specify why not. | |
| 10.8. Do you give feedback to the TEs regarding SAR/SAE recorded at EU level? | |
| Yes No | YES |
| 10.8.1. Please specify. | |
| 10.8.2. Please specify why not. | |
| 10.9. Do you require your TEs to have a recall procedure? | |
| Yes No | YES |
| 10.9.1. If no, please specify why not. | |
| 10.10. How many recalls related to safety and quality of tissues/cells were issued in your country in 2011? Please specify the number and which tissues were recalled and why (e.g. missing consent, quality defects etc). | |
| 10.11. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites in case of a national rapid alert? | |
| Yes No | NO |
| 10.11.1. If yes, please give a short description of the system/procedure. | |
| 10.11.2. If no, please specify why not. | DUE TO THE STUFF LIMITATION |
| 10.12. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites when a | |
| rapid alert is issued via the EU RATC platform? | |
| Yes No | NO |
| 10.12.1. If yes, please give a short description of the system/procedure. | |
| 10.12.2. If no, please specify why not. | DUE TO THE STUFF LIMITATION |
| 10.13. Do you provide data regarding SAR/SAE to the EUROCET registry (non-mandatory reporting)? | |
| Yes No | NO |
| 10.13.1. If yes, please specify what data. | |
| 10.13.2. If no, please specify why not. | |
| 10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national | |
| vigilance/alert systems? | |
| Yes No | YES |

| | |
|---|---|
| 10.14.1. If yes, please specify which of the following systems are usually contacted. (more than 1 answer possible) | |
| Haemovigilance | YES |
| Pharmacovilance | |
| Medical devices | |
| Other | |
| Please specify 'other'. | |
| 10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO | |
| V&S? | |
| Yes No | NO |
| 10.15.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 | |
| (insufficient) - 2 (sufficient) 3 (good) - 4 (very good) to 5 (essential)? | |
| 1 2 3 4 5 | |
| 10.15.2. If no, please specify why not. | |
| 10.16. Do you have any additional comments on SARE reporting? | |
| 11. Consent and personal data protection (Article 13 and 14, Directive 2004/23/EC) | |
| 11.1. What consent system for living tissue/cell donation do you have in place within your Member State? | |
| Presumed consent (opt-out) Explicit consent (opt-in) | Explicit consent |
| 11.1.1. Please specify your choice of consent system for living tissue/cell donation. | |
| | WE KEEP CONSENT FORMS FOR EACH TYPE OF TISSUE TO BE COMPLETED |
| 11.2. What consent system for deceased tissue/cell donation do you have in place within your Member State? | |
| Presumed consent (opt-out) Presumed (opt-out) and explicit (opt-in) consent | explicit consent |
| Explicit consent (opt-in) | |
| 11.2.1. If you have chosen both consent systems for deceased tissue/cell dontation, please specify. | |
| 11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible) | |
| First degree relatives (including spouse) | YES |
| Other relatives | |
| Non-marital partners | |
| Friends | |
| No further authorisation is needed | |
| Other | |
| Please specify 'other'. | |
| 11.4. Is the consent system for deceased tissue donation the same as for organs? | |
| Yes No | YES |
| 11.4.1. If no, please describe the difference. | |
| 11.5. How is this consent verified during inspections? (more than 1 answer possible | |
| Analysis of documentation | YES |
| Interviews with personnel | |
| Interviews with relatives of deceased donors | |
| Interviews with living donors | |
| Other | |
| Please specify 'other'. | |
| 11.6. What measures are in place to ensure that donors/relatives/authorising persons on behalf of donors are provided with the appropriate information, as requested by Art. | |

| | |
|---|---|
| 13(2)? (more than 1 answer possible) | |
| Only trained personnel is allowed to provide such information | YES |
| Information for donors are standardised at national/regional level | |
| Other | |
| Please specify 'other'. | |
| 11.7. What measures are in place to ensure that both donors and recipients remain unidentifiable when access is | WE KEEP AN ANONIMITY FOR TWO YEARS |
| given to third parties (Art. 14(1)). Please specify. | |
| 11.8. Please specify what measures are in place to ensure that the identity of the receipient is not disclosed to the donor and vice versa. | WE GIVE CODE SYSTEM |
| 11.9. Does your national legislation allows disclosure of donor data in case of gametes donation? | |
| Yes No | |
| 11.9.1. If no, please specify the circumstances and measures in place. | |
| 11.10. Do you have any additional comments on consent and data protection? | |
| 12. Selection, evaluation and procurement (Article 15 Directive 2004/23; Annexes I-IV Directive 2006/17) | |
| 12.1. How do you ensure that all requirements related to the evaluation and selection of donors (except donors of reproductive cells) are respected in your country (Art. 15(1), Annex I Directive 2006/17/EC)? (more than 1 answer possible) | |
| Stadardised questionnaires at national levels | YES |
| Inspections of TEs and procurement sites | YES |
| Audit of documentation | YES |
| Regular evaluation of medical personnel | |
| Other | |
| Please specify 'other'. | |
| 12.2. How do you ensure that all requirements related to the evaluation and selection of donors of reproductive cells | |
| are respected in your country (Art 15 (1), Annex III of Directive 2006/17/EC)? (more than 1 answer possible) | |
| Standardised questionnaires at national level | |
| Inspections of ART centres | |
| Audit documentation | |
| Regular evaluation of medical personnel | |
| Other | |
| Please specify 'other'. | |
| 12.3. Do you have more stringent criteria for donor selection than those listed in Annex I of the Directive 2006/17/EC? | |
| Yes No | |
| 12.3.1. If yes, please specify. | |
| 12.4. What sources are required in your MS for the evaluation of a deceased donor of tissues/cells? (more than 1 answer possible) | |
| Interview with the donor's family or a person who knew the donor well | YES |
| Medical records of the donor | YES |
| Interview with the treating physician | YES |
| Interview with the general practitioner | |
| Autopsy report | YES |
| Other | |
| Please specify 'other'. | |
| 12.5. Do you have more stringent criteria for selection of donors of reproductive cells than those listed in Annex III of the Directive 2006/17/EC? | |
| Yes No | |
| 12.5.1. Please specify. | |
| 12.6. Do you have more stringent criteria for autologous donation | |

| | |
|---|---|
| than those listed in Annex I of the Directive 2006/17/EC? | |
| Yes No | YES |
| 12.6.1. If yes, please specify. | ACCORDING TO THE DIRECTIVES |
| 12.7. Do you require more information on the donation of tissues/cells than the mandatory one as laid down in the | |
| Annex of Directive 2004/23/EC (Art 15(3)? | |
| Yes No | NO |
| 12.7.1. If yes, please specify. | |
| 12.8. How do you ensure that all requirements regarding tissues and cells' procurement, packaging and transport are complied with by tissue establishments in your country (Art 15(1), Annex IV of Directive 2006/17/EC? (more than 1 answer possible) (For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)) | |
| Inspection of tissue establishment | YES |
| Audit of tissue establishment | YES |
| Inspection of the centre of human application (e.g. transplantation centre, ART centre) | YES |
| Audit of the centre of human application | YES |
| Other | |
| 12.8.1. Please specify. | |
| 12.9. Do you have any additional comments on selection, evaluation and procurement? | |
| 13. Quality management, responsible person, personnel (Article 16, 17, 18 Directive 2004/23/EC) | |
| 13.1. How do you ensure that tissue establishments in your country have in place a quality system respecting the provisions of the Directive 2004/23/EC Art 16.1? (more than 1 answer possible). (For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)). | |
| Authorisation requirement | |
| Inspections | YES |
| Internal audits | YES |
| External audits | YES |
| Other | |
| Please specify 'other'. | |
| 13.2. How do you ensure that tissue establishments have a responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible) | |
| Authorisation requirement | YES |
| Inspections | YES |
| Regular evaluation of personnel | YES |
| Mandatory trainings | YES |
| Other | |
| Please specify 'other'. | |
| 13.3. How do you ensure an appropriate training for the personnel directly involved in the activities of tissue establishments? (more than 1 answer possible) | |
| Authorisation requirement | YES |
| Inspections | YES |
| Regular evaluation of personnel | YES |

| | |
|---|---|
| Mandatory trainings | YES |
| Other | |
| Please specify 'other'. | |
| 13.4. Do you have national/regional/local training programmes for the personnel of tissue establishments? | |
| Yes No | NO |
| 13.4.1. If yes, please specify. | |
| 13.4.2. If no, in which country(ies) is your personnel trained? | |
| EU countries Non-EU countries | EU countries |
| 13.4.2.1. Please specify EU-countries. | EUSTITE, FACT NETCORD ,<br>JACKIE |
| 13.4.2.2. Please specify non EU-countries. | |
| 13.5. Any additional comments on quality management, responsible person, personnel? | |
| 14. Reception, processing, storage, labelling and packaging (Art 19-22 Directive 2004/23/EC) | |
| 14.1. How do you ensure that tissue establishments in your country fulfill the requirments of the Art. 19 (Tissue and cell reception) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | |
| National regulation/policy for reception of tissues/cells | YES |
| Inspections of tissue establishments | YES |
| Internal audits of tissue establishments | YES |
| External audits of tissue establishments (e.g. ISO) | YES |
| Other | |
| Please specify 'other'. | |
| 14.2. How do you ensure that tissue establishments in your country fulfill the requirements of the Art. 20 (Tissue and cell processing) of Directive 2004/23/EC? (more than 1 answer possible) | |
| SOPs for all processes affecting quality and safety are mandatory for authorisation | YES |
| Inspections of tissue establishments | YES |
| Internal audits of tissue establishments | YES |
| External audits of tissue establishments (e.g. ISO) | YES |
| Other | |
| Please specify 'other'. | |
| 14.3. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 21 (tissue and cell storage conditions) of Directive 2004/23/EC? (more than 1 answer possible) | |
| SOPs for procedures associated with storage of tissues and cells are mandatory for authorisation | YES |
| Inspections of tissue establishments | YES |
| Internal audits of tissue establishments | YES |
| External audits of tissue establishments (e.g. ISO) | YES |
| Other | |
| Please specify 'other'. | |
| 14.4. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 22 (labelling, | |
| documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | |
| SOPs for procedures associated with labelling and packaging are mandatory for authorisation | YES |
| Inspections of tissue establishments | YES |
| Internal audits of tissue establishments | YES |
| External audits of tissue establishments(e.g. ISO) | YES |
| Other | |
| Please specify 'other'. | |

| | |
|---|---|
| 14.5. Any additional comments on reception, processing, storage, labelling and packaging? | |
| 15. Third party agreements (Art. 24 Directive 2004/23/EC) | |
| 15.1. Are third party agreements foreseen/allowed in your national legislation? | |
| Yes No | YES |
| 15.1.1. If yes, have tissue establishments in your Member State notified third party agreements? | |
| Yes No | YES |
| 15.1.1.1. Under which circumstances and for which responsibilities? | CONTRACT |
| 15.1.1.2. How are third party agreements controlled (Art 6.2) by the Competent Auhtority(ies) in your MS? | BY DOCUMENTATION PAPER |
| Please specify. | |
| 15.2. Any additional comments on third party agreements? | |
| 16. General comments - implementation | |
| 16.1. Do you have at national level more stringent quality and safety requirements than those requested by the EU | |
| legislation in this field (e.g. restrictions concerning the donation/use of certain tissues/cells, mandatory unpaid donation etc.)? | |
| Yes No | NO |
| 16.1.1. Please specify. | |
| 16.2. Has your Member State encountered any difficulties in implementing the requirements in the EU Tissues and | |
| Cells Directives? Please choose from the options below. | |
| ART provisions | |
| Procurement provisions | YES |
| Testing provisions | |
| Storage provisions | |
| Distribution provisions | |
| Import-export | |
| Vigilance | YES |
| Authorisation-accreditation-licensing of TEs | YES |
| Inspections | |
| Traceability | |
| Other | |
| No difficulties | |
| 16.2.1. For all selected options in question 16.2., please provide a short description. | STRUCTIONAL DIFFICULTIES & COMMUNICATION PROBLEMS |
| 16.3. In your opinion, in which of the following Directives are there shortcomings (if any)? (more than 1 answer possible) | |
| Directive 2004/23/EC Directive 2006/17/EC Directive 2006/86/EC | |
| No shortcomings | NO |
| 16.3.1. How would you suggest to solve these issues in Directive 2004/23/EC? | |
| 16.3.2. How would you suggest to solve these issues in Directive 2006/17/EC? | |
| 16.3.3. How would you suggest to solve these issues in Directive 2006/86/EC? | |

### *A.1.13. Survey response Hungary*

| **1. Public information** | |
|---|---|
| 1.1. Name of National Competent Authority (NCA) 1: | National Public Health and Medical Officer Service - Office of the Chief Medical Officer (NPHMOS-OCMO) |
| 1.1.2. Address of NCA 1: | 2-6 Gyali ut, Budapest, H-1097, Hungary |
| 1.1.3. Telephone (central access point): | +36-1-476-1100 |
| 1.1.4. E-mail (central access point): | igazgatas@oth.antsz.hu; tisztifoorvos@oth.antsz.hu |
| 1.1.5. Website: | http://www.antsz.hu |
| 1.1.6. The NCA is responsible for? (more than 1 answer possible) | Non-reproductive tissues and cells<br>Reproductive tissues and cells<br>Pharmaceuticals |
| 1.1.7. What are the role/tasks of the NCA? (more than 1 answer possible) | Accreditation, authorisation, licensing of TEs<br>Inspection<br>Vigilance |
| 1.2. National Competent Authority 2? | No |
| 1.5. Please give a short description of the legal status and organisation of the National Competent Authority(ies) (e.g. departments, staffing, number of senior and junior inspectors, staff working on EU affairs and legal matters, vigilance officers, budget, independence from government etc.). | National Public Health and Medical Officer Service - Office of the Chief Medical Officer (NPHMOS-OCMO) is responsible for the professional management, coordination and control of public health, epidemiology, health development (protection and maintenance of health, health education) and health administration activities, as well as the supervision (licencing and control) of healthcare. NPHMOS is directed by the Chief Medical Officer who fulfils his tasks under the direct supervision of the minister responsible for health. Department of Health Administration of NPHMOS-OCMO fulfils the CA tasks, there are about fifty officers in the country that can conduct inspections of TEs and other health care providers as well. |
| 1.6. In case of MS with federal or decentralised systems, please indicate the roles/tasks of the Regional Competent Authority(ies). (more than 1 answer possible) | Not applicable |
| 1.7. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies) for tissues and cells: | Not applicable. |
| **2. Procurement (Article 5 Directive 2004/23/EC)** | |
| 2.1. Do you authorise the "conditions of procurement"? | Yes |
| 2.1.1. How do you authorise the "conditions of procurement"? (more than 1 answer possible) | By inspecting all procurement centres<br>By inspecting the documentation associated with procurement that is available in the tissue establishment working with procurement centres |
| 2.1.2. How many such authorisations were granted in 2011 (01/01-31/12/2011)? | 17 |
| 2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011). | 9 |
| 2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011). | 15 |
| 2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues were carried out in 2011 (01/01-31/12/2011). | 20 |
| 2.2.4. Please provide the number of procurement centers in which procurement of tissues/cells for ATMP manufacturing were carried out in 2011 (01/01-31/12/2011). | NA. |
| 2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC and its implementing Directive 2006/17/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) ? (more than 1 answer possible) | Inspections of the site/centre |
| 2.4. Are you also responsible for the accreditation, designation, | No |

| | |
|---|---|
| authorisation or licensing of laboratories performing donor testing? | |
| 2.4.2. Which National Authority is in charge of this activity? | National Authorities are district institutes of public health under the direction of the government offices |
| 2.5. How do you ensure, as CA for T&C, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art. 5(2))? (more than 1 answer possible) | Other |
| Please specify 'other': | Laboratories must be licenced as health care providers, they have to comply professional requirements prescribed by legal rules. Authorized authorities inspect and control if they fulfil the legal requirements. |
| 2.6. Please provide data on qualified laboratories accredited, authorised or licensed in your country (e.g. number, year of accreditation/authorisation/license, which donor tests are performed etc.). | Our databases do not contain all of data to answer this question, so we cannot give exact numbers. |
| 2.7. Do you have any additional comments on procurement? | |
| **3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)** | |
| 3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>HBs AG<br>Anti HBc<br>Anti HCV-Ab<br>Treponema Pallidum |
| 3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>HBs AG<br>Anti HCV-Ab<br>Treponema Pallidum |
| 3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to encourage its use? Please specify why or why not (e.g. number of additional cases detected, cost-benefit etc.). | NAT testing can be done, but not compulsory. |
| 3.4. Do you have concerns on accuracy of the available tests and test procedures for deceased donors? | No |
| 3.5. Are any other laboratory tests required for donors of non-reproductive tissues and cells in your Member State? | Yes |
| 3.5.1. Please specify. | If it is necessary: RhD, HLA, malaria, CMV, Toxoplasma, EBV, Trypanosoma cruzi |
| 3.6. Are any other laboratory tests required for donors of reproductive tissues and cells in your Member State? | Yes |
| 3.6.1. Please specify. | Neisseria gonorrhoeae, Herpes genitalis, CMV, Chlamidia trachomatis, Trichomonas vaginalis |
| 3.7. Do you request/use international accreditation systems for testing laboratories? | Yes |
| 3.7.1. Please specify. | Using an international accreditation system is not mandatory for each laboratory |
| 3.8. Do you have any additional comments on testing? | |
| **4. Accreditation, designation, authorisation or licensing of tissue establishments (Article 6, Directive 2004/23/EC)** | |
| 4.1. Do you have a system of designation, authorisation, accreditation or licensing for all types of tissue establishments under your responsability? | Yes |
| 4.2. Is inspection a prerequisite for the designation, authorisation, accreditation or licensing of tissue establishments? | Yes |
| 4.2.1. How many inspections were performed in 2011 for authorising/accrediting/licensing/designating TEs? | 10 |
| 4.3. Are preparation processes authorised? | No |
| 4.4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were suspended in 2011? | 0 |
| 4.5. Following inspections/controls (Art. 6.4, Directive | 0 |

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| 2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011? | |
| 4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)? | No |
| **4bis. Overview of tissue/cells establishments authorised by the NCA** | |
| 4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible): | Ocular tissue establishments<br>Cardiovascular tissue establishments |
| 4.7.3. How many ocular tissue establishments? | 1 |
| 4.7.4. How many cardiovascular tissue establishments? | 1 |
| 4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible): | Cord blood tissue establishments |
| 4.8.6. How many cord blood tissue establishments? | 2 |
| 4.9. Tissue establishments first time authorised between 01/01/2011 and 31/12/2011 (more than 1 answer possible): | Ocular tissue establishments<br>Cardiovascular tissue establishments<br>Cord blood tissue establishments<br>ART tissue establishments |
| 4.9.3. How many ocular tissue establishments? | 1 |
| 4.9.4. How many cardiovascular tissue establishments? | 2 |
| 4.9.6. How many cord blood tissue establishments? | 2 |
| 4.9.7. How many ART tissue establishments? | 1 |
| 4.10. All tissue establishments authorised by 31/12/2011 (more than 1 answer possible): | Skin tissue establishments<br>Musculo-skeletal tissue establishments<br>Ocular tissue establishments<br>Cardiovascular tissue establishments<br>HSC tissue establishments<br>Cord blood tissue establishments<br>ART tissue establishments |
| 4.10.1.1. How many public skin tissue establishments? | 2 |
| 4.10.1.2. How many private skin tissue establishments? | 0 |
| 4.10.2.1. How many public musculo-skeletal tissue establishments? | 2 |
| 4.10.2.2. How many private musculo-skeletal tissue establishments? | 0 |
| 4.10.3.1. How many public ocular tissue establishments? | 1 |
| 4.10.3.2. How many private ocular tissue establishments? | 0 |
| 4.10.4.1. How many public cardiovascular tissue establishments? | 2 |
| 4.10.4.2. How many private cardiovascular tissue establishments? | 0 |
| 4.10.5.1. How many public HSC tissue establishments? | 1 |
| 4.10.5.2. How many private HSC tissue establishments? | 0 |
| 4.10.6.1. How many public cord blood tissue establishments? | 4 |
| 4.10.6.2. How many private cord blood tissue establishments? | 2 |
| 4.10.7.1. How many public ART tissue establishments? | 7 |
| 4.10.7.2. How many private ART tissue establishments? | 10 |
| 4.11. How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Art. 6(5) during 2011? Please provide number(s) per type tissues/cells. | 0 |
| **4ter. Sanctions** | |
| 4.16. Have penalties for infringements of the national provisions pursuant to the Directive been defined (Article 27)? | No |
| 4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing? | |
| **5. Inspections (Article 7, Directive 2004/23/EC)** | |
| 5.1. Is a system in place for organising inspections and control measures of tissue establishments? | Yes |
| 5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections. | Officers of the National Public Health and Medical Officer Service - Office of the Chief Medical Officer, Department of Health Administration conducts inspections of tissue establishments. Those of our officers working in large cities of the country, inspect TEs located in the area, participating of medical supervisors if needed |
| 5.1.2. If yes, please specify staffing (how many inspectors). | There are about fifty officers in the country that can conduct inspections of TEs and other health care providers as well. At least |

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| | two officers take part in an inspection, and one medical supervisor, the latter ones do not belong to the NPHMOS-OCMO, they are called upon for a single inspection by the NPHMOS-OCMO |
| 5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible) | No |
| 5.3. How many routine inspections of tissue establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011)? | 10 |
| 5.3.1. How many inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) following serious adverse events or reactions, or suspicion thereof ? | 0 |
| 5.3.2. How many other type of inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | 0 |
| 5.3.3. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | 6 |
| 5.3.4. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where minor shortcomings were noted? | 3 |
| 5.3.5. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where major shortcomings were noted? | 0 |
| 5.3.6. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by suspension of authorisation? | 0 |
| 5.3.7. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by closure? | 0 |
| 5.3.8. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of other inspections carried out? Please specify. | 2 |
| 5.4. How many routine inspections were conducted in ART establishments (from 1/1/2011 to 31/12/2011)? | 2 |
| 5.4.1. How many inspections were conducted in ART establishments following serious adverse events or reactions, or suspicion thereof (from 1/1/2011 to 31/12/2011)? | 0 |
| 5.4.2. How many other type of inspections were conducted on ART establishments (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | 0 |
| 5.4.3. Outcome of inspections of ART tissue establishments carried out in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | 1 |
| 5.4.4. What was the number of inspections carried out in ART establishments where minor shortcomings were noted? | 0 |
| 5.4.5. What was the number of inspections carried out in ART establishments where major shortcomings were noted? | 0 |
| 5.4.6. What was the number of inspections carried out in ART establishments followed by suspension of authorisation? | 0 |
| 5.4.7. What was the number of inspections carried out in ART establishments followed by closure of respective establishements? | 0 |
| 5.4.8. What was the number of other inspections of ART | 4 |

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| establishments? Please specify. | |
| 5.5. Which type of routine inspections do you conduct? (more than 1 answer possible) | General system-oriented inspections |
| 5.6. How do you decide which type of routine inspection to conduct? | In Hungary general system-oriented inspections are the common type of inspections |
| 5.7. Until 2011, did you implement the requirement concerning the time interval between two inspections (Art. 7.3.)? | No |
| 5.7.1. Why not? | According to Hungarian legislation inspections are carried out „regularly". In practice inspections are carried out yearly. |
| 5.7.2. How do you prioritise tissue establishments to be inspected? | General inspections by central arrangement, tissue establishments under licencing process, inspection due to patient complaint. However, inspections can be conducted more frequent than two years, due to some changing in activity of the TEs or other causes. |
| 5.8. How many TEs were inspected at least twice between 2008-2011 (01/01/2008-31/12/2011)? | Most of TEs were inspected at least twice between 2008-2011. |
| 5.9. Did you perform/conduct inspections of procurement sites outside tissue establishments? | No |
| 5.9.2. If no, why not? | Each procurement site had to possess a cell or tissue establishment licence in 2011, even if it operated as a procurement site. |
| 5.10. Did you carry out inspections of third parties? | No |
| 5.10.2. If no, why not? | Because each establishment, which persuits activity connected with cells or tissues, must be a licenced tissue establishment. |
| 5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)? | Yes |
| 5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)? | Yes |
| 5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)? | 5 |
| 5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))? | No |
| 5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))? | No |
| 5.15. Did you organise any inspections of procurement centres or tissue establishments in third countries from which tissues and/or cells were imported in your country (as recorded by 31/12/2011)? | No |
| 5.16. Have you asked another MS, or have you been requested by any other MS, on the results and control measures of your inspections, as part of an enquiry/investigation? | No |
| 5.17. Would you be interested in developing joint inspections? Joint inspections should be understood as inspections of tissue establishments conducted jointly by two or more Member States' Competent Authorities on their territory or in third countries. | Yes |
| 5.18. Do you have any additional comments on inspections? | |
| **6. Import/export (Article 9 Directive 2004/23/EC)** | |
| 6.1. Do you have a register of authorised tissue establishments that are explicitly authorised to perform import/export of tissues and celles from/to third countries? | No |
| 6.2. Please specify the number of tissue establishments authorised to import tissues and cells from third countries (recorded by 31/12/2011). | 0 |
| 6.3. Please specify the number of tissue establishments authorised to export tissues and cells from third countries (recorded by 31/12/2011). | 0 |
| 6.4. Please specify which procedures you have in place for | NA. |

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| verifying the equivalent standards of quality and safety for importation of skin from third countries. | |
| 6.5. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of musculo-skeletal (bone, tendons, fascia etc.) tissues from third countries. | NA. |
| 6.6. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of ophtalmic (cornea, sclera, etc) tissues from third countries. | NA. |
| 6.7. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cardio vascular tissues from third countries. | NA. |
| 6.8. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) (other than cord blood) from third countries. | NA. |
| 6.9. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cord blood from third countries. | NA. |
| 6.10. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of reproductive cells (sperm, egg cells) from third countries. | NA. |
| 6.11. Did you import tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | No |
| 6.12. Did you export tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | No |
| 6.13. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on imports/exports of tissues/cells between your country and other third countries? | No |
| 6.14. What is the relation between import/export of tissues and cells and self-sufficiency? (more than 1 answer possible) | C. Export of tissues/cells is authorised irrespective of national needs |
| 6.15. Did you authorise direct imports of tissues/cells to hospitals/clinics in your country? | No |
| 6.16. Do you have any additional comments on import/export? | |
| **7. Distribution/intra community exchanges (Article 23 Directive 2004/23/EC)** | |
| 7.1. Do you have intra-community exchanges of tissues and cells? | No |
| 7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify. | Inspections of the tissue establishments |
| 7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible). | Yes, but only via an authorised TE in my MS |
| 7.4. Have you authorised direct distribution to the recipient of specific tissues and cells (Art. 6, Directive 2006/17/EC)? | No |
| 7.5. Do you collect data regarding the cross-border exchange of tissue/cells between your country and other EU MS? | No |
| 7.6. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on cross-border exchanges of tissues/cells between your country and other EU MS? | No |
| 7.7. Do you allow brokerage companies for either distribution in EU and/or import/export of tissues/cells? In this context, a brokerage company means a body that arranges transactions between a supplier (tissue establishment/company selling tissues or cells) and a buyer (a tissue establishment/a hospital or clinic/an individual) without undertaking activities of processing, preservation or storage. | No |
| 7.8. Are brokers actively supplying health professionals/establishments in your country? | No |
| 7.9. Do you have any additional comments on distribution? | |

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| **8. Register of tissue establishments and reporting obligations (Article 10, Directive 2004/23/EC)** | |
| 8.1. Do you have an annual report model/template on the activities of tissue establishments in your Member State? (Article 10(1)). If yes, please upload the template. | Yes |
| 8.2. How many tissue establishments submitted annual reports of their activities during 2011. Please provide an estimation. (1 answer possible) | 60-99% |
| 8.3. Are these reports publicly available? (Article 10(1)) | No |
| 8.4. Do you publish a national annual report of the consolidated activities of all tissue establishments in your country? | No |
| 8.4.2. If no, why not? | The Hungarian law changed this summer, tissue establishments shall submit to the competent authority an annual report on these activities and this report shall be publicly available. The reports should be sent by 31 January next year. |
| 8.5. Is there a publicly accessible register of authorised tissue establishements in place? (Article 10(2)) | Yes |
| 8.5.1. If yes, please provide us with the link to the register's web site. | https://www.antsz.hu/bal_menu/igazgatas/sejt_es_szovetbank_nyt.html |
| 8.6. Do you provide data regarding tissues and cells activities to the EUROCET registry (non-mandatory reporting)? | Yes |
| 8.6.1. If yes, what data are provided to EUROCET? Please specify. | - tissues data - HPC data - ART data |
| 8.7. Do you have any additional comments on reporting? | |
| **9. Traceability (Article 8, Directive 2004/23/EC; and Directive 2006/86/EC)** | |
| 9.1. Was the donor identification system (Art. 8(2)) implemented in your country? | Yes |
| 9.2. Who assigns the unique code for each donation? (only 1 answer possible) | Tissue establishment |
| 9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible) | Both paper records and electronic forms |
| 9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify. | 30 years data storage requirement is prescribed for all health care providers – including tissue establishments – in the Act XLVII of 1997 on the Handling and Protection of Medical and Other Related Data |
| 9.5. Do you have any additional comments on traceability? | |
| **10. Notification of serious adverse events and reactions (Article 11 Directive 2004/23, Article 6 Directive 2006/76)** | |
| 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))? | Yes |
| 10.1.1. If yes, which CA/institution is responsible? | National Public Health and Medical Officer Service - Office of the Chief Medical Officer (NPHMOS-OCMO) |
| 10.1.2. If yes, please provide a short description of its organisation. | In case of serious adverse event or reaction the tissue establishment notifies the NPHMOS-OCMO, the NPHMOS-OCMO notifies the affected transplant institutes and the National Institute for Quality- and Organizational Development in Healthcare and Medicines. In case of serious adverse event or reaction the transplant institute notifies the NPHMOS-OCMO. The NPHMOS-OCMO performs the needed actions. |
| 10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use the SAR/E (to the CA (2006/76 art 6.4)) templates developed to the Annual reporting ot the EC also at national level? | Yes |
| 10.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level? | Yes |
| 10.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all TEs? | Yes |
| 10.5. How many tissue establishments provided in 2011 the SAR/SAE data as requested (please provide the % from the total number of TEs authorised in your country). | 100% |
| 10.6. Do you have a mandatory procedure for the transplantation centres when reporting SAR/SAE to the TEs which distributed the tissues/cells (Art 11.2)? | Yes |
| 10.6.1. If yes, please provide a brief description. | In case of serious adverse event or reaction the transplant institute |

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| | notifies the NPHMOS-OCMO. Legal rule determines the form of the report. The NPHMOS-OCMO then performs the needed actions. |
| 10.7. Do you give feedback to the TEs regarding SAR/SAE recorded at national level? | Yes |
| 10.7.1. Please specify. | If NPHMOS-OCMO receives a report on SAR/SAE from a health care provider, NPHMOS-OCMO performs the needed actions including notifying the affected tissue establishment. |
| 10.8. Do you give feedback to the TEs regarding SAR/SAE recorded at EU level? | Yes |
| 10.8.1. Please specify. | If NPHMOS-OCMO receives a report on SAR/SAE from a EU member state, NPHMOS-OCMO performs the needed actions including notifying the affected tissue establishments. |
| 10.9. Do you require your TEs to have a recall procedure? | Yes |
| 10.10. How many recalls related to safety and quality of tissues/cells were issued in your country in 2011? Please specify the number and which tissues were recalled and why (e.g. missing consent, quality defects etc). | 0 |
| 10.11. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites in case of a national rapid alert? | Yes |
| 10.11.1. If yes, please give a short description of the system/procedure. | In case of national rapid alert NPHMOS-OCMO performs the needed actions including notifying the affected tissue establishments and procurement sites. |
| 10.12. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites when a rapid alert is issued via the EU RATC platform? | Yes |
| 10.12.1. If yes, please give a short description of the system/procedure. | In case of rapid alert from the EU, NPHMOS-OCMO performs the needed actions including notifying the affected tissue establishments and procurement sites. |
| 10.13. Do you provide data regarding SAR/SAE to the EUROCET registry (non-mandatory reporting)? | Yes |
| 10.13.1. If yes, please specify what data. | All data. |
| 10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems? | Yes |
| 10.14.1. If yes, please specify which of the following systems are usually contacted. (more than 1 answer possible) | Haemovigilance<br>Pharmacovilance<br>Medical devices |
| 10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S? | Yes |
| 10.15.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (insufficient) - 2 (sufficient) 3 (good) - 4 (very good) to 5 (essential)? | 5 |
| 10.16. Do you have any additional comments on SARE reporting? | |
| **11. Consent and personal data protection (Article 13 and 14, Directive 2004/23/EC)** | |
| 11.1. What consent system for living tissue/cell donation do you have in place within your Member State? | Explicit consent (opt-in) |
| 11.1.1. Please specify your choice of consent system for living tissue/cell donation. | Basically, only a person with legal capacity may donate tissues, except for some circumstances. |
| 11.2. What consent system for deceased tissue/cell donation do you have in place within your Member State? | Presumed (opt-out) and explicit (opt-in) consent |
| 11.2.1. If you have chosen both consent systems for deceased tissue/cell dontation, please specify. | Primely presumed consent (opt-out) system is the sole system in Hungary, but every person can declare an objection in written form. Tissues may only be removed from cadaver donors if the deceased did not make a declaration opposing donation during his lifetime. A person with legal capacity may make a declaration in writing, or verbally at his attending physician in case of inability to, or significant difficulty in making a written declaration. A person with restricted legal capacity may make an opposition declaration without his legal representative's involvement. Such opposition declaration |

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| | may be made on behalf of a person with no legal capacity by his legal representative. |
| 11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible) | Other |
| Please specify 'other'. | If the deceased is under age and no opposition declaration can be found, the organ or |
| 11.4. Is the consent system for deceased tissue donation the same as for organs? | Yes |
| 11.5. How is this consent verified during inspections? (more than 1 answer possible) | Analysis of documentation<br>Interviews with living donors |
| 11.6. What measures are in place to ensure that donors/relatives/authorising persons on behalf of donors are provided with the appropriate information, as requested by Art. 13(2)? (more than 1 answer possible) | Only trained personnel is allowed to provide such information |
| 11.7. What measures are in place to ensure that both donors and recipients remain unidentifiable when access is given to third parties (Art. 14(1)). Please specify. | Name of the donor cannot be recorded on the labelling of the tissue, only an identity number. The institution that removes the tissue from the donor, must apply the privacy rules of the health law. The competent authority controls if the institution applies the legal rules. |
| 11.8. Please specify what measures are in place to ensure that the identity of the receipient is not disclosed to the donor and vice versa. | Legal rule determines that that the identity of the recipient is not disclosed to the donor and vice versa. The competent authority controls if the institution applies the legal rules. |
| 11.9. Does your national legislation allows disclosure of donor data in case of gametes donation? | Yes |
| 11.10. Do you have any additional comments on consent and data protection? | |
| **12. Selection, evaluation and procurement (Article 15 Directive 2004/23; Annexes I-IV Directive 2006/17)** | |
| 12.1. How do you ensure that all requirements related to the evaluation and selection of donors (except donors of reproductive cells) are respected in your country (Art. 15(1), Annex I Directive 2006/17/EC)? (more than 1 answer possible) | Inspections of TEs and procurement sites |
| 12.2. How do you ensure that all requirements related to the evaluation and selection of donors of reproductive cells are respected in your country (Art 15 (1), Annex III of Directive 2006/17/EC)? (more than 1 answer possible) | Inspections of ART centres |
| 12.3. Do you have more stringent criteria for donor selection than those listed in Annex I of the Directive 2006/17/EC? | No |
| 12.4. What sources are required in your MS for the evaluation of a deceased donor of tissues/cells? (more than 1 answer possible) | Medical records of the donor |
| 12.5. Do you have more stringent criteria for selection of donors of reproductive cells than those listed in Annex III of the Directive 2006/17/EC? | No |
| 12.6. Do you have more stringent criteria for autologous donation than those listed in Annex I of the Directive 2006/17/EC? | No |
| 12.7. Do you require more information on the donation of tissues/cells than the mandatory one as laid down in the Annex of Directive 2004/23/EC (Art 15(3)? | No |
| 12.8. How do you ensure that all requirements regarding tissues and cells' procurement, packaging and transport are complied with by tissue establishments in your country (Art 15(1), Annex IV of Directive 2006/17/EC? (more than 1 answer possible)(For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)) | Inspection of tissue establishment<br>Inspection of the centre of human application (e.g. transplantation centre, ART centre) |
| 12.9. Do you have any additional comments on selection, evaluation and procurement? | |
| **13. Quality management, responsible person, personnel (Article 16, 17, 18 Directive 2004/23/EC)** | |

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| 13.1. How do you ensure that tissue establishments in your country have in place a quality system respecting the provisions of the Directive 2004/23/EC Art 16.1? (more than 1 answer possible). (For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)). | Authorisation requirement<br>Inspections |
| 13.2. How do you ensure that tissue establishments have a responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible) | Authorisation requirement<br>Inspections |
| 13.3. How do you ensure an appropriate training for the personnel directly involved in the activities of tissue establishments? (more than 1 answer possible) | Authorisation requirement<br>Inspections |
| 13.4. Do you have national/regional/local training programmes for the personnel of tissue establishments? | Yes |
| 13.4.1. If yes, please specify. | Personnel of health care providers, including tissue establishments, have to take part in regular training programmes. Training programmes can be organized by medical universities, national professional institutes, health care providers. |
| 13.5. Any additional comments on quality management, responsible person, personnel? | |
| **14. Reception, processing, storage, labelling and packaging (Art 19-22 Directive 2004/23/EC)** | |
| 14.1. How do you ensure that tissue establishments in your country fulfill the requirments of the Art. 19 (Tissue and cell reception) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | National regulation/policy for reception of tissues/cells<br>Inspections of tissue establishments |
| 14.2. How do you ensure that tissue establishments in your country fulfill the requirements of the Art. 20 (Tissue and cell processing) of Directive 2004/23/EC? (more than 1 answer possible) | SOPs for all processes affecting quality and safety are mandatory for authorisation<br>Inspections of tissue establishments |
| 14.3. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 21 (tissue and cell storage conditions) of Directive 2004/23/EC? (more than 1 answer possible) | SOPs for procedures associated with storage of tissues and cells are mandatory for authorisation<br>Inspections of tissue establishments |
| 14.4. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | SOPs for procedures associated with labelling and packaging are mandatory for authorisation<br>Inspections of tissue establishments |
| 14.5. Any additional comments on reception, processing, storage, labelling and packaging? | |
| **15. Third party agreements (Art. 24 Directive 2004/23/EC)** | |
| 15.1. Are third party agreements foreseen/allowed in your national legislation? | No |
| 15.2. Any additional comments on third party agreements? | |
| **16. General comments - implementation** | |
| 16.1. Do you have at national level more stringent quality and safety requirements than those requested by the EU legislation in this field (e.g. restrictions concerning the donation/use of certain tissues/cells, mandatory unpaid donation etc.)? | No |
| 16.2. Has your Member State encountered any difficulties in implementing the requirements in the EU Tissues and Cells Directives? Please choose from the options below. | Other |
| 16.2.1. For all selected options in question 16.2., please provide a short description. | The implementation of the Directive has only been completed this summer, as the IT system of NPHMOS-OCMO had to be developed. The Hungarian law (Decree 18 of 1998 of the Minister of Health) changed this summer (from 01.07.2013), tissue establishments shall submit to the competent authority an annual report on these activities and this report shall be publicly available. The reports should be sent by 31 January next year. |

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| 16.3. In your opinion, in which of the following Directives are there shortcomings (if any)? (more than 1 answer possible) | No shortcomings |

## *A.1.14. Survey response Ireland*

| **1. Public information** | |
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| 1.1. Name of National Competent Authority (NCA) 1: | Irish Medicines Board |
| 1.1.2. Address of NCA 1: | Irish Medicines Board, Kevin O Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, Ireland |
| 1.1.3. Telephone (central access point): | 00353 -1- 6764971 |
| 1.1.4. E-mail (central access point): | compliance@imb.ie |
| 1.1.5. Website: | www.imb.ie |
| 1.1.6. The NCA is responsible for? (more than 1 answer possible) | Non-reproductive tissues and cells<br>Reproductive tissues and cells<br>Blood and blood components<br>Human organs<br>Pharmaceuticals<br>Medical devices<br>Other |
| Please specify 'other': | Vetinary Products, Cosmetic Products, Advanced Therapy Medicinal Products, Clinical Trials approval, Protection of Animals. |
| 1.1.7. What are the role/tasks of the NCA? (more than 1 answer possible) | Accreditation, authorisation, licensing of TEs<br>Inspection<br>Vigilance<br>Other |
| Please specify 'other': | Overseeing recalls, Advice to the Government, International Representation, Enforcement. |
| 1.2. National Competent Authority 2? | No |
| 1.5. Please give a short description of the legal status and organisation of the National Competent Authority(ies) (e.g. departments, staffing, number of senior and junior inspectors, staff working on EU affairs and legal matters, vigilance officers, budget, independence from government etc.). | There are four (4) departments directly involved in carrying out IMB's reglatory functions: 1:Compliance (Inspections and audits, Market compliance and enforcememt), 2: Human Products Authorisation and Registration (licensing of medicines for human use, designation and monitoring of notified bodies for medical devices, registration of medical devices) 3: Human products monitoring (monitoring of safety of medicines for human use, blood and blood components, tissues and cells and medical devices), 4: Vetinary Sciences (licensing and safety of medicines for human use, scientific animal protection). There are three (3) departments which provide cross organisational support: 1: Finance and corporate affairs, 2: human resources, 3: IT management and an office of the Chief Executive. Overall there are approximately 300 staff working in the Irish Medicines Board. In the Compliance department there are currently approximately 21 inspectors working accross different specialities including GMP, GDP, GCP, Blood ,Tissues & Cells and Organs (BTO). There is a dedicated team for Tissues & Cells inspection comprised of the BTO manager, two BTO inspectors and a BTO scientific officer. The BTO manager and BTO inspectors represent the competent authority at an EU level through participation in European Commission competent authority meetings, EU working groups and the development of best practice guidance in the field of Tissues and Cells. The human products monitoring department is made up of pharmacovigilance, medical devices vigilance and human products vigilance assessment, comprising of approximately 40 staff, there is 1 dedicated Tissue & Cells vigilance officer. The Irish Medicines Board is 85% Self funded through licensing, inspection fees, The remainder is funded by the Irish Department of Health. |
| 1.6. In case of MS with federal or decentralised systems, please indicate the roles/tasks of the Regional Competent Authority(ies). (more than 1 answer possible) | Not applicable |
| 1.7. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies) for tissues and cells: | Not applicable |
| **2. Procurement (Article 5 Directive 2004/23/EC)** | |
| 2.1. Do you authorise the "conditions of procurement"? | Yes |

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| 2.1.1. How do you authorise the "conditions of procurement"? (more than 1 answer possible) | By inspecting all procurement centres |
| 2.1.2. How many such authorisations were granted in 2011 (01/01-31/12/2011)? | none |
| 2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011). | 4 |
| 2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011). | 6 |
| 2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues were carried out in 2011 (01/01-31/12/2011). | 9 |
| 2.2.4. Please provide the number of procurement centers in which procurement of tissues/cells for ATMP manufacturing were carried out in 2011 (01/01-31/12/2011). | 1 - cartilage for extraction of chondrocytes for use in ATMP (processing performed in another EU Member State) |
| 2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC and its implementing Directive 2006/17/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) ? (more than 1 answer possible) | Inspections of the site/centre<br>Analysis of the mandatory documentation |
| 2.4. Are you also responsible for the accreditation, designation, authorisation or licensing of laboratories performing donor testing? | No |
| 2.4.2. Which National Authority is in charge of this activity? | Irish National Accreditation Board (INAB) |
| 2.5. How do you ensure, as CA for T&C, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art. 5(2))? (more than 1 answer possible) | Analysis of the mandatory documentation requested from the tissue establishment<br>Other |
| Please specify 'other': | All laboratories that perform tests required for donors are listed on each Tissue Establishment's Authorisation. Each laboratory is required to be accredited by the Irish National Accreditation Board. |
| 2.6. Please provide data on qualified laboratories accredited, authorised or licensed in your country (e.g. number, year of accreditation/authorisation/license, which donor tests are performed etc.). | 11 testing laboritories in Ireland who perform tests required for donors; testing at time of donation performed as per Directive requirements: AntiHIV1, AntiHIV2, HBsAG,Anti HBc, Anti- HCV-Ab, HTLV - 1 and 2 (when required) Treponema Pallidum must be excluded |
| 2.7. Do you have any additional comments on procurement? | Where procurement occurs in Ireland, the activity is inspected and the site requires a Tissue Establishment Authorisation. If the procurement occurs outside Ireland, inspection of relevant documentation occurs onsite at the Irish Tissue Establishment. |
| **3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)** | |
| 3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>HBs AG<br>Anti HBc<br>Anti HCV-Ab<br>Treponema Pallidum |
| 3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>HBs AG<br>Anti HBc<br>Anti HCV-Ab<br>Treponema Pallidum |

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| 3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to encourage its use? Please specify why or why not (e.g. number of additional cases detected, cost-benefit etc.). | NAT testing would be encouraged by the NCA; However, a national decision would be required and currently no plans in place. |
| 3.4. Do you have concerns on accuracy of the available tests and test procedures for deceased donors? | Yes |
| 3.4.1. Please specify why: | Post mortem testing may be compromised due to hemolyis, autolysis or bacterial contamination which could lead to the detection of false negatives / positives. There are currently no CE marked comercially available tests on the market. However, no post mortem procurement of tissues and cells occurs in Ireland |
| 3.5. Are any other laboratory tests required for donors of non-reproductive tissues and cells in your Member State? | Yes |
| 3.5.1. Please specify. | HTLV-1 testing of donors living in or originating from areas of high prevalence as per Directive |
| 3.6. Are any other laboratory tests required for donors of reproductive tissues and cells in your Member State? | Yes |
| 3.6.1. Please specify. | HTLV-1 testing of donors living in or originating from areas of high prevalence as per Directive. NAT chlamydia tesing is obligatory for non partner sperm donations as per Directive. |
| 3.7. Do you request/use international accreditation systems for testing laboratories? | Yes |
| 3.7.1. Please specify. | Yes, in Ireland, the Irish National Accreditation Board accredit such laboratories to the International Standard for Medical Testng Laboratories ISO15189. |
| 3.8. Do you have any additional comments on testing? | |
| **4. Accreditation, designation, authorisation or licensing of tissue establishments (Article 6, Directive 2004/23/EC)** | |
| 4.1. Do you have a system of designation, authorisation, accreditation or licensing for all types of tissue establishments under your responsability? | Yes |
| 4.2. Is inspection a prerequisite for the designation, authorisation, accreditation or licensing of tissue establishments? | Yes |
| 4.2.1. How many inspections were performed in 2011 for authorising/accrediting/licensing/designating TEs? | No applications for Tissue Establishment Authorisation were received in 2011. All existing Tissue Estalishments had been authorised in 2011. 3 inspections were performed in relation to applications to vary /change the existing Tissue Establishment Authorisations. Routine (two yearly) inspections of tissue establishments were also performed. |
| 4.3. Are preparation processes authorised? | Yes |
| 4.3.1. How are they authorised? (more than 1 answer possible) | During routine inspections<br>During inspections organised for this purpose<br>By review of a submitted application with supporting documentation |
| 4.4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were suspended in 2011? | none |
| 4.5. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011? | none |
| 4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)? | No |
| **4bis. Overview of tissue/cells establishments authorised by the NCA** | |
| 4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible): | Musculo-skeletal tissue establishments<br>Cardiovascular tissue establishments |
| 4.7.2. How many musculo-skeletal tissue establishments? | 1 |
| 4.7.4. How many cardiovascular tissue establishments? | 1 |
| 4.8. Tissue establishments with authorisations pending | Cardiovascular tissue establishments |

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| approval by 31/12/2011 (more than 1 answer possible): | |
| 4.8.4. How many cardiovascular tissue establishments? | 1 |
| 4.9. Tissue establishments first time authorised between 01/01/2011 and 31/12/2011 (more than 1 answer possible): | Musculo-skeletal tissue establishments |
| 4.9.2. How many musculo-skeletal tissue establishments? | 1 |
| 4.10. All tissue establishments authorised by 31/12/2011 (more than 1 answer possible): | Musculo-skeletal tissue establishments<br>HSC tissue establishments<br>Cord blood tissue establishments<br>ART tissue establishments<br>Multi-tissue establishments |
| 4.10.2.1. How many public musculo-skeletal tissue establishments? | 1 |
| 4.10.2.2. How many private musculo-skeletal tissue establishments? | 2 |
| 4.10.5.1. How many public HSC tissue establishments? | 2 |
| 4.10.5.2. How many private HSC tissue establishments? | none |
| 4.10.6.1. How many public cord blood tissue establishments? | none |
| 4.10.6.2. How many private cord blood tissue establishments? | 1 |
| 4.10.7.1. How many public ART tissue establishments? | none |
| 4.10.7.2. How many private ART tissue establishments? | 9 |
| 4.10.8.1. How many public multi-tissue establishments? | 3 |
| 4.10.8.2. How many private multi-tissue establishments? | 1 |
| 4.11. How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Art. 6(5) during 2011? Please provide number(s) per type tissues/cells. | None |
| **4ter. Sanctions** | |
| 4.16. Have penalties for infringements of the national provisions pursuant to the Directive been defined (Article 27)? | Yes |
| 4.16.1. Have penalties already been imposed? | No |
| 4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing? | |
| **5. Inspections (Article 7, Directive 2004/23/EC)** | |
| 5.1. Is a system in place for organising inspections and control measures of tissue establishments? | Yes |
| 5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections. | The compliance department of the Irish Medicines Board are in charge of inspections. |
| 5.1.2. If yes, please specify staffing (how many inspectors). | 1 Blood, Tissues and Organs Manager, 2 Blood, Tissues and Organs Inspectors, 1 Blood, Tissues and Organs Scientific Officer. |
| 5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible) | Yes |
| 5.2.1. If yes, please specify. (more than 1 answer possible) | Blood<br>Organs<br>Advanced therapies |
| 5.3. How many routine inspections of tissue establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011)? | 6 |
| 5.3.1. How many inspections of tissues establishments | none |

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| for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) following serious adverse events or reactions, or suspicion thereof ? | |
| 5.3.2. How many other type of inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | none |
| 5.3.3. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | none |
| 5.3.4. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where minor shortcomings were noted? | 5 |
| 5.3.5. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where major shortcomings were noted? | 5 |
| 5.3.6. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by suspension of authorisation? | none |
| 5.3.7. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by closure? | none |
| 5.3.8. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of other inspections carried out? Please specify. | none |
| 5.4. How many routine inspections were conducted in ART establishments (from 1/1/2011 to 31/12/2011)? | 4 |
| 5.4.1. How many inspections were conducted in ART establishments following serious adverse events or reactions, or suspicion thereof (from 1/1/2011 to 31/12/2011)? | none |
| 5.4.2. How many other type of inspections were conducted on ART establishments (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | There were three (3) inspections performed which reviewed applications to vary the existing Tissue Establishment Authorisations of two ART clinics. |
| 5.4.3. Outcome of inspections of ART tissue establishments carried out in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | none |
| 5.4.4. What was the number of inspections carried out in ART establishments where minor shortcomings were noted? | 6 |
| 5.4.5. What was the number of inspections carried out in ART establishments where major shortcomings were noted? | 1 |
| 5.4.6. What was the number of inspections carried out in ART establishments followed by suspension of authorisation? | none |
| 5.4.7. What was the number of inspections carried out in ART establishments followed by closure of respective establishements? | none |

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| 5.4.8. What was the number of other inspections of ART establishments? Please specify. | 3 - There were three (3) inspections performed which reviewed applications to vary the existing Tissue Establishment Authorisations of two (2) ART clinics. |
| 5.5. Which type of routine inspections do you conduct? (more than 1 answer possible) | General system-oriented inspections |
| 5.6. How do you decide which type of routine inspection to conduct? | All routine TE inspections comprise of a detailed on-site review of the quality system and processes along with a review of any issues or serious adverse events / reactions (SAE/R's) that may have occured since the last inspection. Routine inspections are performed on-site no less than once every two years as per Directive. |
| 5.7. Until 2011, did you implement the requirement concerning the time interval between two inspections (Art. 7.3.)? | Yes |
| 5.8. How many TEs were inspected at least twice between 2008-2011 (01/01/2008-31/12/2011)? | 19 |
| 5.9. Did you perform/conduct inspections of procurement sites outside tissue establishments? | No |
| 5.9.2. If no, why not? | Where procurement occurs in Ireland, the activity is inspected and the site requires a tissue establishment authorisation. If the procurement occurs outside of Ireland, inspection of the relevant documentation occurs onsite at the irish tissue establishment |
| 5.10. Did you carry out inspections of third parties? | No |
| 5.10.2. If no, why not? | Performing external auditing is mandatory to all TEs and is reviewed as part of the routine IMB inspection |
| 5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)? | Yes |
| 5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)? | Yes |
| 5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)? | 5 |
| 5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))? | No |
| 5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))? | No |
| 5.15. Did you organise any inspections of procurement centres or tissue establishments in third countries from which tissues and/or cells were imported in your country (as recorded by 31/12/2011)? | No |
| 5.16. Have you asked another MS, or have you been requested by any other MS, on the results and control measures of your inspections, as part of an enquiry/investigation? | No |
| 5.17. Would you be interested in developing joint inspections? Joint inspections should be understood as inspections of tissue establishments conducted jointly by two or more Member States' Competent Authorities on their territory or in third countries. | Yes |
| 5.18. Do you have any additional comments on inspections? | The NCA would encourage the development of joint inspections, however, a controlled approach to their development is needed, specifically, with respect to the joint inspection of sites outside of the EEA. |
| **6. Import/export (Article 9 Directive 2004/23/EC)** | |
| 6.1. Do you have a register of authorised tissue establishments that are explicitly authorised to perform | No |

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| import/export of tissues and celles from/to third countries? | |
| 6.2. Please specify the number of tissue establishments authorised to import tissues and cells from third countries (recorded by 31/12/2011). | 7 |
| 6.3. Please specify the number of tissue establishments authorised to export tissues and cells from third countries (recorded by 31/12/2011). | 7 |
| 6.4. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of skin from third countries. | The importation of skin is not performed in Ireland. |
| 6.5. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of musculo-skeletal (bone, tendons, fascia etc.) tissues from third countries. | TE's that wish to import Tissues and Cells on a routine basis from a site outside the EEA are required to list this activity on their TE authorisation.In authorising this routine import, the IMB performs a detailed review of the documentation supplied by the tissue establishment including the national accreditation status of the third country site and the service level agreement (SLA) between both parties. TE's that wish to import tissues and cells on a non routine basis, must notify the IMB of their intent to import using IMB documentation and will document this import as a planned deviation. TE's that wish to import Tissues and Cells on a routine basis from a site outside the EEA are required to list the exporting site on their TE authorisation. In authorising this non - routine import, the IMB performs a detailed review of the documentation supplied by the tissue establishment including the national and international accreditation status of the third country site and the service level agreement (SLA) between both parties. A follow up review this non routine import is perfomed onsite as part of the routine Irish TE inspection. |
| 6.6. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of ophtalmic (cornea, sclera, etc) tissues from third countries. | TE's that wish to import Tissues and Cells on a routine basis from a site outside the EEA are required to list this activity on their TE authorisation.In authorising this routine import, the IMB performs a detailed review of the documentation supplied by the tissue establishment including the national accreditation status of the third country site and the service level agreement (SLA) between both parties. TE's that wish to import tissues and cells on a non routine basis, must notify the IMB of their intent to import using IMB documentation and will document this import as a planned deviation. TE's that wish to import Tissues and Cells on a routine basis from a site outside the EEA are required to list the exporting site on their TE authorisation. In authorising this non - routine import, the IMB performs a detailed review of the documentation supplied by the tissue establishment including the national and international accreditation status of the third country site and the service level agreement (SLA) between both parties. A follow up review this non routine import is perfomed onsite as part of the routine Irish TE inspection. |
| 6.7. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cardio vascular tissues from third countries. | TE's that wish to import Tissues and Cells on a routine basis from a site outside the EEA are required to list this activity on their TE authorisation.In authorising this routine import, the IMB performs a detailed review of the documentation supplied by the tissue establishment including the national accreditation status of the third country site and the service level agreement (SLA) between both parties. TE's that wish to import tissues and cells on a non routine basis, must notify the IMB of their intent to import using IMB documentation and will document this import as a planned deviation. TE's that wish to import Tissues and Cells on a routine basis from a site outside the EEA are required to list the exporting site on their TE authorisation. In authorising this non - routine import, the IMB performs a detailed review of the documentation supplied by the tissue establishment including the national and international accreditation status of the third country site and the service level agreement (SLA) between both parties. A follow up review this non routine import is perfomed onsite as part of the routine Irish TE inspection. |
| 6.8. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) (other than cord blood) from third countries. | TE's that wish to import Tissues and Cells on a routine basis from a site outside the EEA are required to list this activity on their TE authorisation.In authorising this routine import, the IMB performs a detailed review of the documentation supplied by the tissue establishment including the national accreditation status of the third country site and the service level agreement (SLA) between both parties. |

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| | TE's that wish to import tissues and cells on a non routine basis, must notify the IMB of their intent to import using IMB documentation and will document this import as a planned deviation. TE's that wish to import Tissues and Cells on a routine basis from a site outside the EEA are required to list the exporting site on their TE authorisation. In authorising this non - routine import, the IMB performs a detailed review of the documentation supplied by the tissue establishment including the national and international accreditation status of the third country site and the service level agreement (SLA) between both parties. A follow up review this non routine import is perfomed onsite as part of the routine Irish TE inspection. |
| 6.9. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cord blood from third countries. | TE's that wish to import Tissues and Cells on a routine basis from a site outside the EEA are required to list this activity on their TE authorisation.In authorising this routine import, the IMB performs a detailed review of the documentation supplied by the tissue establishment including the national accreditation status of the third country site and the service level agreement (SLA) between both parties. TE's that wish to import tissues and cells on a non routine basis, must notify the IMB of their intent to import using IMB documentation and will document this import as a planned deviation. TE's that wish to import Tissues and Cells on a routine basis from a site outside the EEA are required to list the exporting site on their TE authorisation. In authorising this non - routine import, the IMB performs a detailed review of the documentation supplied by the tissue establishment including the national and international accreditation status of the third country site and the service level agreement (SLA) between both parties. A follow up review this non routine import is perfomed onsite as part of the routine Irish TE inspection. |
| 6.10. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of reproductive cells (sperm, egg cells) from third countries. | TE's that wish to import Tissues and Cells on a routine basis from a site outside the EEA are required to list this activity on their TE authorisation.In authorising this routine import, the IMB performs a detailed review of the documentation supplied by the tissue establishment including the national accreditation status of the third country site and the service level agreement (SLA) between both parties. TE's that wish to import tissues and cells on a non routine basis, must notify the IMB of their intent to import using IMB documentation and will document this import as a planned deviation. TE's that wish to import Tissues and Cells on a routine basis from a site outside the EEA are required to list the exporting site on their TE authorisation. In authorising this non - routine import, the IMB performs a detailed review of the documentation supplied by the tissue establishment including the national and international accreditation status of the third country site and the service level agreement (SLA) between both parties. A follow up review this non routine import is perfomed onsite as part of the routine Irish TE inspection. |
| 6.11. Did you import tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | Yes |
| 6.11.1. If yes, please provide the data concerning the number/volume of imported tissues and cells by country of origin. | 7 TE's inported tissues and cells in 2011. 4 non ART establishments and 3 ART establishments. 2 PBSC's 1 Donor Lymphocyte 4 Cord Blood 34 Bone 11 Pericardium 20 Amnion 14 Sclera 168 Corneas 2040 imports of gametes and embryos from 3 ART clinics. |
| 6.12. Did you export tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | Yes |
| 6.12.1. If yes, please provide the data concerning the number/volume of exported tissues and cells by country of destination. | export of 734 units to a country outside the EEA. |
| 6.13. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on imports/exports of tissues/cells between your country and other third countries? | No |
| 6.14. What is the relation between import/export of tissues and cells and self-sufficiency? (more than 1 answer possible) | D. Import of tissues/cells is authorised only after checking that local/national needs are not fulfilled<br>E. Import of tissues/cells is authorised based on estimations showing that there is chronic deficiency of those tissues/cells |
| 6.14.1. If A or D were selected, please explain how you quantify local/national needs. | Tissues and Cells are imported to Irish Tissue Establishments in cases where Ireland does not provide the resources for patients (e.g procurement of post |

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| | mortem bone, patient specific bone marrow) |
| 6.15. Did you authorise direct imports of tissues/cells to hospitals/clinics in your country? | No |
| 6.16. Do you have any additional comments on import/export? | The development of guidance by the European working group for import/ export of Tissues and Cells is required and the IMB is participating in this working goup. |
| **7. Distribution/intra community exchanges (Article 23 Directive 2004/23/EC)** | |
| 7.1. Do you have intra-community exchanges of tissues and cells? | No |
| 7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify. | It is the responsibility of the TE to perform distribution of tissues and cells in compliance with the requirements of the Directive. |
| 7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible). | Yes, no restrictions apply |
| 7.4. Have you authorised direct distribution to the recipient of specific tissues and cells (Art. 6, Directive 2006/17/EC)? | No |
| 7.5. Do you collect data regarding the cross-border exchange of tissue/cells between your country and other EU MS? | Yes |
| 7.5.1. Please provide us with data (country of destination, type of tissue/cell and number of units distributed) concerning distribution to other MS in 2011 (01/01/2011-31/12/2011). | Allogenic Peripheral Blood Stem Cells - 4 units distributed within the EEA |
| 7.5.2. Please provide us with data (country of origin, type of tissue/cell and number of units distributed) concerning distribution to other MS in 2011 (01/01/2011-31/12/2011) | Bone Marrow Allogenic - 9 Accepted from within EEA Peripheral Blood Stem Cells Allogenic - 14 Accepted from within EEA Bone - 21 Accepted from within EEA Sclera - 4 Accepted from within EEA Amniotic Membrane - 3 Accepted from within EEA Heart Valves - 13 Accepted from within EEA Donor Lymphocyte - 1 Accepted from within EEA Tendons - 5 Accepted from within EEA Corneas - 5 Accepted from within EEA |
| 7.6. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on cross-border exchanges of tissues/cells between your country and other EU MS? | No |
| 7.7. Do you allow brokerage companies for either distribution in EU and/or import/export of tissues/cells? In this context, a brokerage company means a body that arranges transactions between a supplier (tissue establishment/company selling tissues or cells) and a buyer (a tissue establishment/a hospital or clinic/an individual) without undertaking activities of processing, preservation or storage. | No |
| 7.8. Are brokers actively supplying health professionals/establishments in your country? | Yes |
| 7.8.1. Where are the brokers located? | Another country |
| 7.8.2. If the broker is located in another country, how easy/difficult is it to ensure that safety and quality requirements are met? | There are no Irish brokers actively supplying healthcare professionals / establishments in Ireland. However, as no restrictions apply to the distribution of tissues and cells to Ireland from brokers within the EU, it is difficult to control the quality and safety requirements, specifically with respect to the reporting of SAE/R's traceability and recall notifcation. |
| 7.9. Do you have any additional comments on distribution? | The development of guidance in the control of distribution across the EU and directly to health care professionals and recipietns is required. |
| **8. Register of tissue establishments and reporting obligations (Article 10, Directive 2004/23/EC)** | |
| 8.1. Do you have an annual report model/template on the activities of tissue establishments in your Member State? (Article 10(1)). If yes, please upload the template. | Yes |
| 8.2. How many tissue establishments submitted annual reports of their activities during 2011. Please provide | 100% (all) |

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| an estimation. (1 answer possible) | |
| 8.3. Are these reports publicly available? (Article 10(1)) | No |
| 8.4. Do you publish a national annual report of the consolidated activities of all tissue establishments in your country? | No |
| 8.4.2. If no, why not? | This is currently being progressed. Our stakeholders will be consulted in this regard as any annual activity data may be sensitive particularly in the ART field. |
| 8.5. Is there a publicly accessible register of authorised tissue establishements in place? (Article 10(2)) | Yes |
| 8.5.1. If yes, please provide us with the link to the register's web site. | http://www.imb.ie/EN/Blood-Tissues--Cells/Blood--Tissue-Establishments-.aspx?page=1&name=&orderby=name&orderascending=True&type=3&sitestatus=1&withdrawdate= |
| 8.6. Do you provide data regarding tissues and cells activities to the EUROCET registry (non-mandatory reporting)? | No |
| 8.6.2. If no, why not? | The IMB are not legally required to submit data regarding tissues and cells activity to the EUROCET registry. It is felt that the submission of data requires resources not currently available to the IMB. In addition, the IMB have not established agreements with their TE's to submit their data to a publicly accessible registry. |
| 8.7. Do you have any additional comments on reporting? | |
| **9. Traceability (Article 8, Directive 2004/23/EC; and Directive 2006/86/EC)** | |
| 9.1. Was the donor identification system (Art. 8(2)) implemented in your country? | Yes |
| 9.2. Who assigns the unique code for each donation? (only 1 answer possible) | Tissue establishment |
| 9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible) | Both paper records and electronic forms |
| 9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify. | This area is reviewed as part of the inspection process. |
| 9.5. Do you have any additional comments on traceability? | |
| **10. Notification of serious adverse events and reactions (Article 11 Directive 2004/23, Article 6 Directive 2006/76)** | |
| 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))? | Yes |
| 10.1.1. If yes, which CA/institution is responsible? | Irish Medicines Board - Tissue & Cell Vigilance |
| 10.1.2. If yes, please provide a short description of its organisation. | Blood Tissues and Organs Vigilance Officer is responsible for the receipt and analysis of SAE/Rs and provides information to BTO inspectors for follow up during inspections of TEs. |
| 10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use the SAR/E (to the CA (2006/76 art 6.4)) templates developed to the Annual reporting ot the EC also at national level? | Yes |
| 10.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level? | Yes |
| 10.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all TEs? | Yes |
| 10.5. How many tissue establishments provided in 2011 the SAR/SAE data as requested (please provide the % from the total number of TEs authorised in your country). | 100% |
| 10.6. Do you have a mandatory procedure for the transplantation centres when reporting SAR/SAE to the TEs which distributed the tissues/cells (Art 11.2)? | Yes |

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| 10.6.1. If yes, please provide a brief description. | In accordance with this legislation, the IMB has established a reporting system for the notification of suspected Serious Adverse Reactions (SARs) and Serious Adverse Events (SAEs) associated with human tissues and cells. All Tissue Establishments are required, through the Responsible Person (or designee), to notify the IMB of and provide a report analysing the cause of and ensuing outcome of: •Any serious adverse events and reactions which may influence the quality and safety of tissues and cells and which may be attributed to the procurement, testing, processing, storage and distribution of tissues and cells; •Any serious adverse reaction observed during or after clinical application which may be linked to the quality and safety of tissues and cells The reporting requirements to the IMB are inclusive of: - In the case of assisted reproduction, any type of gamete or embryo misidentification or mix-up, which shall be considered a serious adverse event; - 'Near miss' reports where the event was detected prior to transplantation. All reports are submitted using the IMB Guide to Reporting Serious Adverse Reactions (SARs) and Serious Adverse Events (SAEs) associated with Human Tissues and Cells together with the IMB Adverse Reaction / Event Report Form – Human tissues and Cells . These documents may be dowloaded and posted into the IMB or submitted via an on-line form available on the IMB website |
| 10.7. Do you give feedback to the TEs regarding SAR/SAE recorded at national level? | Yes |
| 10.7.1. Please specify. | An annual report of all SAE/Rs reported is issued to all Tissue Establishments. |
| 10.8. Do you give feedback to the TEs regarding SAR/SAE recorded at EU level? | Yes |
| 10.8.1. Please specify. | Information on SAR/SAEs recorded at EU level are provided if they directly impact TE's in Ireland and for learning purposes. |
| 10.9. Do you require your TEs to have a recall procedure? | Yes |
| 10.10. How many recalls related to safety and quality of tissues/cells were issued in your country in 2011? Please specify the number and which tissues were recalled and why (e.g. missing consent, quality defects etc). | No recalls have been performed in Ireland to date. |
| 10.11. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites in case of a national rapid alert? | Yes |
| 10.11.1. If yes, please give a short description of the system/procedure. | The IMB provide national rapid alert information to all affected sites through email notification and issue guidance on the required management procedures. |
| 10.12. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites when a rapid alert is issued via the EU RATC platform? | Yes |
| 10.12.1. If yes, please give a short description of the system/procedure. | The IMB provide rapid alert information to all affected sites through email notification and issue guidance on the required management procedures. |
| 10.13. Do you provide data regarding SAR/SAE to the EUROCET registry (non-mandatory reporting)? | No |
| 10.13.2. If no, please specify why not. | This is primarily a resource issue. This information is already provided on an annual basis to the EC and would be a doubling of effort. |
| 10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems? | Yes |
| 10.14.1. If yes, please specify which of the following systems are usually contacted. (more than 1 answer possible) | Haemovigilance<br>Pharmacovilance<br>Medical devices<br>Other |
| Please specify 'other'. | organ vigilance system (also managed by IMB) |
| 10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S? | Yes |
| 10.15.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 | 5 |

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| (insufficient) - 2 (sufficient) 3 (good) - 4 (very good) to 5 (essential)? | |
| 10.16. Do you have any additional comments on SARE reporting? | |
| **11. Consent and personal data protection (Article 13 and 14, Directive 2004/23/EC)** | |
| 11.1. What consent system for living tissue/cell donation do you have in place within your Member State? | Explicit consent (opt-in) |
| 11.1.1. Please specify your choice of consent system for living tissue/cell donation. | Consent to be revised as part of the development of a national Human Tissues Act. Until its completion - Explicit consent (opt in) |
| 11.2. What consent system for deceased tissue/cell donation do you have in place within your Member State? | Explicit consent (opt-in) |
| 11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible) | First degree relatives (including spouse) |
| 11.4. Is the consent system for deceased tissue donation the same as for organs? | Yes |
| 11.5. How is this consent verified during inspections? (more than 1 answer possible) | Analysis of documentation |
| 11.6. What measures are in place to ensure that donors/relatives/authorising persons on behalf of donors are provided with the appropriate information, as requested by Art. 13(2)? (more than 1 answer possible) | Other |
| Please specify 'other'. | Inspection of donor file, health and lifestyle questionnaires, information provided to donors and their families and practice (as per S.I 158 of 2006 - Schedule 1 - 6 ). |
| 11.7. What measures are in place to ensure that both donors and recipients remain unidentifiable when access is given to third parties (Art. 14(1)). Please specify. | All TEs are required to comply with Data Protection Legislation here in Ireland. A unique identifcation number is given to both donors and recipients and applied to all documentation relating to the transplantation procedure. |
| 11.8. Please specify what measures are in place to ensure that the identity of the receipient is not disclosed to the donor and vice versa. | All TEs are required to comply with Data Protection Legislation here in Ireland. A unique donor code is appied at donation and is used within the TE at all times. |
| 11.9. Does your national legislation allows disclosure of donor data in case of gametes donation? | No |
| 11.9.1. If no, please specify the circumstances and measures in place. | There is no legislation in Ireland in this area. No donor sperm is procured here in Ireland. All donor sperm is obtained from another EU Member state. The donor disclosure rules in that MS would have to be applied to these donors. |
| 11.10. Do you have any additional comments on consent and data protection? | |
| **12. Selection, evaluation and procurement (Article 15 Directive 2004/23; Annexes I-IV Directive 2006/17)** | |
| 12.1. How do you ensure that all requirements related to the evaluation and selection of donors (except donors of reproductive cells) are respected in your country (Art. 15(1), Annex I Directive 2006/17/EC)? (more than 1 answer possible) | Inspections of TEs and procurement sites<br>Audit of documentation |
| 12.2. How do you ensure that all requirements related to the evaluation and selection of donors of reproductive cells are respected in your country (Art 15 (1), Annex III of Directive 2006/17/EC)? (more than 1 answer possible) | Inspections of ART centres<br>Audit documentation |
| 12.3. Do you have more stringent criteria for donor selection than those listed in Annex I of the Directive 2006/17/EC? | No |
| 12.4. What sources are required in your MS for the evaluation of a deceased donor of tissues/cells? (more than 1 answer possible) | Interview with the donor's family or a person who knew the donor well<br>Medical records of the donor |
| 12.5. Do you have more stringent criteria for selection | No |

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| of donors of reproductive cells than those listed in Annex III of the Directive 2006/17/EC? | |
| 12.6. Do you have more stringent criteria for autologous donation than those listed in Annex I of the Directive 2006/17/EC? | No |
| 12.7. Do you require more information on the donation of tissues/cells than the mandatory one as laid down in the Annex of Directive 2004/23/EC (Art 15(3)? | No |
| 12.8. How do you ensure that all requirements regarding tissues and cells' procurement, packaging and transport are complied with by tissue establishments in your country (Art 15(1), Annex IV of Directive 2006/17/EC? (more than 1 answer possible)(For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)) | Inspection of tissue establishment<br>Audit of tissue establishment<br>Inspection of the centre of human application (e.g. transplantation centre, ART centre) |
| 12.9. Do you have any additional comments on selection, evaluation and procurement? | |
| **13. Quality management, responsible person, personnel (Article 16, 17, 18 Directive 2004/23/EC)** | |
| 13.1. How do you ensure that tissue establishments in your country have in place a quality system respecting the provisions of the Directive 2004/23/EC Art 16.1? (more than 1 answer possible). (For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)). | Authorisation requirement<br>Inspections<br>Internal audits<br>External audits |
| 13.2. How do you ensure that tissue establishments have a responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible) | Authorisation requirement<br>Inspections |
| 13.3. How do you ensure an appropriate training for the personnel directly involved in the activities of tissue establishments? (more than 1 answer possible) | Authorisation requirement<br>Inspections |
| 13.4. Do you have national/regional/local training programmes for the personnel of tissue establishments? | Yes |
| 13.4.1. If yes, please specify. | It is the responsibility of the tissue establishments to develop their own internal training processes as per Article 18 of Directive. This is reviewed on inspection. The TEs define the qualification and training of personnel. |
| 13.5. Any additional comments on quality management, responsible person, personnel? | |
| **14. Reception, processing, storage, labelling and packaging (Art 19-22 Directive 2004/23/EC)** | |
| 14.1. How do you ensure that tissue establishments in your country fulfill the requirments of the Art. 19 (Tissue and cell reception) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | National regulation/policy for reception of tissues/cells<br>Inspections of tissue establishments |
| 14.2. How do you ensure that tissue establishments in your country fulfill the requirements of the Art. 20 (Tissue and cell processing) of Directive 2004/23/EC? (more than 1 answer possible) | SOPs for all processes affecting quality and safety are mandatory for authorisation<br>Inspections of tissue establishments |
| 14.3. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 21 (tissue and cell storage conditions) of Directive 2004/23/EC? | SOPs for procedures associated with storage of tissues and cells are mandatory for authorisation<br>Inspections of tissue establishments |

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| (more than 1 answer possible) | |
| 14.4. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | SOPs for procedures associated with labelling and packaging are mandatory for authorisation<br>Inspections of tissue establishments |
| 14.5. Any additional comments on reception, processing, storage, labelling and packaging? | |
| **15. Third party agreements (Art. 24 Directive 2004/23/EC)** | |
| 15.1. Are third party agreements foreseen/allowed in your national legislation? | Yes |
| 15.1.1. If yes, have tissue establishments in your Member State notified third party agreements? | Yes |
| 15.1.1.1. Under which circumstances and for which responsibilities? | The import and export of tissues and cells - For service providers - e.g maintenance, testing, suppliers - For sites performing prescribed activities on behalf of the Tissue Establishment e.g. donation, procurement, processing etc. |
| 15.1.1.2. How are third party agreements controlled (Art 6.2) by the Competent Auhtority(ies) in your MS? Please specify. | Agreements must be established in accordance with Article 24 of Directive and are reviewed as part of inspection process. |
| 15.2. Any additional comments on third party agreements? | |
| **16. General comments - implementation** | |
| 16.1. Do you have at national level more stringent quality and safety requirements than those requested by the EU legislation in this field (e.g. restrictions concerning the donation/use of certain tissues/cells, mandatory unpaid donation etc.)? | No |
| 16.2. Has your Member State encountered any difficulties in implementing the requirements in the EU Tissues and Cells Directives? Please choose from the options below. | Distribution provisions<br>Vigilance |
| 16.2.1. For all selected options in question 16.2., please provide a short description. | Distribution provisions - There is difficulty in controlling the distibution of tissues and cells to healthcare professionals / establishments from other EU Meber States. |
| 16.3. In your opinion, in which of the following Directives are there shortcomings (if any)? (more than 1 answer possible) | No shortcomings |

## *A.1.15. Survey response Italy*

| **1. Public information** | |
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| 1.1. Name of National Competent Authority (NCA) 1: | Ministry of Health. However, the National Transplant Centre as a technical institution of the Ministry, carries out most of the operational activities of the Competent Authority. |
| 1.1.2. Address of NCA 1: | National Transplant Centre Via Giano della Bella, 34 00162 Rome Italy |
| 1.1.3. Telephone (central access point): | +39 06 49904040 |
| 1.1.4. E-mail (central access point): | cnt@iss.it |
| 1.1.5. Website: | http://www.trapianti.salute.gov.it |
| 1.1.6. The NCA is responsible for? (more than 1 answer possible) | Non-reproductive tissues and cells<br>Reproductive tissues and cells<br>Human organs |
| 1.1.7. What are the role/tasks of the NCA? (more than 1 answer possible) | Inspection<br>Vigilance<br>Other |
| Please specify 'other': | Activity data collection (donation and transplantation); traceability (allocation of donation numbers for tissue donations); training; |
| 1.2. National Competent Authority 2? | Yes |
| 1.2.1. Name of National Competent Authority 2: | National Blood Centre |
| 1.2.2. Address of NCA 2: | Via Giano della Bella, 27 00162 Rome Italy |
| 1.2.3. Telephone (central access point): | +39 06 49904953 |
| 1.2.4. E-mail (central access point): | direzione.cns@iss.it |
| 1.2.5. Website: | http://www.centronazionalesangue.it |
| 1.2.6. The NCA is responsible for? (more than 1 answer possible) | Non-reproductive tissues and cells<br>Blood and blood components |
| 1.2.7. What are the role/tasks of the NCA? (more than 1 answer possible) | Inspection<br>Vigilance |
| 1.3. National Competent Authority 3? | No |
| 1.5. Please give a short description of the legal status and organisation of the National Competent Authority(ies) (e.g. departments, staffing, number of senior and junior inspectors, staff working on EU affairs and legal matters, vigilance officers, budget, independence from government etc.). | CNT is a technical instrument of the Ministry of Health and is organised as an independent unit within the Higher Institute of Health (Istituto Superiore di Sanità). It was instituted by a law that provides the legal basis for its activities including the promotion and co-ordination of organ donation and transplantation. Its annual budget is allocated by the government in the context of that law and includes funds for the implementation of Law no. 191 which is the Italian transposition of Directive 2004/23/EC. The centre includes the following sections (departments): Medical (organs); Tissues and Cells; Informatics; International Relations; Communications; Administration. A small number (3) of senior staff work on EU legislative affairs (including the Director) and a similar number support the Ministry in the development of Italian legislation. There are 6 inspectors for tissues and cells who also manage the vigilance activities. There is also a team of experts from the field that are trained by CNT to assist on inspections. The Centre leads and participates in many EU -funded projects in the field of transplantation and assisted reproduction. |
| 1.6. In case of MS with federal or decentralised systems, please indicate the roles/tasks of the Regional Competent Authority(ies). (more than 1 answer possible) | Accreditation, authorisation, licensing of TEs<br>Inspection<br>Vigilance |
| 1.7. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies) for tissues and cells: | The Regional Authorities are responsible for authorising Tissue Establishments and for suspending or revoking that authorisation. They do this on the basis of an initial evaluation of regional minimal structural and organisational requirements. Their subsequent activity is subject to insepction to verify compliance with the national legislation that transposes the EU Directives. For tissues and HPCs, these inspections are carried out by CNT/CNS on a national basis and the results are submitted to the regional authorities. In 2010, the Ministry of Health indicated that for ART, the inspections should be carried out by the regional authorities with the support of CNT; this regional ART centre inspection programme started in 2011. |

| **2. Procurement (Article 5 Directive 2004/23/EC)** | |
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| 2.1. Do you authorise the "conditions of procurement"? | Yes |
| 2.1.1. How do you authorise the "conditions of procurement"? (more than 1 answer possible) | By inspecting some procurement centres<br>By inspecting the documentation associated with procurement that is available in the tissue establishment working with procurement centres |
| 2.1.2. How many such authorisations were granted in 2011 (01/01-31/12/2011)? | In general, authorisation for procurement is integrated into the tissue establishment inspection scheme and is not granted separately. |
| 2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011). | 372 centres |
| 2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011). | 63 procurement centres of bone marrow; 83 procurement centres for PBSC, 279 procurement centres for cord blood |
| 2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues were carried out in 2011 (01/01-31/12/2011). | 195 (excluding centres that carry out only intra-uterine insemination (IUI) |
| 2.2.4. Please provide the number of procurement centers in which procurement of tissues/cells for ATMP manufacturing were carried out in 2011 (01/01-31/12/2011). | 13 authorised ATMP manufacturers (clinical trials) with procurement at their own hospitals. Some may have procurement in other hospitals for whom they manufacture but the numbers of these procurement centres are not available. |
| 2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC and its implementing Directive 2006/17/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) ? (more than 1 answer possible) | Inspections of the site/centre<br>Analysis of the mandatory documentation |
| 2.4. Are you also responsible for the accreditation, designation, authorisation or licensing of laboratories performing donor testing? | No |
| 2.4.2. Which National Authority is in charge of this activity? | Testing laboratories operate within the national healthcare system and are authorised for their activities by the Regional Health Authorities |
| 2.5. How do you ensure, as CA for T&C, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art. 5(2))? (more than 1 answer possible) | Analysis of the mandatory documentation requested from the tissue establishment<br>Other |
| Please specify 'other': | Reliance on the system in place for diagnostic laboratory authorisation. |
| 2.6. Please provide data on qualified laboratories accredited, authorised or licensed in your country (e.g. number, year of accreditation/authorisation/license, which donor tests are performed etc.). | Not possible to provide. See 2.4 |
| 2.7. Do you have any additional comments on procurement? | No |
| **3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)** | |
| 3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>HBs AG<br>Anti HBc<br>Anti HCV-Ab<br>Treponema Pallidum |
| 3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>HBs AG<br>Anti HBc<br>Anti HCV-Ab<br>Treponema Pallidum |
| 3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to encourage its use? Please specify why or why not (e.g. number of additional cases detected, cost-benefit etc.). | NAT testing for HIV, HCV and HBV is mandatory for donors of HPCs (bone marrow, PBSC, cord blood) in line with the national blood legislation. It is not mandatory for tissues or gamete donor, except for living tissue donors where the serology test is not repeated at 180 days). It is, nonetheless, routinely carried out by tissue banks. There are no plans to make it mandatory. HTLV testing is carried out only on donors |

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| | with identified risk as specified in Directive 2006/17/EC. Chlamydia is a required test for gamete donors but it is not performed by NAT. |
| 3.4. Do you have concerns on accuracy of the available tests and test procedures for deceased donors? | Yes |
| 3.4.1. Please specify why: | Many centres use kits that are not certified for use with cadaveric samples. |
| 3.5. Are any other laboratory tests required for donors of non-reproductive tissues and cells in your Member State? | Yes |
| 3.5.1. Please specify. | Depending on the type of donor, the type of tissues/cells or the donor history, testing may be required for CMV, toxoplasma, West Nile Virus, Chikungunya etc. Obviously, blood grouping and HLA typing are required for certain donors and bacteriology testing of tissues/cells is a requirement for all types of donations. |
| 3.6. Are any other laboratory tests required for donors of reproductive tissues and cells in your Member State? | No |
| 3.7. Do you request/use international accreditation systems for testing laboratories? | Yes |
| 3.7.1. Please specify. | For HLA testing laboratories: EFI or ASHI accreditation |
| 3.8. Do you have any additional comments on testing? | No |
| **4. Accreditation, designation, authorisation or licensing of tissue establishments (Article 6, Directive 2004/23/EC)** | |
| 4.1. Do you have a system of designation, authorisation, accreditation or licensing for all types of tissue establishments under your responsability? | Yes |
| 4.2. Is inspection a prerequisite for the designation, authorisation, accreditation or licensing of tissue establishments? | Yes |
| 4.2.1. How many inspections were performed in 2011 for authorising/accrediting/licensing/designating TEs? | Tissues: 13; HPC: 3 inspections at TEs for bone marrow and PBSC and 11 inspections at cord blood banks; ART: 11<br>Please note: many centres are given a preliminary authorisation/accrediation etc. before inspection on the basis of a documentary review. |
| 4.3. Are preparation processes authorised? | Yes |
| 4.3.1. How are they authorised? (more than 1 answer possible) | During routine inspections<br>During inspections organised for this purpose<br>By review of a submitted application with supporting documentation |
| 4.4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were suspended in 2011? | 0 |
| 4.5. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011? | 0 |
| 4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)? | Yes |
| 4.6.1. What is the relation between the indpendent certification(s) (e.g. ISO, JACIE, FACT) and the CA authorisation of the tissue establishments? (more than 1 answer possible) | Mandatory for authorisation<br>Inspections are conducted jointly by the CAs and independent certifying body<br>No relation<br>Other |
| Please specify 'other': | Please note that we selected 'other' in order to be able to add this explanatory note. The situation is different for tissues and ART compared with HPC. HPC centres are inspected in collaboration with JACIE. For cord blood banks ISO certification is mandatory. For tissues and other types of cells, there is no relation with any independent certification system and no such certification is required by legislation. |
| **4bis. Overview of tissue/cells establishments authorised by the NCA** | |
| 4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible): | Musculo-skeletal tissue establishments<br>Cardiovascular tissue establishments<br>HSC tissue establishments<br>Cord blood tissue establishments<br>ART tissue establishments<br>Multi-tissue establishments |

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| | Other tissue establishments |
| 4.7.2. How many musculo-skeletal tissue establishments? | 1 |
| 4.7.4. How many cardiovascular tissue establishments? | 1 |
| 4.7.5. How many HSC tissue establishments? | 69 |
| 4.7.6. How many cord blood tissue establishments? | 16 |
| 4.7.7. How many ART tissue establishments? | 195 |
| 4.7.8. How many multi-tissue establishments? | 1 |
| 4.7.9. Please specify the type of tissues/cells and how many. | We assume this refers to the 'other' category Pancreatic islets: 1 |
| 4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible): | Musculo-skeletal tissue establishments<br>Cardiovascular tissue establishments<br>HSC tissue establishments<br>Cord blood tissue establishments<br>ART tissue establishments<br>Multi-tissue establishments |
| 4.8.2. How many musculo-skeletal tissue establishments? | 1 |
| 4.8.4. How many cardiovascular tissue establishments? | 1 |
| 4.8.5. How many HSC tissue establishments? | 66 |
| 4.8.6. How many cord blood tissue establishments? | 9 |
| 4.8.7. How many ART tissue establishments? | 188 |
| 4.8.8. How many multi-tissue establishments? | 1 |
| 4.9. Tissue establishments first time authorised between 01/01/2011 and 31/12/2011 (more than 1 answer possible): | HSC tissue establishments<br>Cord blood tissue establishments<br>ART tissue establishments<br>Other tissue establishments |
| 4.9.5. How many HSC tissue establishments? | 3 |
| 4.9.6. How many cord blood tissue establishments? | 1 |
| 4.9.7. How many ART tissue establishments? | 7 |
| 4.9.9. Please specify the type of tissues/cells and how many. | We assume this refers to the 'other' category Pancreatic islets: 1 |
| 4.10. All tissue establishments authorised by 31/12/2011 (more than 1 answer possible): | Skin tissue establishments<br>Musculo-skeletal tissue establishments<br>Ocular tissue establishments<br>Cardiovascular tissue establishments<br>HSC tissue establishments<br>Cord blood tissue establishments<br>ART tissue establishments<br>Multi-tissue establishments<br>Other tissue establishments |
| 4.10.1.1. How many public skin tissue establishments? | 5 |
| 4.10.1.2. How many private skin tissue establishments? | 0 |
| 4.10.2.1. How many public musculo-skeletal tissue establishments? | 4 |
| 4.10.2.2. How many private musculo-skeletal tissue establishments? | 0 (although there is 1 private musculo-skeletal processing facility that is inspected and authorised to process tissue as a third party for public banks. |
| 4.10.3.1. How many public ocular tissue establishments? | 7 |
| 4.10.3.2. How many private ocular tissue establishments? | 0 |
| 4.10.4.1. How many public cardiovascular tissue establishments? | 3 |
| 4.10.4.2. How many private cardiovascular tissue establishments? | 0 |
| 4.10.5.1. How many public HSC tissue establishments? | 11 |
| 4.10.5.2. How many private HSC tissue establishments? | 0 |
| 4.10.6.1. How many public cord blood tissue establishments? | 3 |
| 4.10.6.2. How many private cord blood tissue establishments? | 0 |
| 4.10.7.1. How many public ART tissue establishments? | 6 |
| 4.10.7.2. How many private ART tissue establishments? | 1 |
| 4.10.8.1. How many public multi-tissue establishments? | 8 |
| 4.10.8.2. How many private multi-tissue establishments? | 0 |
| 4.10.9.1. Please specify the type of 'other' public tissues/cells establishements and how many. | Pancreatic islets: 2 Amniotic membrane: 1 |
| 4.10.9.2. Please specify the type of 'other' private tissues/cells | Not applicable |

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| establishements and how many. | |
| 4.11. How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Art. 6(5) during 2011? Please provide number(s) per type tissues/cells. | 0 |
| **4ter. Sanctions** | |
| 4.16. Have penalties for infringements of the national provisions pursuant to the Directive been defined (Article 27)? | Yes |
| 4.16.1. Have penalties already been imposed? | No |
| 4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing? | No |
| **5. Inspections (Article 7, Directive 2004/23/EC)** | |
| 5.1. Is a system in place for organising inspections and control measures of tissue establishments? | Yes |
| 5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections. | Tissue and Cell section of CNT. For HPC and cord blood banks, these inspections are carried out in collaboration with CNS |
| 5.1.2. If yes, please specify staffing (how many inspectors). | 6 inspectors although all of these individuals also have other responsibilities. There is also a team of tissue bank expert inspectors, a team of HPC centre expert inspectors and 2 teams of ART centre inspectors (one regional team and one national team) who work in this field or in related fields and have been trained by CNT to assist in inspections on an ad-hoc basis. |
| 5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible) | Yes |
| 5.2.1. If yes, please specify. (more than 1 answer possible) | Blood<br>Accreditation organisations (e.g. JACIE) |
| 5.3. How many routine inspections of tissue establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011)? | CB:10; HPC: 3;Tissues:13 |
| 5.3.1. How many inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) following serious adverse events or reactions, or suspicion thereof ? | 0 |
| 5.3.2. How many other type of inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | 1 cord blood bank inspection to verify traceability and new activity. 1 tissue bank inspection to verify corrective actions following a previous inspection 1 third party processor to review plans for a new preparation process. |
| 5.3.3. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | Tissues: 2;HPC: 0;CB: 2 |
| 5.3.4. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where minor shortcomings were noted? | Tissues: 2;HPC: 3;CB: 9 |
| 5.3.5. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where major shortcomings were noted? | Tissues: 9; HPC: 3; CB:9 We have understood this to mean those where 'major' and/or 'critical' non-compliances were noted, according to the EC Operational Manual. |
| 5.3.6. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by suspension of authorisation? | 0 |
| 5.3.7. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by closure? | 0 |

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| 5.3.8. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of other inspections carried out? Please specify. | See question 5.3.2 |
| 5.4. How many routine inspections were conducted in ART establishments (from 1/1/2011 to 31/12/2011)? | 11 |
| 5.4.1. How many inspections were conducted in ART establishments following serious adverse events or reactions, or suspicion thereof (from 1/1/2011 to 31/12/2011)? | 0 |
| 5.4.2. How many other type of inspections were conducted on ART establishments (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | 0 |
| 5.4.3. Outcome of inspections of ART tissue establishments carried out in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | 0 |
| 5.4.4. What was the number of inspections carried out in ART establishments where minor shortcomings were noted? | 0 |
| 5.4.5. What was the number of inspections carried out in ART establishments where major shortcomings were noted? | 11 |
| 5.4.6. What was the number of inspections carried out in ART establishments followed by suspension of authorisation? | 0 |
| 5.4.7. What was the number of inspections carried out in ART establishments followed by closure of respective establishements? | 0 |
| 5.4.8. What was the number of other inspections of ART establishments? Please specify. | See 5.4.2 above |
| 5.5. Which type of routine inspections do you conduct? (more than 1 answer possible) | General system-oriented inspections<br>Thematic inspections<br>Desk based reviews |
| 5.6. How do you decide which type of routine inspection to conduct? | General system-oriented inspections are the normal type of inspection conducted. They are carried out for the first certification of the centre and normally for subsequent routine inspections also. On rare occasions thematic inspections are carried out, either when the centre has already had a number of general system-oriented inspections and it is decided that it will be more fruitful to choose a specific topic on which to focus or when a particular issue has arisen in relation to e.g. importation, a change in processing or a vigilance incident in the period prior to the routine inspection. Desk-based reviews are carried out when there is a large number of centres to be inspected for the first time. They are used to help prioritise the order of inspections and to allow preliminary certification until a site inspection can be conducted. |
| 5.7. Until 2011, did you implement the requirement concerning the time interval between two inspections (Art. 7.3.)? | No |
| 5.7.1. Why not? | This was achieved, plus or minus a few months, for tissue banks where the number of banks is only 31. It has not been possible for HPC centres due to the high number of centres (> 100). CNT received the mandate to inspect ART centres only in 2011. Although a small number of centres have been inspected twice, there is a very high number of centres(more than 200 excluding centres that do only IUI) and it is likely that the 2 year cycle will not be possible to maintain. |
| 5.7.2. How do you prioritise tissue establishments to be inspected? | Using desk-based review of questionnaires, by the size of the banks and, for HPCs, depending on the timing of JACIE inspections as the CA inspection is carried out jointly with JACIE. |
| 5.8. How many TEs were inspected at least twice between 2008-2011 (01/01/2008-31/12/2011)? | Tissues: 20. HPC: 0 but a system of interim documentary review was implemented at two years following release of certification by the CA. |
| 5.9. Did you perform/conduct inspections of procurement sites outside tissue establishments? | Yes |
| 5.9.1. If yes, how many? | HPC only: 3 |
| 5.10. Did you carry out inspections of third parties? | Yes |

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| 5.10.1. If yes, how many? | in 2011: 1 |
| 5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)? | Yes |
| 5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)? | Yes |
| 5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)? | 4 |
| 5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))? | No |
| 5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))? | No |
| 5.15. Did you organise any inspections of procurement centres or tissue establishments in third countries from which tissues and/or cells were imported in your country (as recorded by 31/12/2011)? | No |
| 5.16. Have you asked another MS, or have you been requested by any other MS, on the results and control measures of your inspections, as part of an enquiry/investigation? | No |
| 5.17. Would you be interested in developing joint inspections? Joint inspections should be understood as inspections of tissue establishments conducted jointly by two or more Member States' Competent Authorities on their territory or in third countries. | Yes |
| 5.18. Do you have any additional comments on inspections? | No |
| **6. Import/export (Article 9 Directive 2004/23/EC)** | |
| 6.1. Do you have a register of authorised tissue establishments that are explicitly authorised to perform import/export of tissues and celles from/to third countries? | No |
| 6.2. Please specify the number of tissue establishments authorised to import tissues and cells from third countries (recorded by 31/12/2011). | At this time, any tissue establishment that is certified by CNT as being compliant with the safety and quality requirements is also allowed to import or export in compliance with our specific decree on Import/export. A specific authorisation will be implemented to allow maintenance of the EU TE compendium. |
| 6.3. Please specify the number of tissue establishments authorised to export tissues and cells from third countries (recorded by 31/12/2011). | to third countries? as 6.2 |
| 6.4. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of skin from third countries. | Inspectors review the agreements that the tissue establishments have with the third country supplier. They also review a selection of donor records that have been reviewed by the importing Italian TE and any other documents associated with the importation. |
| 6.5. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of musculo-skeletal (bone, tendons, fascia etc.) tissues from third countries. | Inspectors review the agreements that the tissue establishments have with the third country supplier. They also review a selection of donor records that have been reviewed by the importing Italian TE and any other documents associated with the importation. |
| 6.6. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of ophtalmic (cornea, sclera, etc) tissues from third countries. | Inspectors review the agreements that the tissue establishments have with the third country supplier. They also review a selection of donor records that have been reviewed by the importing Italian TE and any other documents associated with the importation. |
| 6.7. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cardio vascular tissues from third countries. | Inspectors review the agreements that the tissue establishments have with the third country supplier. They also review a selection of donor records that have been reviewed by the importing Italian TE and any other documents associated with the importation. |
| 6.8. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) (other than cord blood) from third countries. | Inspectors review the compliance of protocols adopted for HSC importation by national (IBMDR, Italian Bone Marrow Transplantation) and international (WMDA, World Marrow Donor Association) standards .They also review a selection of donor records that have been |

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| | reviewed by the importing Italian TE and any other documents associated with the importation. |
| 6.9. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cord blood from third countries. | Inspectors review the compliance of protocols adopted for HSC importation by national (IBMDR, Italian Bone Marrow Transplantation) and international (WMDA, World Marrow Donor Association) standards .They also review a selection of donor records that have been reviewed by the importing Italian TE and any other documents associated with the importation. |
| 6.10. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of reproductive cells (sperm, egg cells) from third countries. | Inspectors review the agreements that the art centers have with the third country art centers. They also review documents associated with the importation. |
| 6.11. Did you import tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | Yes |
| 6.11.1. If yes, please provide the data concerning the number/volume of imported tissues and cells by country of origin. | Tissues: Not collected centrally though could be obtained from the importing banks HPC:Australia 1 PBSC and 5 CB, Canada 2 BM, 6 PBSC, China/Hong Kong 1 BM, Israel 4 BM and 15 PBSC, 1 BM and 1 PBSC, Taiwan 1 CB, USA 55 BM, 63 PBSC and 26 CB, Switzerland 1 BM, 1 PBSC and 1 CB. ART: not known but only imported by couples for their own use (the law prohibits non-partner gamete donation and use). |
| 6.12. Did you export tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | Yes |
| 6.12.1. If yes, please provide the data concerning the number/volume of exported tissues and cells by country of destination. | We assume this intends to mean that we export to third countries. Tissues: 357 corneas (at this time we do not record centrally the country of destination so this includes both EU and non-EU countries. ART: CNT has had responsibility for import/export of gametes and embryos only since January 2013 so we have no data for 2011. HPC: 64; Australia 1 CB, Croatia 1 PBSC and 1 CB; Israel 4 BM and 15 PBSC and 1 CB, Canada 1 PBSC and 1CB, Chile 1 CB, Russia 1 PBSC, South Africa 2 CB, Switzerland 2 PBSC and 2 CB, Turkey 1 CB, USA 4 BM, 6 PBSC and 20 CB. |
| 6.13. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on imports/exports of tissues/cells between your country and other third countries? | No |
| 6.14. What is the relation between import/export of tissues and cells and self-sufficiency? (more than 1 answer possible) | A. Export of tissues/cells is authorised only after checking that local/national needs are fulfilled.<br>C. Export of tissues/cells is authorised irrespective of national needs<br>D. Import of tissues/cells is authorised only after checking that local/national needs are not fulfilled<br>F. Other |
| Please specify 'other': | Other - import of tissues/cells is allowed only when the same time of product is not available within the country from another bank. For HPC import/export depends on the HLA compatibility between donor and recipient, characteristics of the donor and of the cellular product (for cord blood units). |
| 6.14.1. If A or D were selected, please explain how you quantify local/national needs. | For A, tissue banks are asked to check with the other banks for that type of tissue (usually by email or fax) to know if there are unmet requests for that type of tissue or cell product before it is exported. For D, there needs to be a specific request from a clinical user who confirms that the product needs to be imported. |
| 6.15. Did you authorise direct imports of tissues/cells to hospitals/clinics in your country? | No |
| 6.16. Do you have any additional comments on import/export? | Tissues and cells coming from other EU Member States are managed in a manner equivalent to those coming from third countries. We have a recently adopted Decree on Import/Export. Additionally, for HPC import/export an authorisation from the Ministry of Health must be obtained. |
| **7. Distribution/intra community exchanges (Article 23 Directive 2004/23/EC)** | |
| 7.1. Do you have intra-community exchanges of tissues and cells? | Yes |

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| 7.1.1. If yes, how do you address the possible more stringent quality and safety measures established by other Member States? Please specify. | Our decree requires that imports, even from EU MS, enter via an authorised Italian TE which must verify quality and safety. Any additional requirements need to be stipulated in the quality agreement between the tissue establishment in Italy and that in the other MS. |
| 7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States? | Yes |
| 7.1.2.1. How do you address this difference for tissues and cells coming from a MS with minimum quality requirements? Please specify. | See 7.1.1 For HPC it is necessary to carry out the NAT test for HIV, HBV and HCV. |
| 7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify. | Through the control of the documentation relating to the donor and the product. |
| 7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible). | Yes, but only via an authorised TE in my MS |
| 7.4. Have you authorised direct distribution to the recipient of specific tissues and cells (Art. 6, Directive 2006/17/EC)? | No |
| 7.5. Do you collect data regarding the cross-border exchange of tissue/cells between your country and other EU MS? | Yes |
| 7.5.1. Please provide us with data (country of destination, type of tissue/cell and number of units distributed) concerning distribution to other MS in 2011 (01/01/2011-31/12/2011). | We understand this question to refer to distribution from Italy to other EU MS. For tissues, 357 corneas were sent out of Italy. At this time we do not record centrally the countries of destination so this will include EU and non-EU countries. For HPCs: Total 84: Austria 1 BM, 2 PBSC, Belgium 3 CB, Czech Republic 1 BM, Denmark 1 BM and 3 CB, France 7 BM, 6 PBSC and 16 CB, Germany 3 BM, 10 PBSC and 5 CB, Greece 1 PBSC and 2 CB, Netherlands 3 CB, Poland 1 PBSC, Portugal 1 CB, Slovakia 1 CB, Slovenia 1 CB, Spain 2 BM, 2 PBSC and 3 CB, Sweden 1 PBSC, UK 1 BM, 4 PBSC and 4 CB. |
| 7.5.2. Please provide us with data (country of origin, type of tissue/cell and number of units distributed) concerning distribution to other MS in 2011 (01/01/2011-31/12/2011) | We understand this to mean distribution from EU MS into Italy. The numbers are not centrally available at this time for tissues. For HPC, Total: 429: Austria 2 CB, Belgium 2 CB, Cyprus 3 PBSC, Denmark 1 PBSC, France 6 BM, 6 PBSC and 9 CB, Germany 106 BM, 240 PBSC and 7 CB, Greece 1 CB, Ireland 1 PBSC, Netherlands 1 CB, Poland 2 BM, 7 PBSC, Portugal 3 BM, 12 PBSC, Spain 10 CB, Sweden 1 CB, UK 6 BM, 3 PBSC. |
| 7.6. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on cross-border exchanges of tissues/cells between your country and other EU MS? | No |
| 7.7. Do you allow brokerage companies for either distribution in EU and/or import/export of tissues/cells? In this context, a brokerage company means a body that arranges transactions between a supplier (tissue establishment/company selling tissues or cells) and a buyer (a tissue establishment/a hospital or clinic/an individual) without undertaking activities of processing, preservation or storage. | Yes |
| 7.7.1. Please describe the legal requirements and your role (if any) as a Competent Authority, in their authorisation/monitoring or inspection. | For tissues, such companies are only allowed to operate under a third party agreement with an authorised tissue establishment (which must be public sector). This happening currently only for processed bone products. They can organise the importation on behalf of the TE and can also store and transport on behalf of the TE. The TE must take responsibility for ensuring equivalent quality and safety and for taking orders from clinical users and allocating products to them for distribution. The TE must also take responsibility for traceability and vigilance. |
| 7.8. Are brokers actively supplying health professionals/establishments in your country? | Yes |
| 7.8.1. Where are the brokers located? | Another country |
| 7.8.2. If the broker is located in another country, how easy/difficult is it to ensure that safety and quality requirements are met? | See 7.7.1 above for the limitations that are put on their activities. They are actively supplying only in this context. Any activities outside of an agreement with a TE are not legal. Please note: having selected 'Another country' above, it was not possible to also select 'Your country'. Some of these distributors also operate in Italy. |

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| 7.9. Do you have any additional comments on distribution? | No |
| **8. Register of tissue establishments and reporting obligations (Article 10, Directive 2004/23/EC)** | |
| 8.1. Do you have an annual report model/template on the activities of tissue establishments in your Member State? (Article 10(1)). If yes, please upload the template. | Yes |
| 8.2. How many tissue establishments submitted annual reports of their activities during 2011. Please provide an estimation. (1 answer possible) | 100% (all) |
| 8.3. Are these reports publicly available? (Article 10(1)) | Yes |
| 8.3.1. If yes, please insert the link(s) to the report(s). | They are available on the Eurocet Registry website at www.eurocet.org and on the CNT website. |
| 8.4. Do you publish a national annual report of the consolidated activities of all tissue establishments in your country? | No |
| 8.4.2. If no, why not? | The data are published on the Eurocet platform and the CNT website and presented at conferences, congresses etc. |
| 8.5. Is there a publicly accessible register of authorised tissue establishements in place? (Article 10(2)) | Yes |
| 8.5.1. If yes, please provide us with the link to the register's web site. | http://www.trapianti.salute.gov.it/cnt/cntHomeSezione.jsp?id=10&area=cnt-tessuti&menu=menuPrincipale |
| 8.6. Do you provide data regarding tissues and cells activities to the EUROCET registry (non-mandatory reporting)? | Yes |
| 8.6.1. If yes, what data are provided to EUROCET? Please specify. | CA details TE detaila Activity data |
| 8.7. Do you have any additional comments on reporting? | Regarding 8.1, our reply referred only to tissue banking procurement, processing and distribution activity. The following is information regarding tissue donation, and HPC activity reporting. Tissues: For donation, each donation is entered electronically on the national computer software (SIT) managed by CNT. These data are available on the system in real time and it generates the annual donation data. Every 3 months each tissue bank completes a standard form with activity data and each Regional Tranpsplant Centre provides data on tissue transplants. The form completed by the banks is attached. HPC: For HPCs data on transplants are inserted in EBMT's informatic software (Promise). This system sends a quarterly report to GITMO (the Italian Bone Marrow Transplant Group) who forwards it to CNT. For donation activity of cord blood, each cord blood bank reports on a quarterly basis to CNT and CNS (the Excel form used is attached). ART: the ART centres enter their activity data directly into an informatic system managed by the National ART Registry. An annual report is produced by the Registry. |
| **9. Traceability (Article 8, Directive 2004/23/EC; and Directive 2006/86/EC)** | |
| 9.1. Was the donor identification system (Art. 8(2)) implemented in your country? | Yes |
| 9.2. Who assigns the unique code for each donation? (only 1 answer possible) | Other |
| Please specify 'other'. | For tissues: National CA; For HPC: IBMDR (Italian Bone Marrow Donor Registry) for unrelated donors; for autologous and related donors, codes are allocated by TEs. For ART: allocated by TEs. |
| 9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible) | Both paper records and electronic forms |
| 9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify. | Verified during inspection |
| 9.5. Do you have any additional comments on traceability? | No |
| **10. Notification of serious adverse events and reactions (Article 11 Directive 2004/23, Article 6 Directive 2006/76)** | |
| 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))? | Yes |
| 10.1.1. If yes, which CA/institution is responsible? | CNT for tissues and ART. CNT in collaboration with CNS for HPC and cord blood. |

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| 10.1.2. If yes, please provide a short description of its organisation. | There are three slightly different systems in place for Tissues, HPC and ART. In each case the centres are informed regarding how they should notify using forms that are based on those in the annexes of Directive 2006/86/EC. The TEs are responsible for informing clinical users, procurement centres and third parties on how to notify SARE and what to notify. Their procedures for doing this are reviewed during routine inspections. |
| 10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use the SAR/E (to the CA (2006/76 art 6.4)) templates developed to the Annual reporting ot the EC also at national level? | No |
| 10.2.1. If no, what template do you use? You are welcome to upload the template if you wish. | We use the templates in the annexes to Directive 2006/86/EC. |
| 10.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level? | Yes |
| 10.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all TEs? | No |
| 10.4.1. Why not? | The role is shared by the inspector team although one inspector takes the lead for tissues and ART and one for HPC. |
| 10.5. How many tissue establishments provided in 2011 the SAR/SAE data as requested (please provide the % from the total number of TEs authorised in your country). | 100% |
| 10.6. Do you have a mandatory procedure for the transplantation centres when reporting SAR/SAE to the TEs which distributed the tissues/cells (Art 11.2)? | No |
| 10.6.2. If no, how do you ensure that SAR/SAE are reported to the TEs? | By ensuring that TEs when distributing tissues and cells provide full instructions for reporting. |
| 10.7. Do you give feedback to the TEs regarding SAR/SAE recorded at national level? | Yes |
| 10.7.1. Please specify. | At this time we do not produce an annual SARE report but we do provide summaries during training courses for TE professionals and at professional society meetings. |
| 10.8. Do you give feedback to the TEs regarding SAR/SAE recorded at EU level? | No |
| 10.8.2. Please specify why not. | Until now, there has not been an EC Annual Report to share with the TEs. Once available (2013), it will be shared. |
| 10.9. Do you require your TEs to have a recall procedure? | Yes |
| 10.10. How many recalls related to safety and quality of tissues/cells were issued in your country in 2011? Please specify the number and which tissues were recalled and why (e.g. missing consent, quality defects etc). | 0 |
| 10.11. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites in case of a national rapid alert? | No |
| 10.11.2. If no, please specify why not. | Up to now, we communicate by email on a case-by-case basis. This has not yet been formalised in a written procedure. |
| 10.12. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites when a rapid alert is issued via the EU RATC platform? | No |
| 10.12.2. If no, please specify why not. | Up to now, we communicate by email on a case-by-case basis. This has not yet been formalised in a written procedure. |
| 10.13. Do you provide data regarding SAR/SAE to the EUROCET registry (non-mandatory reporting)? | No |
| 10.13.2. If no, please specify why not. | this data is not requested or reported by Eurocet. |
| 10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems? | No |
| 10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S? | Yes |
| 10.15.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (insufficient) - 2 (sufficient) 3 (good) - 4 (very good) to 5 (essential)? | 4 |

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| 10.16. Do you have any additional comments on SARE reporting? | Regarding question 10.5, we entered 100% in order to be able to continue compiling the questionnaire. However, the TEs are not required to provide an annual SARE report. They report SARE as they occur and the CA compiles the annual report. The TEs must provide detailed information to transplant centres on how and when to report SARE. They manage the interaction with the transplant centres. The way they do this is reviewed during routine inspection. See 10.1.2 |
| **11. Consent and personal data protection (Article 13 and 14, Directive 2004/23/EC)** | |
| 11.1. What consent system for living tissue/cell donation do you have in place within your Member State? | Explicit consent (opt-in) |
| 11.1.1. Please specify your choice of consent system for living tissue/cell donation. | Living donor must sign a consent form. |
| 11.2. What consent system for deceased tissue/cell donation do you have in place within your Member State? | Presumed (opt-out) and explicit (opt-in) consent |
| 11.2.1. If you have chosen both consent systems for deceased tissue/cell dontation, please specify. | Explicit for cornea; presumed for other tissues. However, normal practice is always to consult the family to establish a 'lack of objection'. |
| 11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible) | First degree relatives (including spouse)<br>Non-marital partners |
| 11.4. Is the consent system for deceased tissue donation the same as for organs? | Yes |
| 11.5. How is this consent verified during inspections? (more than 1 answer possible) | Analysis of documentation<br>Interviews with personnel |
| 11.6. What measures are in place to ensure that donors/relatives/authorising persons on behalf of donors are provided with the appropriate information, as requested by Art. 13(2)? (more than 1 answer possible) | Only trained personnel is allowed to provide such information |
| 11.7. What measures are in place to ensure that both donors and recipients remain unidentifiable when access is given to third parties (Art. 14(1)). Please specify. | For tissues and HPC, an anonymous donation number must be used. The requirements for maintenance of anonymity are defined in national guidelines against which inspectors inspect. For ART, no non-partner donation is allowed by law. |
| 11.8. Please specify what measures are in place to ensure that the identity of the receipient is not disclosed to the donor and vice versa. | See 11.7 |
| 11.9. Does your national legislation allows disclosure of donor data in case of gametes donation? | No |
| 11.9.1. If no, please specify the circumstances and measures in place. | No non-partner donation of gametes is allowed by the national legislation (Law No. 40). |
| 11.10. Do you have any additional comments on consent and data protection? | No |
| **12. Selection, evaluation and procurement (Article 15 Directive 2004/23; Annexes I-IV Directive 2006/17)** | |
| 12.1. How do you ensure that all requirements related to the evaluation and selection of donors (except donors of reproductive cells) are respected in your country (Art. 15(1), Annex I Directive 2006/17/EC)? (more than 1 answer possible) | Stadardised questionnaires at national levels<br>Inspections of TEs and procurement sites<br>Audit of documentation<br>Other |
| Please specify 'other'. | For tissues and HPC, detailed requirements are specified in national guidelines. |
| 12.2. How do you ensure that all requirements related to the evaluation and selection of donors of reproductive cells are respected in your country (Art 15 (1), Annex III of Directive 2006/17/EC)? (more than 1 answer possible) | Inspections of ART centres<br>Audit documentation |
| 12.3. Do you have more stringent criteria for donor selection than those listed in Annex I of the Directive 2006/17/EC? | Yes |
| 12.3.1. If yes, please specify. | NAT testing for HPC donors for HIV, HBV and HCV is required. - toxoplasma IgM for amniotic membrane (in case of positivity the tissue cannot be used for transplant); - CMV IgM for hear valves and vessels and amniotic membrane, in case of positivity CMV DNA must be performed, if negative the donor is suitable. - CMV for skin: if positive the result must be communicated to the centre that has requested the tissue for clinical use CMV,toxoplasma and EBV testing for HPC |

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| | unrelated donors Serum archive for all donors Chlamydia testing for gamete donors |
| 12.4. What sources are required in your MS for the evaluation of a deceased donor of tissues/cells? (more than 1 answer possible) | Interview with the donor's family or a person who knew the donor well<br>Medical records of the donor<br>Interview with the treating physician<br>Interview with the general practitioner<br>Autopsy report |
| 12.5. Do you have more stringent criteria for selection of donors of reproductive cells than those listed in Annex III of the Directive 2006/17/EC? | Yes |
| 12.5.1. Please specify. | Only partner donation is permitted |
| 12.6. Do you have more stringent criteria for autologous donation than those listed in Annex I of the Directive 2006/17/EC? | No |
| 12.7. Do you require more information on the donation of tissues/cells than the mandatory one as laid down in the Annex of Directive 2004/23/EC (Art 15(3)? | No |
| 12.8. How do you ensure that all requirements regarding tissues and cells' procurement, packaging and transport are complied with by tissue establishments in your country (Art 15(1), Annex IV of Directive 2006/17/EC? (more than 1 answer possible)(For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)) | Inspection of tissue establishment<br>Audit of tissue establishment<br>Other |
| 12.8.1. Please specify. | Audits are included in the sense that the CA inspection verifies that internal audits are performed as part of the quality management of the TE. Other: for tissues, national guidelines define the requirements in more detail, including for specific tissues. |
| 12.9. Do you have any additional comments on selection, evaluation and procurement? | No |
| **13. Quality management, responsible person, personnel (Article 16, 17, 18 Directive 2004/23/EC)** | |
| 13.1. How do you ensure that tissue establishments in your country have in place a quality system respecting the provisions of the Directive 2004/23/EC Art 16.1? (more than 1 answer possible). (For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)). | Authorisation requirement<br>Inspections<br>Internal audits<br>External audits<br>Other |
| Please specify 'other'. | Please note that the external audits refer only to the field of HPCs. Internal audits are a requirement of the quality system and are verified during inspection. The authorisation is performed by the Regional Health authority and is verified during the CA inspection.For tissues, national guidelines are issued that include requirements for specific tissues. |
| 13.2. How do you ensure that tissue establishments have a responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible) | Inspections |
| 13.3. How do you ensure an appropriate training for the personnel directly involved in the activities of tissue establishments? (more than 1 answer possible) | Inspections<br>Other |
| Please specify 'other'. | Non-mandatory training |
| 13.4. Do you have national/regional/local training programmes for the personnel of tissue establishments? | Yes |
| 13.4.1. If yes, please specify. | CNT organises basic and advanced training courses for personnel of tissues banks and for personnel of ART centres. For HPC CNT |

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| | participates in national and regional courses for professionals in the field; the courses are organised by the professional societies. |
| 13.5. Any additional comments on quality management, responsible person, personnel? | No |
| **14. Reception, processing, storage, labelling and packaging (Art 19-22 Directive 2004/23/EC)** | |
| 14.1. How do you ensure that tissue establishments in your country fulfill the requirments of the Art. 19 (Tissue and cell reception) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | Inspections of tissue establishments<br>Internal audits of tissue establishments |
| 14.2. How do you ensure that tissue establishments in your country fulfill the requirements of the Art. 20 (Tissue and cell processing) of Directive 2004/23/EC? (more than 1 answer possible) | SOPs for all processes affecting quality and safety are mandatory for authorisation<br>Inspections of tissue establishments<br>Internal audits of tissue establishments |
| 14.3. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 21 (tissue and cell storage conditions) of Directive 2004/23/EC? (more than 1 answer possible) | SOPs for procedures associated with storage of tissues and cells are mandatory for authorisation<br>Inspections of tissue establishments<br>Internal audits of tissue establishments |
| 14.4. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | SOPs for procedures associated with labelling and packaging are mandatory for authorisation<br>Inspections of tissue establishments<br>Internal audits of tissue establishments |
| 14.5. Any additional comments on reception, processing, storage, labelling and packaging? | No |
| **15. Third party agreements (Art. 24 Directive 2004/23/EC)** | |
| 15.1. Are third party agreements foreseen/allowed in your national legislation? | Yes |
| 15.1.1. If yes, have tissue establishments in your Member State notified third party agreements? | Yes |
| 15.1.1.1. Under which circumstances and for which responsibilities? | - for processing of tissues - for storage of tissues, HPC, gametes or embryos - for gamma sterilisation of tissues - for tissue or cell transportation - for monitoring and management of liquid nitrogen facilities |
| 15.1.1.2. How are third party agreements controlled (Art 6.2) by the Competent Auhtority(ies) in your MS? Please specify. | Reviewed during routine inspections |
| 15.2. Any additional comments on third party agreements? | Third parties that carry our critical steps such as processing or storage of tissues or cells on behalf of TEs must have a direct authorisation from the Ministry of Health. These authorisations are issued on the basis of an inspection by CNT. |
| **16. General comments - implementation** | |
| 16.1. Do you have at national level more stringent quality and safety requirements than those requested by the EU legislation in this field (e.g. restrictions concerning the donation/use of certain tissues/cells, mandatory unpaid donation etc.)? | Yes |
| 16.1.1. Please specify. | More stringent requirements for receiving tissues/cells from EU Member States. Some more stringent requirements for testing and serum archiving as mentioned above. |
| 16.2. Has your Member State encountered any difficulties in implementing the requirements in the EU Tissues and Cells Directives? Please choose from the options below. | Procurement provisions<br>Testing provisions<br>Inspections |
| 16.2.1. For all selected options in question 16.2., please provide a short description. | Procurement: where tissues/cells - notably cord blood for autologous/family use - is procured but then sent to another EU country (as banking is not allowed in Italy) the CA does not verify the compliance of the conditions of procurement as there is no TE in Italy where this could be performed - we rely on the CA of the receiving MS to confirm this through document review at the receiving TE. Testing: the tissue and cell CA is not competent to inspect and verify the compliance of testing laboratories with the requirements. Inspections: with the high number of centres - particularly HPC and ART centres - and the number of inspectors trained and available to conduct |

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| | inspections, it has not been possible to conduct site inspections at every centre and at an interval of every two years. |
| 16.3. In your opinion, in which of the following Directives are there shortcomings (if any)? (more than 1 answer possible) | Directive 2004/23/EC<br>Directive 2006/17/EC<br>Directive 2006/86/EC |
| 16.3.1. How would you suggest to solve these issues in Directive 2004/23/EC? | See comments sent on June 2nd 2013 in reply to request from Sanco on potential shorcomings in the current tissues and cells directives and resubmitted now in an email to Ioana Siska. |
| 16.3.2. How would you suggest to solve these issues in Directive 2006/17/EC? | We would have comments on this directive but they would depend on which comments are accepted for the mother directive. |
| 16.3.3. How would you suggest to solve these issues in Directive 2006/86/EC? | We would have comments on this directive but they would depend on which comments are accepted for the mother directive. |

## *A.1.16. Survey response Latvia*

| **1. Public information** | |
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| 1.1. Name of National Competent Authority (NCA) 1: | State Agency of Medicines of the Republic of Latvia |
| 1.1.2. Address of NCA 1: | 15 Jersikas Street, Riga, LV-1003 |
| 1.1.3. Telephone (central access point): | +371 67078424 |
| 1.1.4. E-mail (central access point): | info@zva.gov.lv |
| 1.1.5. Website: | www.zva.gov.lv |
| 1.1.6. The NCA is responsible for? (more than 1 answer possible) | Non-reproductive tissues and cells<br>Reproductive tissues and cells<br>Blood and blood components<br>Human organs<br>Pharmaceuticals<br>Medical devices |
| 1.1.7. What are the role/tasks of the NCA? (more than 1 answer possible) | Accreditation, authorisation, licensing of TEs<br>Inspection<br>Vigilance |
| 1.2. National Competent Authority 2? | No |
| 1.5. Please give a short description of the legal status and organisation of the National Competent Authority(ies) (e.g. departments, staffing, number of senior and junior inspectors, staff working on EU affairs and legal matters, vigilance officers, budget, independence from government etc.). | State Agency of Medicines is the state institution under supervision of the Ministry of Health of the Republic of Latvia, that carries out evaluation, marketing authorisation, monitoring, control and regulation of distribution of medicines and medical devices in Latvia. It is a state agency not financed from the state budget (agency's budget is formed from service fees). There are 13 departments and 144 employees (www.zva.gov.lv). 2 senior inspectors for blood, tissues, cells, and organs, including vigilance in the Agency. Legal department consists of 4 employees. EU matters - no dedicated staff. |
| 1.6. In case of MS with federal or decentralised systems, please indicate the roles/tasks of the Regional Competent Authority(ies). (more than 1 answer possible) | Not applicable |
| 1.7. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies) for tissues and cells: | No regional authority. |
| **2. Procurement (Article 5 Directive 2004/23/EC)** | |
| 2.1. Do you authorise the "conditions of procurement"? | Yes |
| 2.1.1. How do you authorise the "conditions of procurement"? (more than 1 answer possible) | By inspecting the documentation associated with procurement that is available in the tissue establishment working with procurement centres |
| 2.1.2. How many such authorisations were granted in 2011 (01/01-31/12/2011)? | 0 |
| 2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011). | 0 |
| 2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011). | 0 |
| 2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues were carried out in 2011 (01/01-31/12/2011). | 0 |
| 2.2.4. Please provide the number of procurement centers in which procurement of tissues/cells for ATMP manufacturing were carried out in 2011 (01/01-31/12/2011). | 0 |
| 2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC and its implementing Directive 2006/17/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) ? (more than 1 answer possible) | Inspections of the site/centre<br>Analysis of the mandatory documentation |
| 2.4. Are you also responsible for the accreditation, designation, | No |

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| authorisation or licensing of laboratories performing donor testing? | |
| 2.4.2. Which National Authority is in charge of this activity? | Latvian National Accreditation Bureau |
| 2.5. How do you ensure, as CA for T&C, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art. 5(2))? (more than 1 answer possible) | Analysis of the mandatory documentation requested from the tissue establishment |
| 2.6. Please provide data on qualified laboratories accredited, authorised or licensed in your country (e.g. number, year of accreditation/authorisation/license, which donor tests are performed etc.). | 6, information available on www.latak.lv |
| 2.7. Do you have any additional comments on procurement? | |
| **3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)** | |
| 3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>HBs AG<br>Anti HBc<br>Anti HCV-Ab<br>Treponema Pallidum |
| 3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>HBs AG<br>Anti HBc<br>Anti HCV-Ab<br>NAT Chlamydia<br>Treponema Pallidum |
| 3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to encourage its use? Please specify why or why not (e.g. number of additional cases detected, cost-benefit etc.). | In practice NAT HBV, NAT HCV, NAT HIV1 are being performed routinely. |
| 3.4. Do you have concerns on accuracy of the available tests and test procedures for deceased donors? | No |
| 3.5. Are any other laboratory tests required for donors of non-reproductive tissues and cells in your Member State? | Yes |
| 3.5.1. Please specify. | On certain circumstances tests for HTLV-1; RhD; HLA; malaria; CMV; toxoplasma; EBV; Trypanosoma cruzi should be considered. |
| 3.6. Are any other laboratory tests required for donors of reproductive tissues and cells in your Member State? | Yes |
| 3.6.1. Please specify. | On certain circumstances tests for HTLV-1; RhD; malaria; CMV; Trypanosoma cruzi should be considered. |
| 3.7. Do you request/use international accreditation systems for testing laboratories? | Yes |
| 3.7.1. Please specify. | Most testing laboratories are accredited according to EN ISO 15189 and /or EN ISO 17025 standards. |
| 3.8. Do you have any additional comments on testing? | |
| **4. Accreditation, designation, authorisation or licensing of tissue establishments (Article 6, Directive 2004/23/EC)** | |
| 4.1. Do you have a system of designation, authorisation, accreditation or licensing for all types of tissue establishments under your responsability? | Yes |
| 4.2. Is inspection a prerequisite for the designation, authorisation, accreditation or licensing of tissue establishments? | Yes |
| 4.2.1. How many inspections were performed in 2011 for authorising/accrediting/licensing/designating TEs? | 0 |
| 4.3. Are preparation processes authorised? | Yes |
| 4.3.1. How are they authorised? (more than 1 answer possible) | During routine inspections<br>By review of a submitted application with supporting documentation |
| 4.4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were suspended in 2011? | 0 |
| 4.5. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were revoked in | 0 |

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| 2011? | |
| 4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)? | No |
| **4bis. Overview of tissue/cells establishments authorised by the NCA** | |
| 4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible): | Cord blood tissue establishments |
| 4.7.6. How many cord blood tissue establishments? | 1 |
| 4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible): | Other tissue establishments |
| 4.8.9. Please specify the type of tissues/cells and how many. | ,,1 ( mononuclear stem cells) |
| 4.9. Tissue establishments first time authorised between 01/01/2011 and 31/12/2011 (more than 1 answer possible): | ART tissue establishments |
| 4.9.7. How many ART tissue establishments? | 1 |
| 4.10. All tissue establishments authorised by 31/12/2011 (more than 1 answer possible): | Musculo-skeletal tissue establishments<br>Cord blood tissue establishments<br>ART tissue establishments<br>Multi-tissue establishments<br>Other tissue establishments |
| 4.10.2.1. How many public musculo-skeletal tissue establishments? | 1 |
| 4.10.2.2. How many private musculo-skeletal tissue establishments? | 0 |
| 4.10.6.1. How many public cord blood tissue establishments? | 0 |
| 4.10.6.2. How many private cord blood tissue establishments? | 1 |
| 4.10.7.1. How many public ART tissue establishments? | 0 |
| 4.10.7.2. How many private ART tissue establishments? | 1 |
| 4.10.8.1. How many public multi-tissue establishments? | 1 |
| 4.10.8.2. How many private multi-tissue establishments? | 0 |
| 4.10.9.1. Please specify the type of 'other' public tissues/cells establishements and how many. | 0 |
| 4.10.9.2. Please specify the type of 'other' private tissues/cells establishements and how many. | Placental tissues |
| 4.11. How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Art. 6(5) during 2011? Please provide number(s) per type tissues/cells. | 0 |
| **4ter. Sanctions** | |
| 4.16. Have penalties for infringements of the national provisions pursuant to the Directive been defined (Article 27)? | Yes |
| 4.16.1. Have penalties already been imposed? | No |
| 4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing? | Penalties: - The Criminal law:Section 139. Illegal Removal of Tissue and Organs from a Human Being (1) For a person who commits illegal removal of tissue or organs from a deceased human being in order to use such for medical purposes, where commission thereof is by a medical practitioner, the applicable punishment is deprivation of liberty for a term not exceeding four years or temporary deprivation of liberty, or community service, or a fine, with deprivation of the right to engage in the practice of medical treatment for a term not exceeding five years. (2) For a person who commits illegal removal of tissue or organs from a living human being in order to use such for medical purposes, where commission thereof is by a medical practitioner, the applicable punishment is deprivation of liberty for a term not exceeding seven years, with deprivation of the right to engage in the practice of medical treatment for a term not exceeding five years. - State Agency of Medicines has powers to suspend or revoke authorization issued to tissue establishment if it no longer fullfils requirements of implementing national provisions. |
| **5. Inspections (Article 7, Directive 2004/23/EC)** | |
| 5.1. Is a system in place for organising inspections and control measures of tissue establishments? | Yes |
| 5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections. | State Agency of Medicines. Pharmaceutical activities compliance evaluation department is responsible for inspections. |

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| 5.1.2. If yes, please specify staffing (how many inspectors). | 2 inspectors (senior experts). |
| 5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible) | Yes |
| 5.2.1. If yes, please specify. (more than 1 answer possible) | Blood<br>Organs<br>Pharmaceuticals<br>Advanced therapies |
| 5.3. How many routine inspections of tissue establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011)? | 0 |
| 5.3.1. How many inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) following serious adverse events or reactions, or suspicion thereof ? | 0 |
| 5.3.2. How many other type of inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | 0 |
| 5.3.3. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | 0 |
| 5.3.4. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where minor shortcomings were noted? | 0 |
| 5.3.5. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where major shortcomings were noted? | 0 |
| 5.3.6. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by suspension of authorisation? | 0 |
| 5.3.7. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by closure? | 0 |
| 5.3.8. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of other inspections carried out? Please specify. | 0 |
| 5.4. How many routine inspections were conducted in ART establishments (from 1/1/2011 to 31/12/2011)? | 0 |
| 5.4.1. How many inspections were conducted in ART establishments following serious adverse events or reactions, or suspicion thereof (from 1/1/2011 to 31/12/2011)? | 0 |
| 5.4.2. How many other type of inspections were conducted on ART establishments (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | ,,1 inspection related to establishment authorization |
| 5.4.3. Outcome of inspections of ART tissue establishments carried out in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | 0 |
| 5.4.4. What was the number of inspections carried out in ART establishments where minor shortcomings were noted? | 0 |
| 5.4.5. What was the number of inspections carried out in ART establishments where major shortcomings were noted? | 0 |
| 5.4.6. What was the number of inspections carried out in ART establishments followed by suspension of authorisation? | 0 |
| 5.4.7. What was the number of inspections carried out in ART | 0 |

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| establishments followed by closure of respective establishements? | |
| 5.4.8. What was the number of other inspections of ART establishments? Please specify. | 0 |
| 5.5. Which type of routine inspections do you conduct? (more than 1 answer possible) | General system-oriented inspections<br>Thematic inspections |
| 5.6. How do you decide which type of routine inspection to conduct? | Type for routine Inspections is selected depending on the particular situation and information available to NCA. |
| 5.7. Until 2011, did you implement the requirement concerning the time interval between two inspections (Art. 7.3.)? | Yes |
| 5.8. How many TEs were inspected at least twice between 2008-2011 (01/01/2008-31/12/2011)? | 0 |
| 5.9. Did you perform/conduct inspections of procurement sites outside tissue establishments? | No |
| 5.9.2. If no, why not? | Currently there are no procurement sites outside tissue establishments. |
| 5.10. Did you carry out inspections of third parties? | No |
| 5.10.2. If no, why not? | None of authorized tissues establisments declared contracts with 3rd parties (except laboratories, please also see answer to 2.4). |
| 5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)? | Yes |
| 5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)? | Yes |
| 5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)? | 4 |
| 5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))? | No |
| 5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))? | No |
| 5.15. Did you organise any inspections of procurement centres or tissue establishments in third countries from which tissues and/or cells were imported in your country (as recorded by 31/12/2011)? | No |
| 5.16. Have you asked another MS, or have you been requested by any other MS, on the results and control measures of your inspections, as part of an enquiry/investigation? | No |
| 5.17. Would you be interested in developing joint inspections? Joint inspections should be understood as inspections of tissue establishments conducted jointly by two or more Member States' Competent Authorities on their territory or in third countries. | Yes |
| 5.18. Do you have any additional comments on inspections? | |
| **6. Import/export (Article 9 Directive 2004/23/EC)** | |
| 6.1. Do you have a register of authorised tissue establishments that are explicitly authorised to perform import/export of tissues and celles from/to third countries? | No |
| 6.2. Please specify the number of tissue establishments authorised to import tissues and cells from third countries (recorded by 31/12/2011). | 0 |
| 6.3. Please specify the number of tissue establishments authorised to export tissues and cells from third countries (recorded by 31/12/2011). | 0 |
| 6.4. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of skin from third countries. | None, because not relevant so far. If Agency would be receiving such request for imports equivalency of standards will be evaluated on case by case basis. |
| 6.5. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of | None, because not relevant so far. If Agency would be receiving such request for imports equivalency of standards will be evaluated |

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| musculo-skeletal (bone, tendons, fascia etc.) tissues from third countries. | on case by case basis. |
| 6.6. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of ophtalmic (cornea, sclera, etc) tissues from third countries. | None, because not relevant so far. If Agency would be receiving such request for imports equivalency of standards will be evaluated on case by case basis. |
| 6.7. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cardio vascular tissues from third countries. | None, because not relevant so far. If Agency would be receiving such request for imports equivalency of standards will be evaluated on case by case basis. |
| 6.8. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) (other than cord blood) from third countries. | None, because not relevant so far. If Agency would be receiving such request for imports equivalency of standards will be evaluated on case by case basis. |
| 6.9. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cord blood from third countries. | None, because not relevant so far. If Agency would be receiving such request for imports equivalency of standards will be evaluated on case by case basis. |
| 6.10. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of reproductive cells (sperm, egg cells) from third countries. | None, because not relevant so far. If Agency would be receiving such request for imports equivalency of standards will be evaluated on case by case basis. |
| 6.11. Did you import tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | No |
| 6.12. Did you export tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | No |
| 6.13. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on imports/exports of tissues/cells between your country and other third countries? | No |
| 6.14. What is the relation between import/export of tissues and cells and self-sufficiency? (more than 1 answer possible) | B. Export of tissues/cells is authorised based on estimations performed on an annual basis<br>F. Other |
| Please specify 'other': | No special conditions regarding sufficiency for authorization of imports |
| 6.15. Did you authorise direct imports of tissues/cells to hospitals/clinics in your country? | No |
| 6.16. Do you have any additional comments on import/export? | |
| **7. Distribution/intra community exchanges (Article 23 Directive 2004/23/EC)** | |
| 7.1. Do you have intra-community exchanges of tissues and cells? | No |
| 7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify. | By inspecting the SOPs and records regarding distribution, labelling. |
| 7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible). | Other |
| Please specify 'other'. | No provisions regarding distribution from TE in another MS to Latvian hospitals |
| 7.4. Have you authorised direct distribution to the recipient of specific tissues and cells (Art. 6, Directive 2006/17/EC)? | No |
| 7.5. Do you collect data regarding the cross-border exchange of tissue/cells between your country and other EU MS? | No |
| 7.6. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on cross-border exchanges of tissues/cells between your country and other EU MS? | No |
| 7.7. Do you allow brokerage companies for either distribution in EU and/or import/export of tissues/cells? In this context, a brokerage company means a body that arranges transactions between a supplier (tissue establishment/company selling tissues or cells) and a buyer (a tissue establishment/a hospital or clinic/an individual) without undertaking activities of processing, preservation or storage. | No |
| 7.8. Are brokers actively supplying health professionals/establishments in your country? | No |
| 7.9. Do you have any additional comments on distribution? | |
| **8. Register of tissue establishments and reporting obligations (Article 10, Directive 2004/23/EC)** | |

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| 8.1. Do you have an annual report model/template on the activities of tissue establishments in your Member State? (Article 10(1)). If yes, please upload the template. | No |
| 8.1.1. If no, why not? | EUROCET template is being used. |
| 8.2. How many tissue establishments submitted annual reports of their activities during 2011. Please provide an estimation. (1 answer possible) | 100% (all) |
| 8.3. Are these reports publicly available? (Article 10(1)) | No |
| 8.4. Do you publish a national annual report of the consolidated activities of all tissue establishments in your country? | No |
| 8.4.2. If no, why not? | It is still under implementation |
| 8.5. Is there a publicly accessible register of authorised tissue establishements in place? (Article 10(2)) | Yes |
| 8.5.1. If yes, please provide us with the link to the register's web site. | http://www.zva.gov.lv/doc_upl/audu-sunu-20130726.pdf |
| 8.6. Do you provide data regarding tissues and cells activities to the EUROCET registry (non-mandatory reporting)? | Yes |
| 8.6.1. If yes, what data are provided to EUROCET? Please specify. | ART data activity Tissues data activity |
| 8.7. Do you have any additional comments on reporting? | |
| **9. Traceability (Article 8, Directive 2004/23/EC; and Directive 2006/86/EC)** | |
| 9.1. Was the donor identification system (Art. 8(2)) implemented in your country? | Yes |
| 9.2. Who assigns the unique code for each donation? (only 1 answer possible) | Tissue establishment |
| 9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible) | Only paper records |
| 9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify. | Procedures ( SOP) are in place in tissue establishments, checked during inspection. |
| 9.5. Do you have any additional comments on traceability? | |
| **10. Notification of serious adverse events and reactions (Article 11 Directive 2004/23, Article 6 Directive 2006/76)** | |
| 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))? | Yes |
| 10.1.1. If yes, which CA/institution is responsible? | State Agency of Medicines |
| 10.1.2. If yes, please provide a short description of its organisation. | Senior expert of Pharmaceutical Activities Compliance Evaluation Department is responsible of data collection, documentation, analysis, corrective and preventive actions. Also for issue of RATC (if necessary) at a national level or communication to EU RATC platform, coordination of actions to be taken if RATC issued by another member state affects tissues and cells procured, processed or distributed in Latvia. |
| 10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use the SAR/E (to the CA (2006/76 art 6.4)) templates developed to the Annual reporting ot the EC also at national level? | Yes |
| 10.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level? | Yes |
| 10.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all TEs? | No |
| 10.4.1. Why not? | As the number of tissue establishments in the country is small, this task is assigned to one of inspectors. |
| 10.5. How many tissue establishments provided in 2011 the SAR/SAE data as requested (please provide the % from the total number of TEs authorised in your country). | 100% |
| 10.6. Do you have a mandatory procedure for the transplantation centres when reporting SAR/SAE to the TEs which distributed the tissues/cells (Art 11.2)? | Yes |
| 10.6.1. If yes, please provide a brief description. | All establishments using human tissues and cells for human application have to report any SAR/SAE - relevant information to tissue establishments engaged in the donation, procurement, testing, processing, storage and distribution of human tissues and cells in order to facilitate traceability and ensure quality and safety. |
| 10.7. Do you give feedback to the TEs regarding SAR/SAE recorded | No |

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| at national level? | |
| 10.7.2. Please specify why not. | No SAR/SAE was reported so far |
| 10.8. Do you give feedback to the TEs regarding SAR/SAE recorded at EU level? | No |
| 10.8.2. Please specify why not. | Still under implementation. If Latvia is affected by alert issued at EU level then TEs are contacted. Please also see answer to 10.1.2. |
| 10.9. Do you require your TEs to have a recall procedure? | Yes |
| 10.10. How many recalls related to safety and quality of tissues/cells were issued in your country in 2011? Please specify the number and which tissues were recalled and why (e.g. missing consent, quality defects etc). | 0 |
| 10.11. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites in case of a national rapid alert? | Yes |
| 10.11.1. If yes, please give a short description of the system/procedure. | According to SOP if the rapid alert is issued then all tissue establishments potentially affected are identified and contacted by phone and in writing. Depending on the information feedback the follow up measures are decided. |
| 10.12. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites when a rapid alert is issued via the EU RATC platform? | Yes |
| 10.12.1. If yes, please give a short description of the system/procedure. | According to SOP if the rapid alert is issued via EU RATC platform then all tissue establishments potentially affected are identified and contacted by phone and in writing. Depending on the information feedback the follow up measures are decided. |
| 10.13. Do you provide data regarding SAR/SAE to the EUROCET registry (non-mandatory reporting)? | No |
| 10.13.2. If no, please specify why not. | Still under implementation. |
| 10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems? | No |
| 10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S? | Yes |
| 10.15.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (insufficient) - 2 (sufficient) 3 (good) - 4 (very good) to 5 (essential)? | 4 |
| 10.16. Do you have any additional comments on SARE reporting? | |
| **11. Consent and personal data protection (Article 13 and 14, Directive 2004/23/EC)** | |
| 11.1. What consent system for living tissue/cell donation do you have in place within your Member State? | Explicit consent (opt-in) |
| 11.1.1. Please specify your choice of consent system for living tissue/cell donation. | According to national provisions in this case the explicit consent( opt-in) is mandatory |
| 11.2. What consent system for deceased tissue/cell donation do you have in place within your Member State? | Presumed (opt-out) and explicit (opt-in) consent |
| 11.2.1. If you have chosen both consent systems for deceased tissue/cell dontation, please specify. | For deceased donors consent is checked in the Citizens Register where any person during life can provide information whether he/she allows or prohibits donation of tissues/cells after death. According to national provisions if there is no information in the Citizens Register (neither authorization, nor prohibition) then it is to be considered as presumed consent but in this case first degree relatives have option to inform in writing the medical establishment regarding the deceased persons will on donation expressed during his/her life. |
| 11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible) | First degree relatives (including spouse) |
| 11.4. Is the consent system for deceased tissue donation the same as for organs? | Yes |
| 11.5. How is this consent verified during inspections? (more than 1 answer possible) | Analysis of documentation<br>Interviews with personnel |

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| 11.6. What measures are in place to ensure that donors/relatives/authorising persons on behalf of donors are provided with the appropriate information, as requested by Art. 13(2)? (more than 1 answer possible) | Only trained personnel is allowed to provide such information |
| 11.7. What measures are in place to ensure that both donors and recipients remain unidentifiable when access is given to third parties (Art. 14(1)). Please specify. | Law on protection of personal data contains provisions for handling personal data, incl. obligation to get authoriztion for handling of such data. Systems and Pprocedures must are in place that ensure that information provided to third parties is in coded/anonymized form. If personal information has to be provided to third party then provisions of the Law applies . |
| 11.8. Please specify what measures are in place to ensure that the identity of the receipient is not disclosed to the donor and vice versa. | Law on protection of personal data contains provisions for handling personal data, incl. obligation to get authoriztion for handling such data. Procedures are in place that ensure that information is in coded/anonymized form. In the Regulations there are provisions prohibiting disclosure of such data therefore tissue establishments are obliged to implement appropriate systems and procedures. |
| 11.9. Does your national legislation allows disclosure of donor data in case of gametes donation? | No |
| 11.9.1. If no, please specify the circumstances and measures in place. | Law on sexual and reproductive health paragraph 14 provisions ensures that donor data should not be dislosed: 14. Secrecy of Medical Impregnation (1) It is prohibited to disclose any data on potential parents to a gamete donor. (2) Potential parents may only obtain information regarding a gamete donors genetic and anthropometric data. |
| 11.10. Do you have any additional comments on consent and data protection? | |
| **12. Selection, evaluation and procurement (Article 15 Directive 2004/23; Annexes I-IV Directive 2006/17)** | |
| 12.1. How do you ensure that all requirements related to the evaluation and selection of donors (except donors of reproductive cells) are respected in your country (Art. 15(1), Annex I Directive 2006/17/EC)? (more than 1 answer possible) | Inspections of TEs and procurement sites<br>Audit of documentation |
| 12.2. How do you ensure that all requirements related to the evaluation and selection of donors of reproductive cells are respected in your country (Art 15 (1), Annex III of Directive 2006/17/EC)? (more than 1 answer possible) | Inspections of ART centres<br>Audit documentation<br>Regular evaluation of medical personnel |
| 12.3. Do you have more stringent criteria for donor selection than those listed in Annex I of the Directive 2006/17/EC? | No |
| 12.4. What sources are required in your MS for the evaluation of a deceased donor of tissues/cells? (more than 1 answer possible) | Interview with the donor's family or a person who knew the donor well<br>Medical records of the donor<br>Interview with the treating physician<br>Interview with the general practitioner<br>Autopsy report |
| 12.5. Do you have more stringent criteria for selection of donors of reproductive cells than those listed in Annex III of the Directive 2006/17/EC? | No |
| 12.6. Do you have more stringent criteria for autologous donation than those listed in Annex I of the Directive 2006/17/EC? | No |
| 12.7. Do you require more information on the donation of tissues/cells than the mandatory one as laid down in the Annex of Directive 2004/23/EC (Art 15(3)? | No |
| 12.8. How do you ensure that all requirements regarding tissues and cells' procurement, packaging and transport are complied with by tissue establishments in your country (Art 15(1), Annex IV of Directive 2006/17/EC? (more than 1 answer possible)(For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)) | Inspection of tissue establishment<br>Audit of tissue establishment |

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| 12.9. Do you have any additional comments on selection, evaluation and procurement? | |
| **13. Quality management, responsible person, personnel (Article 16, 17, 18 Directive 2004/23/EC)** | |
| 13.1. How do you ensure that tissue establishments in your country have in place a quality system respecting the provisions of the Directive 2004/23/EC Art 16.1? (more than 1 answer possible). (For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)). | Authorisation requirement<br>Inspections<br>Internal audits |
| 13.2. How do you ensure that tissue establishments have a responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible) | Authorisation requirement<br>Inspections |
| 13.3. How do you ensure an appropriate training for the personnel directly involved in the activities of tissue establishments? (more than 1 answer possible) | Authorisation requirement<br>Inspections<br>Regular evaluation of personnel<br>Mandatory trainings |
| 13.4. Do you have national/regional/local training programmes for the personnel of tissue establishments? | Yes |
| 13.4.1. If yes, please specify. | Each tissue establishment has local training programmes for their personnel. |
| 13.5. Any additional comments on quality management, responsible person, personnel? | |
| **14. Reception, processing, storage, labelling and packaging (Art 19-22 Directive 2004/23/EC)** | |
| 14.1. How do you ensure that tissue establishments in your country fulfill the requirments of the Art. 19 (Tissue and cell reception) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | National regulation/policy for reception of tissues/cells<br>Inspections of tissue establishments<br>Internal audits of tissue establishments |
| 14.2. How do you ensure that tissue establishments in your country fulfill the requirements of the Art. 20 (Tissue and cell processing) of Directive 2004/23/EC? (more than 1 answer possible) | SOPs for all processes affecting quality and safety are mandatory for authorisation<br>Inspections of tissue establishments<br>Internal audits of tissue establishments |
| 14.3. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 21 (tissue and cell storage conditions) of Directive 2004/23/EC? (more than 1 answer possible) | SOPs for procedures associated with storage of tissues and cells are mandatory for authorisation<br>Inspections of tissue establishments<br>Internal audits of tissue establishments |
| 14.4. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | SOPs for procedures associated with labelling and packaging are mandatory for authorisation<br>Inspections of tissue establishments<br>Internal audits of tissue establishments |
| 14.5. Any additional comments on reception, processing, storage, labelling and packaging? | |
| **15. Third party agreements (Art. 24 Directive 2004/23/EC)** | |
| 15.1. Are third party agreements foreseen/allowed in your national legislation? | Yes |
| 15.1.1. If yes, have tissue establishments in your Member State notified third party agreements? | Yes |
| 15.1.1.1. Under which circumstances and for which responsibilities? | Donor testing |
| 15.1.1.2. How are third party agreements controlled (Art 6.2) by the Competent Auhtority(ies) in your MS? Please specify. | Tissue establishments provide copies of agreements with third parties at the request of the competent authority for evaluation. During inspections agreements are reviewed and practices checked against their requirements. |
| 15.2. Any additional comments on third party agreements? | |
| **16. General comments - implementation** | |
| 16.1. Do you have at national level more stringent quality and safety requirements than those requested by the EU legislation in this field (e.g. restrictions concerning the donation/use of certain tissues/cells, mandatory unpaid donation etc.)? | No |

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| 16.2. Has your Member State encountered any difficulties in implementing the requirements in the EU Tissues and Cells Directives? Please choose from the options below. | ART provisions<br>Testing provisions<br>Distribution provisions<br>Import-export<br>Vigilance<br>Traceability |
| 16.2.1. For all selected options in question 16.2., please provide a short description. | ART provisions - very specific area therefore we think it should be regulated separately from other types or general tissues and cells Testing provisions - in small countries it is not always possible to perform testing for rare diseases Distribution provisions - if many entities are involved in procurement, transportation and other activities it is very difficult to delineate responsibilities of each involved party. Also provisions for direct distribution could be elaborated in more detail. Import-export - provisions could be elaborated in more detail. Vigilance - low awareness at tissue establishments level Traceability - if many entities (located in different countries) are involved in different activities with tissues/cells (e.g., procurement, testing, processing, banking) it is very difficult to evaluate the integrity of traceability when inspecting only local entity. Other (direct distribution, authorization for direct application) - criteria and conditions could be elaborated |
| 16.3. In your opinion, in which of the following Directives are there shortcomings (if any)? (more than 1 answer possible) | Directive 2004/23/EC<br>Directive 2006/17/EC |
| 16.3.1. How would you suggest to solve these issues in Directive 2004/23/EC? | Explain and define requirements for brokers, import/export. Also harmonize with provisions of organ directive 2010/53/EU where possible |
| 16.3.2. How would you suggest to solve these issues in Directive 2006/17/EC? | Elaborate detailed provisions regarding criteria for direct use/direct distribution |

## *A.1.17. Survey response Liechtenstein*

| **1. Public information** | |
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| 1.1. Name of National Competent Authority (NCA) 1: | Amt für Gesundheit |
| 1.1.2. Address of NCA 1: | Aeulestrasse 51 9490 Vaduz Liechtenstein |
| 1.1.3. Telephone (central access point): | 00423 236 73 25 |
| 1.1.4. E-mail (central access point): | pharminfo@llv.li |
| 1.1.5. Website: | |
| 1.1.6. The NCA is responsible for? (more than 1 answer possible) | Non-reproductive tissues and cells<br>Reproductive tissues and cells<br>Blood and blood components<br>Pharmaceuticals<br>Medical devices<br>Other |
| Please specify 'other': | reimbursement of pharmaceuticals and medical devices, public medical office, health prevention and promotion |
| 1.1.7. What are the role/tasks of the NCA? (more than 1 answer possible) | Accreditation, authorisation, licensing of TEs<br>Inspection<br>Vigilance |
| 1.2. National Competent Authority 2? | No |
| 1.5. Please give a short description of the legal status and organisation of the National Competent Authority(ies) (e.g. departments, staffing, number of senior and junior inspectors, staff working on EU affairs and legal matters, vigilance officers, budget, independence from government etc.). | The office of Public Health is a part of the Liechtenstein Administration which is dependent of the government. It consists of 6 departments and secretariat and legal support.The staff consists of 18 persons. For the issues of pharmaceuticals, medical devices, human tissues and cells and blood including vigilance two persons are in charge. More information can be found at the http://www.llv.li/amtsstellen/llv-ag-home.htm. |
| 1.6. In case of MS with federal or decentralised systems, please indicate the roles/tasks of the Regional Competent Authority(ies). (more than 1 answer possible) | Not applicable |
| 1.7. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies) for tissues and cells: | not applicable |
| **2. Procurement (Article 5 Directive 2004/23/EC)** | |
| 2.1. Do you authorise the "conditions of procurement"? | Yes |
| 2.1.1. How do you authorise the "conditions of procurement"? (more than 1 answer possible) | By inspecting all procurement centres |
| 2.1.2. How many such authorisations were granted in 2011 (01/01-31/12/2011)? | 1 |
| 2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011). | 0 |
| 2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011). | 1 |
| 2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues were carried out in 2011 (01/01-31/12/2011). | 2 |
| 2.2.4. Please provide the number of procurement centers in which procurement of tissues/cells for ATMP manufacturing were carried out in 2011 (01/01-31/12/2011). | 0 |
| 2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC and its implementing Directive 2006/17/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) ? (more than 1 answer possible) | Inspections of the site/centre |
| 2.4. Are you also responsible for the accreditation, designation, authorisation or licensing of laboratories performing donor testing? | Yes |
| 2.4.1. Please provide the number of the laboratories performing | 1 |

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| donor testing. | |
| 2.5. How do you ensure, as CA for T&C, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art. 5(2))? (more than 1 answer possible) | Analysis of the mandatory documentation requested from the tissue establishment |
| 2.6. Please provide data on qualified laboratories accredited, authorised or licensed in your country (e.g. number, year of accreditation/authorisation/license, which donor tests are performed etc.). | Labor Risch, authorisation for microbiolog. , serolog. diagnostic for blood, blood products or tissues and cells, by Swissmedic, valid till 02.11.2014 |
| 2.7. Do you have any additional comments on procurement? | |
| **3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)** | |
| 3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>HBs AG<br>Anti HBc<br>Anti HCV-Ab<br>Treponema Pallidum |
| 3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>HBs AG<br>Anti HBc<br>Anti HCV-Ab |
| 3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to encourage its use? Please specify why or why not (e.g. number of additional cases detected, cost-benefit etc.). | NAT testing is not mandatory due to the requirements of dir. 2006/17/EU, annex II and III |
| 3.4. Do you have concerns on accuracy of the available tests and test procedures for deceased donors? | No |
| 3.5. Are any other laboratory tests required for donors of non-reproductive tissues and cells in your Member State? | No |
| 3.6. Are any other laboratory tests required for donors of reproductive tissues and cells in your Member State? | No |
| 3.7. Do you request/use international accreditation systems for testing laboratories? | No |
| 3.8. Do you have any additional comments on testing? | |
| **4. Accreditation, designation, authorisation or licensing of tissue establishments (Article 6, Directive 2004/23/EC)** | |
| 4.1. Do you have a system of designation, authorisation, accreditation or licensing for all types of tissue establishments under your responsability? | Yes |
| 4.2. Is inspection a prerequisite for the designation, authorisation, accreditation or licensing of tissue establishments? | Yes |
| 4.2.1. How many inspections were performed in 2011 for authorising/accrediting/licensing/designating TEs? | 2 |
| 4.3. Are preparation processes authorised? | Yes |
| 4.3.1. How are they authorised? (more than 1 answer possible) | During routine inspections |
| 4.4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were suspended in 2011? | 0 |
| 4.5. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011? | 0 |
| 4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)? | No |
| **4bis. Overview of tissue/cells establishments authorised by the NCA** | |
| 4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible): | ART tissue establishments |
| 4.7.7. How many ART tissue establishments? | 2 |
| 4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible): | Cord blood tissue establishments |
| 4.8.6. How many cord blood tissue establishments? | 1 |

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| 4.9. Tissue establishments first time authorised between 01/01/2011 and 31/12/2011 (more than 1 answer possible): | ART tissue establishments |
| 4.9.7. How many ART tissue establishments? | 2 |
| 4.10. All tissue establishments authorised by 31/12/2011 (more than 1 answer possible): | Cord blood tissue establishments<br>ART tissue establishments |
| 4.10.6.1. How many public cord blood tissue establishments? | 1 |
| 4.10.6.2. How many private cord blood tissue establishments? | 0 |
| 4.10.7.1. How many public ART tissue establishments? | 0 |
| 4.10.7.2. How many private ART tissue establishments? | 2 |
| 4.11. How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Art. 6(5) during 2011? Please provide number(s) per type tissues/cells. | 0 |
| **4ter. Sanctions** | |
| 4.16. Have penalties for infringements of the national provisions pursuant to the Directive been defined (Article 27)? | Yes |
| 4.16.1. Have penalties already been imposed? | No |
| 4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing? | |
| **5. Inspections (Article 7, Directive 2004/23/EC)** | |
| 5.1. Is a system in place for organising inspections and control measures of tissue establishments? | Yes |
| 5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections. | Arzneimittelkontrolle, for coordination and the Swissmedic inspectorate by agreement |
| 5.1.2. If yes, please specify staffing (how many inspectors). | 3 Swissmedic inspectors |
| 5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible) | No |
| 5.3. How many routine inspections of tissue establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011)? | 0 |
| 5.3.1. How many inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) following serious adverse events or reactions, or suspicion thereof ? | 0 |
| 5.3.2. How many other type of inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | 0 |
| 5.3.3. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | none |
| 5.3.4. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where minor shortcomings were noted? | none |
| 5.3.5. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where major shortcomings were noted? | none |
| 5.3.6. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by suspension of authorisation? | none |
| 5.3.7. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by closure? | none |
| 5.3.8. Outcome of inspections of TEs for non-reproductive | none |

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| tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of other inspections carried out? Please specify. | |
| 5.4. How many routine inspections were conducted in ART establishments (from 1/1/2011 to 31/12/2011)? | 2 |
| 5.4.1. How many inspections were conducted in ART establishments following serious adverse events or reactions, or suspicion thereof (from 1/1/2011 to 31/12/2011)? | 0 |
| 5.4.2. How many other type of inspections were conducted on ART establishments (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | 0 |
| 5.4.3. Outcome of inspections of ART tissue establishments carried out in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | none |
| 5.4.4. What was the number of inspections carried out in ART establishments where minor shortcomings were noted? | 2 |
| 5.4.5. What was the number of inspections carried out in ART establishments where major shortcomings were noted? | none |
| 5.4.6. What was the number of inspections carried out in ART establishments followed by suspension of authorisation? | 0 |
| 5.4.7. What was the number of inspections carried out in ART establishments followed by closure of respective establishements? | 0 |
| 5.4.8. What was the number of other inspections of ART establishments? Please specify. | n/a |
| 5.5. Which type of routine inspections do you conduct? (more than 1 answer possible) | General system-oriented inspections |
| 5.6. How do you decide which type of routine inspection to conduct? | based on inspection results |
| 5.7. Until 2011, did you implement the requirement concerning the time interval between two inspections (Art. 7.3.)? | Yes |
| 5.8. How many TEs were inspected at least twice between 2008-2011 (01/01/2008-31/12/2011)? | n/a |
| 5.9. Did you perform/conduct inspections of procurement sites outside tissue establishments? | Yes |
| 5.9.1. If yes, how many? | 1 |
| 5.10. Did you carry out inspections of third parties? | No |
| 5.10.2. If no, why not? | n/a |
| 5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)? | Yes |
| 5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)? | Yes |
| 5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)? | 4 |
| 5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))? | No |
| 5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))? | No |
| 5.15. Did you organise any inspections of procurement centres or tissue establishments in third countries from which tissues and/or cells were imported in your country (as recorded by 31/12/2011)? | No |
| 5.16. Have you asked another MS, or have you been requested by any other MS, on the results and control measures of your inspections, as part of an enquiry/investigation? | No |
| 5.17. Would you be interested in developing joint inspections? Joint inspections should be understood as inspections of tissue establishments conducted jointly by two or more Member States' | No |

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| Competent Authorities on their territory or in third countries. | |
| 5.17.1. Could you please explain why not? | no ressources |
| 5.18. Do you have any additional comments on inspections? | |
| **6. Import/export (Article 9 Directive 2004/23/EC)** | |
| 6.1. Do you have a register of authorised tissue establishments that are explicitly authorised to perform import/export of tissues and celles from/to third countries? | No |
| 6.2. Please specify the number of tissue establishments authorised to import tissues and cells from third countries (recorded by 31/12/2011). | 0 |
| 6.3. Please specify the number of tissue establishments authorised to export tissues and cells from third countries (recorded by 31/12/2011). | 0 |
| 6.4. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of skin from third countries. | na |
| 6.5. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of musculo-skeletal (bone, tendons, fascia etc.) tissues from third countries. | na |
| 6.6. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of ophtalmic (cornea, sclera, etc) tissues from third countries. | na |
| 6.7. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cardio vascular tissues from third countries. | na |
| 6.8. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) (other than cord blood) from third countries. | na |
| 6.9. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cord blood from third countries. | na |
| 6.10. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of reproductive cells (sperm, egg cells) from third countries. | not legal |
| 6.11. Did you import tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | No |
| 6.12. Did you export tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | No |
| 6.13. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on imports/exports of tissues/cells between your country and other third countries? | No |
| 6.14. What is the relation between import/export of tissues and cells and self-sufficiency? (more than 1 answer possible) | F. Other |
| Please specify 'other': | na |
| 6.15. Did you authorise direct imports of tissues/cells to hospitals/clinics in your country? | No |
| 6.16. Do you have any additional comments on import/export? | |
| **7. Distribution/intra community exchanges (Article 23 Directive 2004/23/EC)** | |
| 7.1. Do you have intra-community exchanges of tissues and cells? | No |
| 7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify. | n/a |
| 7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible). | No |
| 7.4. Have you authorised direct distribution to the recipient of specific tissues and cells (Art. 6, Directive 2006/17/EC)? | No |
| 7.5. Do you collect data regarding the cross-border exchange of | No |

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| tissue/cells between your country and other EU MS? | |
| 7.6. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on cross-border exchanges of tissues/cells between your country and other EU MS? | No |
| 7.7. Do you allow brokerage companies for either distribution in EU and/or import/export of tissues/cells? In this context, a brokerage company means a body that arranges transactions between a supplier (tissue establishment/company selling tissues or cells) and a buyer (a tissue establishment/a hospital or clinic/an individual) without undertaking activities of processing, preservation or storage. | Yes |
| 7.7.1. Please describe the legal requirements and your role (if any) as a Competent Authority, in their authorisation/monitoring or inspection. | The legal requirements are based on the standards of dir 2004/23/EG |
| 7.8. Are brokers actively supplying health professionals/establishments in your country? | No |
| 7.9. Do you have any additional comments on distribution? | |
| **8. Register of tissue establishments and reporting obligations (Article 10, Directive 2004/23/EC)** | |
| 8.1. Do you have an annual report model/template on the activities of tissue establishments in your Member State? (Article 10(1)). If yes, please upload the template. | Yes |
| 8.2. How many tissue establishments submitted annual reports of their activities during 2011. Please provide an estimation. (1 answer possible) | <50% |
| 8.3. Are these reports publicly available? (Article 10(1)) | No |
| 8.4. Do you publish a national annual report of the consolidated activities of all tissue establishments in your country? | No |
| 8.4.2. If no, why not? | Due to data protection legislation it is not possible to publish activities of only 2 ART tissue establishments, in a tiny country the anonymity would not be given; no annual report is requested for the establishment with blood cord activities. |
| 8.5. Is there a publicly accessible register of authorised tissue establishements in place? (Article 10(2)) | No |
| 8.5.2. If no, why not? | no legal basis |
| 8.6. Do you provide data regarding tissues and cells activities to the EUROCET registry (non-mandatory reporting)? | No |
| 8.6.2. If no, why not? | no contact |
| 8.7. Do you have any additional comments on reporting? | |
| **9. Traceability (Article 8, Directive 2004/23/EC; and Directive 2006/86/EC)** | |
| 9.1. Was the donor identification system (Art. 8(2)) implemented in your country? | No |
| 9.1.1. If no, why not? | we are waiting for the new European code for tissues and cells |
| 9.2. Who assigns the unique code for each donation? (only 1 answer possible) | Other |
| Please specify 'other'. | see 9.1.1. |
| 9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible) | Only paper records |
| 9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify. | legal requirement, ensured by inspections |
| 9.5. Do you have any additional comments on traceability? | |
| **10. Notification of serious adverse events and reactions (Article 11 Directive 2004/23, Article 6 Directive 2006/76)** | |
| 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))? | Yes |
| 10.1.1. If yes, which CA/institution is responsible? | Amt für Gesundheit |
| 10.1.2. If yes, please provide a short description of its organisation. | one person resposnible for vigilance |
| 10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use the SAR/E (to the CA (2006/76 art 6.4)) templates developed to the Annual reporting ot the EC also at national level? | Yes |
| 10.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level? | Yes |
| 10.4. Do you have a dedicated vigilance officer in charge of | Yes |

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| collecting SAR/E from all TEs? | |
| 10.5. How many tissue establishments provided in 2011 the SAR/SAE data as requested (please provide the % from the total number of TEs authorised in your country). | <50% |
| 10.6. Do you have a mandatory procedure for the transplantation centres when reporting SAR/SAE to the TEs which distributed the tissues/cells (Art 11.2)? | Yes |
| 10.6.1. If yes, please provide a brief description. | by legislation |
| 10.7. Do you give feedback to the TEs regarding SAR/SAE recorded at national level? | No |
| 10.7.2. Please specify why not. | Should we? |
| 10.8. Do you give feedback to the TEs regarding SAR/SAE recorded at EU level? | No |
| 10.8.2. Please specify why not. | Should we? |
| 10.9. Do you require your TEs to have a recall procedure? | Yes |
| 10.10. How many recalls related to safety and quality of tissues/cells were issued in your country in 2011? Please specify the number and which tissues were recalled and why (e.g. missing consent, quality defects etc). | 0 |
| 10.11. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites in case of a national rapid alert? | Yes |
| 10.11.1. If yes, please give a short description of the system/procedure. | by fax and Phone |
| 10.12. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites when a rapid alert is issued via the EU RATC platform? | Yes |
| 10.12.1. If yes, please give a short description of the system/procedure. | if necessary by fax and phone |
| 10.13. Do you provide data regarding SAR/SAE to the EUROCET registry (non-mandatory reporting)? | No |
| 10.13.2. If no, please specify why not. | no contact |
| 10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems? | No |
| 10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S? | No |
| 10.15.2. If no, please specify why not. | lack of time |
| 10.16. Do you have any additional comments on SARE reporting? | |
| **11. Consent and personal data protection (Article 13 and 14, Directive 2004/23/EC)** | |
| 11.1. What consent system for living tissue/cell donation do you have in place within your Member State? | Presumed consent (opt-out) |
| 11.1.1. Please specify your choice of consent system for living tissue/cell donation. | not regulated |
| 11.2. What consent system for deceased tissue/cell donation do you have in place within your Member State? | Presumed consent (opt-out) |
| 11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible) | First degree relatives (including spouse)<br>Other |
| Please specify 'other'. | see art. 88 f-90 of Gesundheitsverordnung, LR 811.011, www.gesetze.li |
| 11.4. Is the consent system for deceased tissue donation the same as for organs? | Yes |
| 11.5. How is this consent verified during inspections? (more than 1 answer possible) | Analysis of documentation |
| 11.6. What measures are in place to ensure that donors/relatives/authorising persons on behalf of donors are provided with the appropriate information, as requested by Art. 13(2)? (more than 1 answer possible) | Only trained personnel is allowed to provide such information |
| 11.7. What measures are in place to ensure that both donors and | ID numbers are generated |

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| recipients remain unidentifiable when access is given to third parties (Art. 14(1)). Please specify. | |
| 11.8. Please specify what measures are in place to ensure that the identity of the receipient is not disclosed to the donor and vice versa. | see 11.7 |
| 11.9. Does your national legislation allows disclosure of donor data in case of gametes donation? | No |
| 11.9.1. If no, please specify the circumstances and measures in place. | not allowed |
| 11.10. Do you have any additional comments on consent and data protection? | |
| **12. Selection, evaluation and procurement (Article 15 Directive 2004/23; Annexes I-IV Directive 2006/17)** | |
| 12.1. How do you ensure that all requirements related to the evaluation and selection of donors (except donors of reproductive cells) are respected in your country (Art. 15(1), Annex I Directive 2006/17/EC)? (more than 1 answer possible) | Inspections of TEs and procurement sites |
| 12.2. How do you ensure that all requirements related to the evaluation and selection of donors of reproductive cells are respected in your country (Art 15 (1), Annex III of Directive 2006/17/EC)? (more than 1 answer possible) | Inspections of ART centres |
| 12.3. Do you have more stringent criteria for donor selection than those listed in Annex I of the Directive 2006/17/EC? | No |
| 12.4. What sources are required in your MS for the evaluation of a deceased donor of tissues/cells? (more than 1 answer possible) | Other |
| Please specify 'other'. | there are only living donors, for cord blood cells |
| 12.5. Do you have more stringent criteria for selection of donors of reproductive cells than those listed in Annex III of the Directive 2006/17/EC? | No |
| 12.6. Do you have more stringent criteria for autologous donation than those listed in Annex I of the Directive 2006/17/EC? | No |
| 12.7. Do you require more information on the donation of tissues/cells than the mandatory one as laid down in the Annex of Directive 2004/23/EC (Art 15(3)? | No |
| 12.8. How do you ensure that all requirements regarding tissues and cells' procurement, packaging and transport are complied with by tissue establishments in your country (Art 15(1), Annex IV of Directive 2006/17/EC? (more than 1 answer possible)(For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)) | Inspection of tissue establishment |
| 12.9. Do you have any additional comments on selection, evaluation and procurement? | |
| **13. Quality management, responsible person, personnel (Article 16, 17, 18 Directive 2004/23/EC)** | |
| 13.1. How do you ensure that tissue establishments in your country have in place a quality system respecting the provisions of the Directive 2004/23/EC Art 16.1? (more than 1 answer possible). (For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)). | Inspections |
| 13.2. How do you ensure that tissue establishments have a responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible) | Inspections |
| 13.3. How do you ensure an appropriate training for the personnel directly involved in the activities of tissue establishments? (more than 1 answer possible) | Inspections |

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| 13.4. Do you have national/regional/local training programmes for the personnel of tissue establishments? | No |
| 13.4.2. If no, in which country(ies) is your personnel trained? | EU countries |
| 13.4.2.1. Please specify EU-countries. | The Swissmedic inspectors have their own training programm.They participated in the EUSTITE training and PIC/s quality circles. |
| 13.5. Any additional comments on quality management, responsible person, personnel? | |
| **14. Reception, processing, storage, labelling and packaging (Art 19-22 Directive 2004/23/EC)** | |
| 14.1. How do you ensure that tissue establishments in your country fulfill the requirments of the Art. 19 (Tissue and cell reception) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | Inspections of tissue establishments |
| 14.2. How do you ensure that tissue establishments in your country fulfill the requirements of the Art. 20 (Tissue and cell processing) of Directive 2004/23/EC? (more than 1 answer possible) | Inspections of tissue establishments |
| 14.3. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 21 (tissue and cell storage conditions) of Directive 2004/23/EC? (more than 1 answer possible) | Inspections of tissue establishments |
| 14.4. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | Inspections of tissue establishments |
| 14.5. Any additional comments on reception, processing, storage, labelling and packaging? | |
| **15. Third party agreements (Art. 24 Directive 2004/23/EC)** | |
| 15.1. Are third party agreements foreseen/allowed in your national legislation? | Yes |
| 15.1.1. If yes, have tissue establishments in your Member State notified third party agreements? | No |
| 15.2. Any additional comments on third party agreements? | |
| **16. General comments - implementation** | |
| 16.1. Do you have at national level more stringent quality and safety requirements than those requested by the EU legislation in this field (e.g. restrictions concerning the donation/use of certain tissues/cells, mandatory unpaid donation etc.)? | No |
| 16.2. Has your Member State encountered any difficulties in implementing the requirements in the EU Tissues and Cells Directives? Please choose from the options below. | Other |
| 16.2.1. For all selected options in question 16.2., please provide a short description. | many activities are not applicable in Liechtenstein. |
| 16.3. In your opinion, in which of the following Directives are there shortcomings (if any)? (more than 1 answer possible) | Directive 2004/23/EC<br>Directive 2006/17/EC<br>Directive 2006/86/EC |
| 16.3.1. How would you suggest to solve these issues in Directive 2004/23/EC? | I do not know if there are shortcomings as already mentioned many activities do not take place in Liechtenstein. |
| 16.3.2. How would you suggest to solve these issues in Directive 2006/17/EC? | |
| 16.3.3. How would you suggest to solve these issues in Directive 2006/86/EC? | |

## *A.1.18. Survey response Lithuania*

| **1. Public information** | |
|---|---|
| 1.1. Name of National Competent Authority (NCA) 1: | National Transplants Bureau under the Ministry of Health of the Republic of Lithuania |
| 1.1.2. Address of NCA 1: | 2, Santariskiu street LT 08661 Vilnius Lithuania |
| 1.1.3. Telephone (central access point): | + 370 52 79 6096 |
| 1.1.4. E-mail (central access point): | info@transplantacija.lt |
| 1.1.5. Website: | www.transplantacija.lt |
| 1.1.6. The NCA is responsible for? (more than 1 answer possible) | Non-reproductive tissues and cells<br>Human organs |
| 1.1.7. What are the role/tasks of the NCA? (more than 1 answer possible) | Inspection<br>Vigilance<br>Other |
| Please specify 'other': | Coordination of all national activities in the field of donation and transplantation of human organs, tissues and cells; responsibility for crafting all necessary legislating acts regulating the field of HOTC donation and transplantation; maintenance of the National Register of Donors and Recipients for HOTC |
| 1.2. National Competent Authority 2? | Yes |
| 1.2.1. Name of National Competent Authority 2: | Ministry of Health of the Republic of Lithuania |
| 1.2.2. Address of NCA 2: | Ministry of Health of the Republic of Lithuania Vilnius str. 33, LT-01506 Vilnius, Lithuania Tel. (+370 5) 268 5110 Fax. (+370 5) 2661402 |
| 1.2.3. Telephone (central access point): | +37052685110 |
| 1.2.4. E-mail (central access point): | ministerija@sam.lt |
| 1.2.5. Website: | www.sam.lt |
| 1.2.6. The NCA is responsible for? (more than 1 answer possible) | Reproductive tissues and cells |
| 1.2.7. What are the role/tasks of the NCA? (more than 1 answer possible) | Other |
| Please specify 'other': | - |
| 1.3. National Competent Authority 3? | Yes |
| 1.3.1. Name of National Competent Authority 3: | State Health Care Accreditation Agency under the Ministry of Health |
| 1.3.2. Address of NCA 3: | Jeruzalės str. 21, LT-08420 Vilnius Tel. (+370) 5 261 51 77, Fax. (+370) 5 212 73 10 |
| 1.3.3. Telephone (central access point): | (+370) 5 261 51 77 |
| 1.3.4. E-mail (central access point): | vaspvt@vaspvt.gov.lt |
| 1.3.5. Website: | http://www.vaspvt.gov.lt/en |
| 1.3.6. The NCA is responsible for? (more than 1 answer possible) | Medical devices<br>Other |
| Please specify 'other': | - |
| 1.3.7. What are the role/tasks of the NCA? (more than 1 answer possible) | Accreditation, authorisation, licensing of TEs |
| 1.4. National Competent Authority 4? | No |
| 1.5. Please give a short description of the legal status and organisation of the National Competent Authority(ies) (e.g. departments, staffing, number of senior and junior inspectors, staff working on EU affairs and legal matters, vigilance officers, budget, independence from government etc.). | 1. National Transplant Bureau(NTB) is a National Competent Authority in charge of the implementation of quality and safety standards related to donation, procurement, testing, processing, preservation, storage, distribution and transplantation of human tissues, cells and organs. It is also engaged in inspection procedures for tissue banks and in supervising procedures for tissues, cells and organs procurement, transportation and transplantation. NTB is a State budgetary institution with staff of 25: administration 5 persons (director, deputy director, administrator, chief accountant, accountant); Transplants Coordination Division with 10 specialists (1 senior specialist for organs, 1 senior specialist for tissues and cells also acting as a vigilance officer, and the rest transplant coordinators); Legal and Supervisory Division with Head of division and 4 specialists (2 of them inspectors); Public Communications Division with Head and 4 specialists. Budget for the year 2013 is 283 thousand EUR; of which 204,5 thousand euros will be spent on salaries. 2. Family health division of the Ministry of Health is responsible for the preparation of the bill on artificial |

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| | fertilization and transposition of EU Directives. 3. State Health Care Accreditation Agency under the Ministry of Health is responsible for the accreditation, licencing and supervision of comformity to licencing conditions. |
| 1.6. In case of MS with federal or decentralised systems, please indicate the roles/tasks of the Regional Competent Authority(ies). (more than 1 answer possible) | Not applicable |
| 1.7. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies) for tissues and cells: | Not applicable |
| **2. Procurement (Article 5 Directive 2004/23/EC)** | |
| 2.1. Do you authorise the "conditions of procurement"? | Yes |
| 2.1.1. How do you authorise the "conditions of procurement"? (more than 1 answer possible) | By inspecting the documentation associated with procurement that is available in the tissue establishment working with procurement centres |
| 2.1.2. How many such authorisations were granted in 2011 (01/01-31/12/2011)? | 1 |
| 2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011). | 3 |
| 2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011). | 2 |
| 2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues were carried out in 2011 (01/01-31/12/2011). | 0 |
| 2.2.4. Please provide the number of procurement centers in which procurement of tissues/cells for ATMP manufacturing were carried out in 2011 (01/01-31/12/2011). | 0 |
| 2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC and its implementing Directive 2006/17/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) ? (more than 1 answer possible) | Analysis of the mandatory documentation |
| 2.4. Are you also responsible for the accreditation, designation, authorisation or licensing of laboratories performing donor testing? | No |
| 2.4.2. Which National Authority is in charge of this activity? | State Health Care Accreditation Agency under the Ministry of Health (VASPVT) www.vaspvt.gov.lt |
| 2.5. How do you ensure, as CA for T&C, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art. 5(2))? (more than 1 answer possible) | Inspections of the laboratories<br>Analysis of the mandatory documentation requested from the tissue establishment |
| 2.6. Please provide data on qualified laboratories accredited, authorised or licensed in your country (e.g. number, year of accreditation/authorisation/license, which donor tests are performed etc.). | There are 4 licensed laboratories, which perform donor tests: 1) laboratory of the Vilnius University Hospital Santariskiu Klinikos, licensed in 1999; 2) laboratory of the Hospital of Lithuanian University of Health Sciences Kauno klinikos, licensed in 2000; 3) laboratory of Klaipda University Hospital, licensed in 1990; 4) National Public Health Surveillance Laboratory, licensed in 2005. |
| 2.7. Do you have any additional comments on procurement? | |
| **3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)** | |
| 3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>Ag HIV<br>HBs AG<br>Anti HBc |

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| | NAT HBV<br>Anti HCV-Ab<br>NAT HCV<br>Treponema Pallidum<br>HTLV-2 |
| 3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>Treponema Pallidum |
| 3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to encourage its use? Please specify why or why not (e.g. number of additional cases detected, cost-benefit etc.). | NAT testing is mandatory for HCV, HBV. It is not mandatory for HTLV as Lithuania is not high prevalence area. NAT HIV could be mandatory to avoid ,,window period mistakes as it could shorten it from 15 to 10-12 days. But it will prolong the time of donor testing from 6 to 7.5 hrs that means in some cases (when we have multiorgan donor) organs could be lost. AntiHIV-1,2 and Ag HIV is enough to prove the negative results. From Lithuania's long practice in testin of the donated blood by NAT method there were no one case positive with HIV. |
| 3.4. Do you have concerns on accuracy of the available tests and test procedures for deceased donors? | No |
| 3.5. Are any other laboratory tests required for donors of non-reproductive tissues and cells in your Member State? | Yes |
| 3.5.1. Please specify. | Syphilis RPR, CMV IgM, CMV IgG, EBV IgG, Toxo IgG, Anti HTLV-1 |
| 3.6. Are any other laboratory tests required for donors of reproductive tissues and cells in your Member State? | No |
| 3.7. Do you request/use international accreditation systems for testing laboratories? | Yes |
| 3.7.1. Please specify. | ISO |
| 3.8. Do you have any additional comments on testing? | |
| **4. Accreditation, designation, authorisation or licensing of tissue establishments (Article 6, Directive 2004/23/EC)** | |
| 4.1. Do you have a system of designation, authorisation, accreditation or licensing for all types of tissue establishments under your responsability? | Yes |
| 4.2. Is inspection a prerequisite for the designation, authorisation, accreditation or licensing of tissue establishments? | Yes |
| 4.2.1. How many inspections were performed in 2011 for authorising/accrediting/licensing/designating TEs? | 1 |
| 4.3. Are preparation processes authorised? | Yes |
| 4.3.1. How are they authorised? (more than 1 answer possible) | By review of a submitted application with supporting documentation |
| 4.4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were suspended in 2011? | 0 |
| 4.5. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011? | 0 |
| 4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)? | No |
| **4bis. Overview of tissue/cells establishments authorised by the NCA** | |
| 4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible): | Multi-tissue establishments |
| 4.7.8. How many multi-tissue establishments? | 1 |
| 4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible): | Multi-tissue establishments |
| 4.8.8. How many multi-tissue establishments? | 0 |
| 4.9. Tissue establishments first time authorised between 01/01/2011 and 31/12/2011 (more than 1 answer possible): | Multi-tissue establishments |
| 4.9.8. How many multi-tissue establishments? | 1 |
| 4.10. All tissue establishments authorised by 31/12/2011 (more than 1 answer possible): | Cord blood tissue establishments<br>Multi-tissue establishments |

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| 4.10.6.1. How many public cord blood tissue establishments? | 0 |
| 4.10.6.2. How many private cord blood tissue establishments? | 1 |
| 4.10.8.1. How many public multi-tissue establishments? | 1 |
| 4.10.8.2. How many private multi-tissue establishments? | 0 |
| 4.11. How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Art. 6(5) during 2011? Please provide number(s) per type tissues/cells. | All together - 36 (35 units of PBSC (every time 500 ml) and 1 unit of m/sceletal tissue) |
| **4ter. Sanctions** | |
| 4.16. Have penalties for infringements of the national provisions pursuant to the Directive been defined (Article 27)? | No |
| 4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing? | |
| **5. Inspections (Article 7, Directive 2004/23/EC)** | |
| 5.1. Is a system in place for organising inspections and control measures of tissue establishments? | Yes |
| 5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections. | Legal and Supervisory Division of the National Transplant Bureau under the Ministry of Health of Lithuania in charge of inspections of non-reproductive tissues and cells |
| 5.1.2. If yes, please specify staffing (how many inspectors). | 1 (2) |
| 5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible) | No |
| 5.3. How many routine inspections of tissue establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011)? | 1 |
| 5.3.1. How many inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) following serious adverse events or reactions, or suspicion thereof ? | 0 |
| 5.3.2. How many other type of inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | 0 |
| 5.3.3. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | 1 |
| 5.3.4. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where minor shortcomings were noted? | 0 |
| 5.3.5. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where major shortcomings were noted? | 0 |
| 5.3.6. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by suspension of authorisation? | 0 |
| 5.3.7. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by closure? | 0 |
| 5.3.8. Outcome of inspections of TEs for non-reproductive | 1, just desk based inspection before TE getting licensed |

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| tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of other inspections carried out? Please specify. | |
| 5.4. How many routine inspections were conducted in ART establishments (from 1/1/2011 to 31/12/2011)? | 0 |
| 5.4.1. How many inspections were conducted in ART establishments following serious adverse events or reactions, or suspicion thereof (from 1/1/2011 to 31/12/2011)? | 0 |
| 5.4.2. How many other type of inspections were conducted on ART establishments (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | 0 |
| 5.4.3. Outcome of inspections of ART tissue establishments carried out in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | 0 |
| 5.4.4. What was the number of inspections carried out in ART establishments where minor shortcomings were noted? | 0 |
| 5.4.5. What was the number of inspections carried out in ART establishments where major shortcomings were noted? | 0 |
| 5.4.6. What was the number of inspections carried out in ART establishments followed by suspension of authorisation? | 0 |
| 5.4.7. What was the number of inspections carried out in ART establishments followed by closure of respective establishements? | 0 |
| 5.4.8. What was the number of other inspections of ART establishments? Please specify. | 0 |
| 5.5. Which type of routine inspections do you conduct? (more than 1 answer possible) | Desk based reviews |
| 5.6. How do you decide which type of routine inspection to conduct? | We are entitled to conduct only desk based reviews |
| 5.7. Until 2011, did you implement the requirement concerning the time interval between two inspections (Art. 7.3.)? | Yes |
| 5.8. How many TEs were inspected at least twice between 2008-2011 (01/01/2008-31/12/2011)? | 1 |
| 5.9. Did you perform/conduct inspections of procurement sites outside tissue establishments? | No |
| 5.9.2. If no, why not? | We were not entitled to perform such inspections between 2008-2011 |
| 5.10. Did you carry out inspections of third parties? | No |
| 5.10.2. If no, why not? | We were not entitled to perform such inspections between 2008-2011 |
| 5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)? | No |
| 5.11.1. If no, which guidelines/regulations are used for inspections at national level? | 1. For routine inspections: Law on public administration of the Republic of Lithuania. 2. The National Transplant Bureau Director's Order NoT1-37 about non-routine inspections of tissue banks and T&C&O procurement organizations : „Asmens sveikatos prie~ikros /staigs, teikian is ~mogaus audinis, lstelis ir organs bei ia ~mogaus gauts audinis ir lstelis pagamints produkts, skirts naudoti ~monms, donorysts, /sigijimo, iatyrimo, apdorojimo, konservavimo, laikymo ir paskirstymo paslaugas, neplaninis patikrinims atlikimo taisykls" |
| 5.11.2. If no, please provide a hyperlink to these guidelines/inspections. | 1. http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=123381 ; 2. http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=432986&p_query=&p_tr2=2 |
| 5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)? | Yes |
| 5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = | 5 |

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| not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)? | |
| 5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))? | No |
| 5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))? | No |
| 5.15. Did you organise any inspections of procurement centres or tissue establishments in third countries from which tissues and/or cells were imported in your country (as recorded by 31/12/2011)? | No |
| 5.16. Have you asked another MS, or have you been requested by any other MS, on the results and control measures of your inspections, as part of an enquiry/investigation? | No |
| 5.17. Would you be interested in developing joint inspections? Joint inspections should be understood as inspections of tissue establishments conducted jointly by two or more Member States' Competent Authorities on their territory or in third countries. | Yes |
| 5.18. Do you have any additional comments on inspections? | |
| **6. Import/export (Article 9 Directive 2004/23/EC)** | |
| 6.1. Do you have a register of authorised tissue establishments that are explicitly authorised to perform import/export of tissues and celles from/to third countries? | No |
| 6.2. Please specify the number of tissue establishments authorised to import tissues and cells from third countries (recorded by 31/12/2011). | 0 |
| 6.3. Please specify the number of tissue establishments authorised to export tissues and cells from third countries (recorded by 31/12/2011). | 0 |
| 6.4. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of skin from third countries. | No procedures yet as Lithuania doesn't import skin from third countries. If in the future TEs will perform import of skin, they should follow requirements of Health Care Minister Order No V-397; (21 May 2007); No V-188 (13 March 2009); No V-463 (22 June 2004); No V-401 (22 May 2007); No V-364 (14 May 2004) |
| 6.5. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of musculo-skeletal (bone, tendons, fascia etc.) tissues from third countries. | The Health Care minister Order No V-463 (22 June 2004) and other orders (see above) |
| 6.6. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of ophtalmic (cornea, sclera, etc) tissues from third countries. | The Health Care minister Order No V-463 (22 June 2004) and other orders (see above) |
| 6.7. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cardio vascular tissues from third countries. | The Health Care minister Order No V-463 (22 June 2004) and other orders (see above) |
| 6.8. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) (other than cord blood) from third countries. | The Health Care minister Order No V-463 (22 June 2004) |
| 6.9. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cord blood from third countries. | Same procedures as for other tissues and cells (see above) |
| 6.10. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of reproductive cells (sperm, egg cells) from third countries. | no (importation is not allowed) |
| 6.11. Did you import tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | Yes |

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| 6.11.1. If yes, please provide the data concerning the number/volume of imported tissues and cells by country of origin. | 4x500 ml PBSC from USA |
| 6.12. Did you export tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | No |
| 6.13. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on imports/exports of tissues/cells between your country and other third countries? | No |
| 6.14. What is the relation between import/export of tissues and cells and self-sufficiency? (more than 1 answer possible) | C. Export of tissues/cells is authorised irrespective of national needs<br>E. Import of tissues/cells is authorised based on estimations showing that there is chronic deficiency of those tissues/cells |
| 6.15. Did you authorise direct imports of tissues/cells to hospitals/clinics in your country? | Yes |
| 6.15.1. If yes, please specify the number of cases and for which type of tissues/cells. | PBSC, 32 cases (including cases from EU countries) or only 4 cases from third country (USA) |
| 6.16. Do you have any additional comments on import/export? | |
| **7. Distribution/intra community exchanges (Article 23 Directive 2004/23/EC)** | |
| 7.1. Do you have intra-community exchanges of tissues and cells? | Yes |
| 7.1.1. If yes, how do you address the possible more stringent quality and safety measures established by other Member States? Please specify. | Quality and safety measures should be the same. If we do not perform the test required in another MS, we should do it before export. |
| 7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States? | Yes |
| 7.1.2.1. How do you address this difference for tissues and cells coming from a MS with minimum quality requirements? Please specify. | Quality and safety measures should be the same. If no, there is upon the specialists who decide if they will transplant such tissues/cells or not. |
| 7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify. | Health Care Minister's Order No V-1010 Chapter X (about distribution of T&C): X. AUDINIr, LSTELIr PASKIRSTYMAS 57. Apdoroti audiniai ir lstels neturi bkti paskirstomos, kol neatitinka viss aio Apraao nustatyts reikalavims. 58. Paskirstymas atlikus audinis, lstelis /sigijim: 58.1. Kiekvienam audinis, lstelis gabenimui turi bkti skirtas lydraatis, kuriame pateikiama ai informacija: 58.1.1. donorysts data (ir laikas, jeigu galima); 58.1.2. perspjimas apie pavojs; 58.1.3. bet kokie priedai (jeigu tokie naudojami); 58.1.4. autologins donorysts atveju nurodant, kad audiniai, lstels skirti tik autologiniam naudojimui; 58.1.5. tikslins donorysts atveju nurodomas recipientas. 58.2. Jei audinius, lsteles gabena tarpininkas, kiekvienas gabenamas konteineris turi bkti pa~enklintas pateikiant toki informacij: 58.2.1. nuorod, kad konteineryje gabenami audiniai, lstels; u~raa Elgtis atsargiai; 58.2.2. /staigos, ia kurios gabenamas konteineris, pavadinim (adres, telefono numer/) ir asmen/, / kur/ galima kreiptis kilus problemoms; 58.2.3. /staigos, / kuri gabenamas konteineris, pavadinim (adres, telefono numer/) ir asmen/, / kur/ galima kreiptis, kad jis paimts konteiner/; 58.2.4. gabenimo prad~ios dat ir laik; 58.2.5. gabenimo slygs techninius reikalavimus, svarbius audinis, lstelis kokybei ir saugai; 58.2.6. audinis, lstelis produkts atveju pridti /raa Neavitinti; 58.2.7. jei ~inoma, jog audiniai, lstels teigiamai reaguoja / atitinkam u~kre iamos ligos ~ymen/, pridti u~raa Biologinis pavojus; 58.2.8. autologinis donors atveju pridti u~raa Tik autologiniam naudojimui; 58.2.9. laikymo slygs techninius reikalavimus (tokius kaip Neaaldyti). 59. Paskirstymas recipientui arba sveikatos prie~ikros /staigai: 59.1. Galutinis paskirstoms audinis, lstelis ~enklinimas: 59.1.1. Ant pirmins audinis, lstelis talpos bktina nurodyti ai informacij: 59.1.1.1. audinis, lstelis tip; 59.1.1.2. audinis, lstelis identifikavimo numer/ (prireikus, siuntos arba partijos numer/); 59.1.1.3. Audinis banko identifikavimo duomenis; 59.1.1.4. galiojimo dat; 59.1.1.5. autologins donorysts atveju reikia u~raayti nuorod (Tik autologiniam naudojimui) ir nurodyti donoro / recipiento tapatyb; 59.1.1.6. tikslins donorysts atveju etiketje reikia nurodyti numatom recipient; 59.1.1.7. kai ~inoma, kad audiniai, lstels teigiamai reaguoja / atitinkam u~kre iamos ligos ~ymen/, bktina pridti u~raa BIOLOGINIS PAVOJUS. 59.1.2. Jeigu / pirmins talpos |

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| | etiket negalima /raayti jokios 51.1 punkte nurodytos informacijos, j reikia pateikti atskirame lape, pridedamame prie pirmins talpos. `is lapas pridedamas prie pirmins talpos taip, kad bkts u~tikrinta, jog jie liks kartu. 59.1.3. Etiketje arba lydraa iuose turi bkti nurodyta ai informacija: 59.1.3.1. audinis, lstelis apraaymas (apibr~tis) ir, jei taikoma, matmenys; 59.1.3.2. jei taikoma, morfologiniai ir funkciniai duomenys; 59.1.3.3. audinis, lstelis paskirstymo data; 59.1.3.4. su donoru atlikti biologiniai tyrimai ir js rezultatai; 59.1.3.5. laikymo rekomendacijos; 59.1.3.6. talpos, pakuots atidarymo taisykls ir kita reikiama informacija, susijusi su manipuliavimu; 59.1.3.7. galiojimo datos po atidarymo / manipuliavimo; 59.1.3.8. praneaimo apie nepageidaujamas reakcijas ir (arba) reiakinius taisykls; 59.1.3.9. cheminis med~iags liku is, kurie gali bkti kenksmingi (pvz., antibiotiks, etilinoksido ir kt.), buvimas. 59.2. Gabenimo konteinerio iaors ~enklinimas: 59.2.1. Gabenant pirmin talpa turi bkti pakrauta / gabenimo konteiner/, kur/ bktina ~enklinti, nurodant bent jau ai informacij: 59.2.1.1. Audinis banko, ia kurio gabenama, identifikavimo duomenis, /skaitant adres ir telefono numer/; 59.2.1.2. u~ audinis, lstelis naudojim ~monms atsakingos /staigos (ar organizacijos), kuriai gabenama, identifikavimo duomenis, /skaitant adres ir telefono numer/; 59.2.1.3. nuorod, kad pakuotje yra ~mogaus audiniai, lstels, bei u~raa ELGTIS ATSARGIAI; 59.2.1.4. kai reikia persodinti lsteles, pavyzd~iui, kamienines lsteles, turi bkti u~raaas NE`VITINTI; 59.2.1.5. rekomenduojamos gabenimo slygos (pvz., laikyti aaltai, neapversti ir kt.); 59.2.1.6. saugos taisykles ir (arba) aaldymo bkd (kai taikoma). 59.3. Siekiant ialaikyti reikiamas audinis, lstelis savybes turi bkti nurodytos svarbios gabenimo slygos, pavyzd~iui, temperatkra ir trukm. 59.4. Talpa ir (arba) pakuot turi bkti saugi ir u~tikrinti, kad nustatytomis slygomis audiniai, lstels ialaikys reikiamas tolesniam naudojimui savybes. |
| 7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible). | Yes, but only via an authorised TE in my MS |
| 7.4. Have you authorised direct distribution to the recipient of specific tissues and cells (Art. 6, Directive 2006/17/EC)? | Yes |
| 7.4.1. If yes, how many authorisations were given in 2011 (01/01/2011 to 31/12/2011)? | 32 |
| 7.4.2. If yes, for which tissues/cells? | PBSC, musculo/sceletal |
| 7.5. Do you collect data regarding the cross-border exchange of tissue/cells between your country and other EU MS? | Yes |
| 7.5.1. Please provide us with data (country of destination, type of tissue/cell and number of units distributed) concerning distribution to other MS in 2011 (01/01/2011-31/12/2011). | From Lithuania to Irland PBSC - 1x500ml; |
| 7.5.2. Please provide us with data (country of origin, type of tissue/cell and number of units distributed) concerning distribution to other MS in 2011 (01/01/2011-31/12/2011) | From Germany to Lithuania PBSC 28x500ml; from UK to Lithuania PBSC 2x500ml; from Poland to Lithuania m/s -1 unit |
| 7.6. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on cross-border exchanges of tissues/cells between your country and other EU MS? | No |
| 7.7. Do you allow brokerage companies for either distribution in EU and/or import/export of tissues/cells? In this context, a brokerage company means a body that arranges transactions between a supplier (tissue establishment/company selling tissues or cells) and a buyer (a tissue establishment/a hospital or clinic/an individual) without undertaking activities of processing, preservation or storage. | No |
| 7.8. Are brokers actively supplying health professionals/establishments in your country? | No |
| 7.9. Do you have any additional comments on distribution? | |
| **8. Register of tissue establishments and reporting obligations (Article 10, Directive 2004/23/EC)** | |
| 8.1. Do you have an annual report model/template on the activities of tissue establishments in your Member State? (Article 10(1)). If yes, please upload the template. | Yes |

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| 8.2. How many tissue establishments submitted annual reports of their activities during 2011. Please provide an estimation. (1 answer possible) | 60-99% |
| 8.3. Are these reports publicly available? (Article 10(1)) | No |
| 8.4. Do you publish a national annual report of the consolidated activities of all tissue establishments in your country? | Yes |
| 8.4.1. Please insert the link to the published national annual report. | www.eurocet.org |
| 8.5. Is there a publicly accessible register of authorised tissue establishements in place? (Article 10(2)) | Yes |
| 8.5.1. If yes, please provide us with the link to the register's web site. | www.transplantacija.lt |
| 8.6. Do you provide data regarding tissues and cells activities to the EUROCET registry (non-mandatory reporting)? | Yes |
| 8.6.1. If yes, what data are provided to EUROCET? Please specify. | All the data regarding T&C (except ART) activities filled in the attached forms as requested by EUROCET. |
| 8.7. Do you have any additional comments on reporting? | |
| **9. Traceability (Article 8, Directive 2004/23/EC; and Directive 2006/86/EC)** | |
| 9.1. Was the donor identification system (Art. 8(2)) implemented in your country? | Yes |
| 9.2. Who assigns the unique code for each donation? (only 1 answer possible) | Tissue establishment |
| 9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible) | Both paper records and electronic forms |
| 9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify. | The Order of Health Care minister No V-397 (Lietuvos Respublikos sveikatos apsaugos ministro 2007 m. gegu~s 21 d. /sakymas Nr. V-397 "Dl mirusio ~mogaus audinis ir gyvo ~mogaus audinis ir lstelis donorysts, /sigijimo, iatyrimo, apdorojimo, konservavimo, laikymo, paskirstymo slygs bei tvarkos apraao tvirtinimo" }in., 2007, Nr. 132-5393): 34. Informacija apie donorus, siekiant visiako atsekamumo, saugoma 30 mets po js audinis, lstelis klinikinio panaudojimo arba galiojimo laiko pasibaigimo. |
| 9.5. Do you have any additional comments on traceability? | |
| **10. Notification of serious adverse events and reactions (Article 11 Directive 2004/23, Article 6 Directive 2006/76)** | |
| 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))? | Yes |
| 10.1.1. If yes, which CA/institution is responsible? | National Transplant Bureau under the Ministry of Health |
| 10.1.2. If yes, please provide a short description of its organisation. | See the answers to the question 1.1.7. and to 1.2. National Transplant Bureau performs the vigilance role according to the Order of Health Care Minister No V-401 (2007 m. gegu~s 22 d. /sakymas Nr. V-401 "Dl praneaims apie nepageidaujamas reakcijas ir (ar) reiakinius, susijusius su audinis ir lstelis /sigijimu,iatyrimu, apdorojimu, laikymu, paskirstymu ir transplantacija, tvarkos apraao patvirtinimo" (}in., 2007, Nr.58-2253; 2010, Nr. 138-7081). TE, PO and Transplant centers should report to CA about SARE, should investigate and take measures. CA submit annual reports to Health Care Ministry and to European Commission. |
| 10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use the SAR/E (to the CA (2006/76 art 6.4)) templates developed to the Annual reporting ot the EC also at national level? | Yes |
| 10.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level? | Yes |
| 10.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all TEs? | Yes |
| 10.5. How many tissue establishments provided in 2011 the SAR/SAE data as requested (please provide the % from the | 70-99% |

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| total number of TEs authorised in your country). | |
| 10.6. Do you have a mandatory procedure for the transplantation centres when reporting SAR/SAE to the TEs which distributed the tissues/cells (Art 11.2)? | Yes |
| 10.6.1. If yes, please provide a brief description. | The Health Care Minister's Order No V-401 (2007 m. gegu~s 22 d. /sakymas Nr. V-401 "Dl praneaims apie nepageidaujamas reakcijas ir (ar) reiakinius, susijusius su audinis ir lstelis /sigijimu, iatyrimu, apdorojimu, laikymu, paskirstymu ir transplantacija, tvarkos apraao patvirtinimo" (}in., 2007, Nr.58-2253; 2010, Nr. 138- 081)), article 4.3, which says exactly, that institution should report about SARE to TE which distributed T&C : 4. Praneaan ioji /staiga privalo taikyti SVP, skirtas informacijai apie /sigytus ir transplantuotus audinius ir lsteles iasaugoti, irnedelsdama praneati apie visas nepageidaujamas reakcijas aioms /staigoms: 4.1. Nacionaliniam organs transplantacijos biurui; 4.2. /staigai, gavusiai audinius, lsteles ir organus, susijusius su nepageidaujama reakcija, skirtus transplantacijai, jeigu juos paskirst praneaan ioji /staiga; 4.3. /staigai, paskirs iusiai audinius, lsteles ir organus, susijusius su nepageidaujama reakcija, jeigu juos paskirst kita /staiga. |
| 10.7. Do you give feedback to the TEs regarding SAR/SAE recorded at national level? | Yes |
| 10.7.1. Please specify. | We communicate with all TEs in case of SARE reported at national level and give them feedback according to the same Health Care Minister's Order No V-401 (see above) and according to the Order of the Director of National Transplant Bureau T1-44, 11 October 2010 „Dl keitimosi informacija apie pavojingus nepageidaujamus reiskinius ir reakcijas ~mogaus audinis ir lastelis donorysts, /sigijimo, iatyrimo, apdorojimo, konservavimo, laikymo ir paskirstymo srityje tvarkos apraao" |
| 10.8. Do you give feedback to the TEs regarding SAR/SAE recorded at EU level? | Yes |
| 10.8.1. Please specify. | We inform our TEs in cases of SARE recorded at EU level if these cases could be relevant to them according to both Orders mentioned above. |
| 10.9. Do you require your TEs to have a recall procedure? | Yes |
| 10.10. How many recalls related to safety and quality of tissues/cells were issued in your country in 2011? Please specify the number and which tissues were recalled and why (e.g. missing consent, quality defects etc). | 0 |
| 10.11. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites in case of a national rapid alert? | Yes |
| 10.11.1. If yes, please give a short description of the system/procedure. | The Order of the Director of National Transplant Bureau No T1-44, 11 October 2010 „Dl keitimosi informacija apie pavojingus nepageidaujamus reiskinius ir reakcijas ~mogaus audinis ir lastelis donorysts, /sigijimo, iatyrimo, apdorojimo, konservavimo, laikymo ir paskirstymo srityje tvarkos apraao", which stays that information about national rapid alert should be communicated to all TEs, POs, Transplant centers, Health Care Ministry and other related Competent Authorities |
| 10.12. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites when a rapid alert is issued via the EU RATC platform? | Yes |
| 10.12.1. If yes, please give a short description of the system/procedure. | The Order of the Director of National Transplant Bureau No T1-44, 11 October 2010 „Dl keitimosi informacija apie pavojingus nepageidaujamus reiskinius ir reakcijas ~mogaus audinis ir lastelis donorysts, /sigijimo, iatyrimo, apdorojimo, konservavimo, laikymo ir paskirstymo srityje tvarkos apraao" Article 2(2), which stays that information from RATC should be communicated to all TEs, POs, Transplant centers, Health Care Ministry and other related Competent Authorities. |
| 10.13. Do you provide data regarding SAR/SAE to the EUROCET registry (non-mandatory reporting)? | No |
| 10.13.2. If no, please specify why not. | it was not requested from EUROCET yet |
| 10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national | Yes |

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| vigilance/alert systems? | |
| 10.14.1. If yes, please specify which of the following systems are usually contacted. (more than 1 answer possible) | Haemovigilance<br>Medical devices |
| 10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S? | Yes |
| 10.15.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (insufficient) - 2 (sufficient) 3 (good) - 4 (very good) to 5 (essential)? | 4 |
| 10.16. Do you have any additional comments on SARE reporting? | |
| **11. Consent and personal data protection (Article 13 and 14, Directive 2004/23/EC)** | |
| 11.1. What consent system for living tissue/cell donation do you have in place within your Member State? | Explicit consent (opt-in) |
| 11.1.1. Please specify your choice of consent system for living tissue/cell donation. | The Transplant Law, Article 10(2) specifies that consent for living donation should be given by person him/herself in written form: 10 straipsnis. Transplantavimo ia gyvo donoro tvarka 1. Transplantacijai audiniai, lstels ir organai gali bkti imami ia gyvo asmens tik recipientui gydyti ir kai nra mirusio asmens tinkams audinis, lstelis ar organo bei kits efektyvis gydymo alternatyvs. 2. Imti audinius, lsteles bei organus ia gyvo veiksnaus donoro leid~iama tik gavus jo raatiak sutikim. Donoras turi teis ataaukti savo sutikim. |
| 11.2. What consent system for deceased tissue/cell donation do you have in place within your Member State? | Explicit consent (opt-in) |
| 11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible) | First degree relatives (including spouse) |
| 11.4. Is the consent system for deceased tissue donation the same as for organs? | Yes |
| 11.5. How is this consent verified during inspections? (more than 1 answer possible) | Analysis of documentation |
| 11.6. What measures are in place to ensure that donors/relatives/authorising persons on behalf of donors are provided with the appropriate information, as requested by Art. 13(2)? (more than 1 answer possible) | Only trained personnel is allowed to provide such information<br>Information for donors are standardised at national/regional level |
| 11.7. What measures are in place to ensure that both donors and recipients remain unidentifiable when access is given to third parties (Art. 14(1)). Please specify. | These rules are described in 3 Acts: I. The Order of Health Care Minister No V-1010 (7 December 2007), Art 9(6): 9.6. Visi duomenys, /skaitant bendrj informacij, sulyginami su Apraao taikymo sritimi, kuriais gali naudotis tre iosios aalys, turi bkti anoniminiai, kad nei donorai, nei recipientai nebkts identifikuoti. `iam tikslui Audinis bankas turi u~tikrinti, kad: 9.6.1. bkts pritaikytos duomens apsaugos priemons ir apsaugos /renginiai, neleid~iantys papildyti, iatrinti arba pakeisti duomens donors bylose arba /raauose apie donorysts sustabdym bei perkelti informacij; 9.6.2. bkts nustatyta tvarka, padedanti panaikinti duomens neatitikimus; 9.6.3. nebkts informacijos atskleidimo be leidimo atvejs, tuo pa iu metu garantuojant transplantants siet/. II.Government Decree on Registry (Dl }mogaus audinis, lstelis ir organs donors bei recipients registro /steigimo ir jo nuostats patvirtinimo (}in., 2000, Nr. 72-2230, 2012, Nr. 115-5834), chapter VI article 38 and 39: 38. Registro duomenys vieaai neskelbiami, iaskyrus nurodytuosius 39 punkte. 39. Vieaai gali bkti pateikiami tik apibendrinti, suvestiniai registro duomenys. III. in Transplant Law Art 3(4): 3 straipsnis. }mogaus audinis, lstelis ir organs donors bei recipients registras 1. Transplantacijos atvejai ir duomenys apie donorus ir recipientus atskirais sraaais turi bkti /raaomi / }mogaus audinis, lstelis ir organs donors bei recipients registr. 2. }mogaus audinis, lstelis ir organs donors bei recipients registr steigia ir jo nuostatus tvirtina Lietuvos Respublikos Vyriausyb. 3. Kad bkts iasaugotas donors bei recipients konfidencialumas, naudojimosi }mogaus audinis, lstelis ir organs donors bei recipients registro duomenimis tvark nustato Sveikatos apsaugos ministerija. 4. U~ }mogaus audinis, lstelis ir organs donors bei recipients registro duomens konfidencialum atsako visi fiziniai ir juridiniai asmenys, |

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| | kurie naudojasi aio registro duomenimis. |
| 11.8. Please specify what measures are in place to ensure that the identity of the receipient is not disclosed to the donor and vice versa. | Transplant Law Art 3 (3,4) and Art 5: 3. Kad bkts iasaugotas donors bei recipients konfidencialumas, naudojimosi }mogaus audinis, lstelis ir organs donors bei recipients registro duomenimis tvark nustato Sveikatos apsaugos ministerija. 4. U~ }mogaus audinis, lstelis ir organs donors bei recipients registro duomens konfidencialum atsako visi fiziniai ir juridiniai asmenys, kurie naudojasi aio registro duomenimis. 5 straipsnis. Donoro, recipiento duomens konfidencialumas Informacija apie donoro ir recipiento sveikatos bkkl, taip pat visa kita asmeninio pobkd~io informacija, tarp js ir duomenys apie asmens tapatyb, yra konfidenciali ir suteikiama tik Pacients teisis ir ~alos sveikatai atlyginimo /statymo ir kits teiss akts nustatyta tvarka. Also see above (question 11.7) |
| 11.9. Does your national legislation allows disclosure of donor data in case of gametes donation? | No |
| 11.9.1. If no, please specify the circumstances and measures in place. | 0 (gametes donation is not allowed) |
| 11.10. Do you have any additional comments on consent and data protection? | |
| **12. Selection, evaluation and procurement (Article 15 Directive 2004/23; Annexes I-IV Directive 2006/17)** | |
| 12.1. How do you ensure that all requirements related to the evaluation and selection of donors (except donors of reproductive cells) are respected in your country (Art. 15(1), Annex I Directive 2006/17/EC)? (more than 1 answer possible) | Audit of documentation |
| 12.2. How do you ensure that all requirements related to the evaluation and selection of donors of reproductive cells are respected in your country (Art 15 (1), Annex III of Directive 2006/17/EC)? (more than 1 answer possible) | Audit documentation<br>Other |
| Please specify 'other'. | Reproductive cells donation is not allowed |
| 12.3. Do you have more stringent criteria for donor selection than those listed in Annex I of the Directive 2006/17/EC? | No |
| 12.4. What sources are required in your MS for the evaluation of a deceased donor of tissues/cells? (more than 1 answer possible) | Interview with the donor's family or a person who knew the donor well<br>Medical records of the donor<br>Interview with the treating physician<br>Interview with the general practitioner<br>Autopsy report |
| 12.5. Do you have more stringent criteria for selection of donors of reproductive cells than those listed in Annex III of the Directive 2006/17/EC? | No |
| 12.6. Do you have more stringent criteria for autologous donation than those listed in Annex I of the Directive 2006/17/EC? | No |
| 12.7. Do you require more information on the donation of tissues/cells than the mandatory one as laid down in the Annex of Directive 2004/23/EC (Art 15(3)? | No |
| 12.8. How do you ensure that all requirements regarding tissues and cells' procurement, packaging and transport are complied with by tissue establishments in your country (Art 15(1), Annex IV of Directive 2006/17/EC? (more than 1 answer possible)(For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)) | Audit of tissue establishment |
| 12.9. Do you have any additional comments on selection, evaluation and procurement? | |
| **13. Quality management, responsible person, personnel (Article 16, 17, 18 Directive 2004/23/EC)** | |
| 13.1. How do you ensure that tissue establishments in your country have in place a quality system respecting the | Authorisation requirement<br>Inspections |

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| provisions of the Directive 2004/23/EC Art 16.1? (more than 1 answer possible). (For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)). | Internal audits<br>External audits |
| 13.2. How do you ensure that tissue establishments have a responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible) | Authorisation requirement<br>Inspections<br>Regular evaluation of personnel<br>Mandatory trainings |
| 13.3. How do you ensure an appropriate training for the personnel directly involved in the activities of tissue establishments? (more than 1 answer possible) | Authorisation requirement<br>Inspections<br>Regular evaluation of personnel<br>Mandatory trainings |
| 13.4. Do you have national/regional/local training programmes for the personnel of tissue establishments? | No |
| 13.4.2. If no, in which country(ies) is your personnel trained? | EU countries |
| 13.4.2.1. Please specify EU-countries. | Czech Republic, Spain |
| 13.5. Any additional comments on quality management, responsible person, personnel? | |
| **14. Reception, processing, storage, labelling and packaging (Art 19-22 Directive 2004/23/EC)** | |
| 14.1. How do you ensure that tissue establishments in your country fulfill the requirments of the Art. 19 (Tissue and cell reception) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | National regulation/policy for reception of tissues/cells<br>Inspections of tissue establishments<br>Internal audits of tissue establishments |
| 14.2. How do you ensure that tissue establishments in your country fulfill the requirements of the Art. 20 (Tissue and cell processing) of Directive 2004/23/EC? (more than 1 answer possible) | SOPs for all processes affecting quality and safety are mandatory for authorisation<br>Inspections of tissue establishments<br>Internal audits of tissue establishments |
| 14.3. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 21 (tissue and cell storage conditions) of Directive 2004/23/EC? (more than 1 answer possible) | SOPs for procedures associated with storage of tissues and cells are mandatory for authorisation<br>Inspections of tissue establishments<br>Internal audits of tissue establishments |
| 14.4. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | SOPs for procedures associated with labelling and packaging are mandatory for authorisation<br>Inspections of tissue establishments<br>Internal audits of tissue establishments |
| 14.5. Any additional comments on reception, processing, storage, labelling and packaging? | |
| **15. Third party agreements (Art. 24 Directive 2004/23/EC)** | |
| 15.1. Are third party agreements foreseen/allowed in your national legislation? | Yes |
| 15.1.1. If yes, have tissue establishments in your Member State notified third party agreements? | Yes |
| 15.1.1.1. Under which circumstances and for which responsibilities? | According Directive Art 24 and according Health Care Minister's Order No V-1010: 5.10. Audinis bankas sudaro raatiakus susitarimus su tre iosiomis aalimis kiekvien kart, kai vykdoma iaorin veikla, kuri veikia audinis, lstelis, apdorots kartu su tre ija aalimi, kokyb ir saug, ypa aiomis aplinkybmis: 5.10.1. kai Audinis bankas patiki vien ia audinis, lstelis apdorojimo etaps tre iajai aaliai; 5.10.2. kai tre ioji aalis teikia prekes ir paslaugas, kurios daro poveik/ audinis, lstelis kokybs ir saugos garantijai, taip pat ir js paskirstymui; 5.10.3. kai Audinis bankas teikia paslaugas sveikatos prie~ikros /staigai, kuri neturi licencijos Audinis banko veiklai; 5.10.4. kai Audinis bankas paskirsto tre isjs aalis apdorotus audinius, lsteles. 5.11. Audinis bankas vertina ir atrenka tre isias aalis, remdamasis js galimybmis atitikti Apraae nustatytus reikalavimus. 5.12. Susitarimai tarp Audinis banko ir tre isjs aalis tiksliai nustato tre isjs aalis atsakomyb ir iasami veiklos tvark. |

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| | 5.14. Nacionalinio transplantacijos biuro praaymu Audinis bankai privalo pateikti susitarims su tre iosiomis aalimis kopijas. |
| 15.1.1.2. How are third party agreements controlled (Art 6.2) by the Competent Auhtority(ies) in your MS? Please specify. | According Health Care Minister's Order No V-1010: 5.14. Nacionalinio transplantacijos biuro praaymu Audinis bankai privalo pateikti susitarims su tre iosiomis aalimis kopijas. |
| 15.2. Any additional comments on third party agreements? | |
| **16. General comments - implementation** | |
| 16.1. Do you have at national level more stringent quality and safety requirements than those requested by the EU legislation in this field (e.g. restrictions concerning the donation/use of certain tissues/cells, mandatory unpaid donation etc.)? | Yes |
| 16.1.1. Please specify. | Mandatory unpaid donation. Commercial donation is forbidden. According Transplant Law Art.11(1): 11 straipsnis. Komercinis sandoris neleistinumas 1. Gyvo ar mirusio ~mogaus audiniai, lstels ir organai negali bkti civilinis komercinis sandoris objektas. Taip pat draud~iama skelbti apie ~mogaus audinis, lstelis ir organs poreik/ arba js prieinamum, siekiant finansins arba panaaios naudos. |
| 16.2. Has your Member State encountered any difficulties in implementing the requirements in the EU Tissues and Cells Directives? Please choose from the options below. | ART provisions<br>Other |
| 16.2.1. For all selected options in question 16.2., please provide a short description. | The Law on ART has not been approved since 2001 due to differences of political parties views |
| 16.3. In your opinion, in which of the following Directives are there shortcomings (if any)? (more than 1 answer possible) | No shortcomings |

## *A.1.19. Survey response Luxembourg*

| **1. Public information** | |
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| 1.1. Name of National Competent Authority (NCA) 1: | Ministère de la Santé |
| 1.1.2. Address of NCA 1: | Villa Louvigny - allée Marconi L-2120 LUXEMBOURG |
| 1.1.3. Telephone (central access point): | +352 2478 5505 |
| 1.1.4. E-mail (central access point): | Ministere-Sante@ms.etat.lu |
| 1.1.5. Website: | http://www.ms.public.lu/fr/ |
| 1.1.6. The NCA is responsible for? (more than 1 answer possible) | Non-reproductive tissues and cells<br>Reproductive tissues and cells<br>Blood and blood components<br>Human organs<br>Pharmaceuticals<br>Medical devices |
| 1.1.7. What are the role/tasks of the NCA? (more than 1 answer possible) | Accreditation, authorisation, licensing of TEs<br>Inspection<br>Vigilance |
| 1.2. National Competent Authority 2? | No |
| 1.5. Please give a short description of the legal status and organisation of the National Competent Authority(ies) (e.g. departments, staffing, number of senior and junior inspectors, staff working on EU affairs and legal matters, vigilance officers, budget, independence from government etc.). | Ministry of Health with the Directorate of Health - Governemental Institution |
| 1.6. In case of MS with federal or decentralised systems, please indicate the roles/tasks of the Regional Competent Authority(ies). (more than 1 answer possible) | Not applicable |
| 1.7. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies) for tissues and cells: | / |
| **2. Procurement (Article 5 Directive 2004/23/EC)** | |
| 2.1. Do you authorise the "conditions of procurement"? | Yes |
| 2.1.1. How do you authorise the "conditions of procurement"? (more than 1 answer possible) | By inspecting all procurement centres<br>By inspecting the documentation associated with procurement that is available in the tissue establishment working with procurement centres |
| 2.1.2. How many such authorisations were granted in 2011 (01/01-31/12/2011)? | none |
| 2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011). | 5 |
| 2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011). | 0 |
| 2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues were carried out in 2011 (01/01-31/12/2011). | 1 |
| 2.2.4. Please provide the number of procurement centers in which procurement of tissues/cells for ATMP manufacturing were carried out in 2011 (01/01-31/12/2011). | 0 |
| 2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC and its implementing Directive 2006/17/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) ? (more than 1 answer possible) | Inspections of the site/centre<br>Analysis of the mandatory documentation |
| 2.4. Are you also responsible for the accreditation, designation, authorisation or licensing of laboratories performing donor testing? | Yes |
| 2.4.1. Please provide the number of the laboratories performing donor testing. | 3 |
| 2.5. How do you ensure, as CA for T&C, that tests required for | Inspections of the laboratories |

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| donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art. 5(2))? (more than 1 answer possible) | Analysis of the mandatory documentation requested from the tissue establishment |
| 2.6. Please provide data on qualified laboratories accredited, authorised or licensed in your country (e.g. number, year of accreditation/authorisation/license, which donor tests are performed etc.). | laboratories accreditated according our general legislation on laboratories; all donor tests as foreseen in the directives |
| 2.7. Do you have any additional comments on procurement? | / |
| **3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)** | |
| 3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>HBs AG<br>Anti HBc<br>Anti HCV-Ab<br>Treponema Pallidum |
| 3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>HBs AG<br>Anti HBc<br>Anti HCV-Ab<br>HTLV-2<br>Treponema Pallidum |
| 3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to encourage its use? Please specify why or why not (e.g. number of additional cases detected, cost-benefit etc.). | / |
| 3.4. Do you have concerns on accuracy of the available tests and test procedures for deceased donors? | No |
| 3.5. Are any other laboratory tests required for donors of non-reproductive tissues and cells in your Member State? | No |
| 3.6. Are any other laboratory tests required for donors of reproductive tissues and cells in your Member State? | No |
| 3.7. Do you request/use international accreditation systems for testing laboratories? | No |
| 3.8. Do you have any additional comments on testing? | / |
| **4. Accreditation, designation, authorisation or licensing of tissue establishments (Article 6, Directive 2004/23/EC)** | |
| 4.1. Do you have a system of designation, authorisation, accreditation or licensing for all types of tissue establishments under your responsability? | Yes |
| 4.2. Is inspection a prerequisite for the designation, authorisation, accreditation or licensing of tissue establishments? | Yes |
| 4.2.1. How many inspections were performed in 2011 for authorising/accrediting/licensing/designating TEs? | 0 |
| 4.3. Are preparation processes authorised? | No |
| 4.4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were suspended in 2011? | 0 |
| 4.5. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011? | 0 |
| 4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)? | No |
| **4bis. Overview of tissue/cells establishments authorised by the NCA** | |
| 4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible): | Musculo-skeletal tissue establishments |
| 4.7.2. How many musculo-skeletal tissue establishments? | 0 |
| 4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible): | Musculo-skeletal tissue establishments |
| 4.8.2. How many musculo-skeletal tissue establishments? | 0 |
| 4.9. Tissue establishments first time authorised between 01/01/2011 | Other tissue establishments |

| | |
|---|---|
| and 31/12/2011 (more than 1 answer possible): | |
| 4.9.9. Please specify the type of tissues/cells and how many. | / |
| 4.10. All tissue establishments authorised by 31/12/2011 (more than 1 answer possible): | Musculo-skeletal tissue establishments<br>ART tissue establishments |
| 4.10.2.1. How many public musculo-skeletal tissue establishments? | 0 |
| 4.10.2.2. How many private musculo-skeletal tissue establishments? | 1 |
| 4.10.7.1. How many public ART tissue establishments? | 0 |
| 4.10.7.2. How many private ART tissue establishments? | 1 |
| 4.11. How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Art. 6(5) during 2011? Please provide number(s) per type tissues/cells. | / |
| **4ter. Sanctions** | |
| 4.16. Have penalties for infringements of the national provisions pursuant to the Directive been defined (Article 27)? | Yes |
| 4.16.1. Have penalties already been imposed? | No |
| 4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing? | |
| **5. Inspections (Article 7, Directive 2004/23/EC)** | |
| 5.1. Is a system in place for organising inspections and control measures of tissue establishments? | Yes |
| 5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections. | Division de la médecine curative |
| 5.1.2. If yes, please specify staffing (how many inspectors). | 2 |
| 5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible) | No |
| 5.3. How many routine inspections of tissue establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011)? | 1 |
| 5.3.1. How many inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) following serious adverse events or reactions, or suspicion thereof ? | 0 |
| 5.3.2. How many other type of inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | 0 |
| 5.3.3. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | 0 |
| 5.3.4. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where minor shortcomings were noted? | 0 |
| 5.3.5. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where major shortcomings were noted? | 0 |
| 5.3.6. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by suspension of authorisation? | 0 |
| 5.3.7. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by closure? | 0 |
| 5.3.8. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What | 0 |

| | |
|---|---|
| was the number of other inspections carried out? Please specify. | |
| 5.4. How many routine inspections were conducted in ART establishments (from 1/1/2011 to 31/12/2011)? | 1 |
| 5.4.1. How many inspections were conducted in ART establishments following serious adverse events or reactions, or suspicion thereof (from 1/1/2011 to 31/12/2011)? | 0 |
| 5.4.2. How many other type of inspections were conducted on ART establishments (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | 0 |
| 5.4.3. Outcome of inspections of ART tissue establishments carried out in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | 0 |
| 5.4.4. What was the number of inspections carried out in ART establishments where minor shortcomings were noted? | 0 |
| 5.4.5. What was the number of inspections carried out in ART establishments where major shortcomings were noted? | 0 |
| 5.4.6. What was the number of inspections carried out in ART establishments followed by suspension of authorisation? | 0 |
| 5.4.7. What was the number of inspections carried out in ART establishments followed by closure of respective establishements? | 0 |
| 5.4.8. What was the number of other inspections of ART establishments? Please specify. | 0 |
| 5.5. Which type of routine inspections do you conduct? (more than 1 answer possible) | General system-oriented inspections<br>Desk based reviews |
| 5.6. How do you decide which type of routine inspection to conduct? | / |
| 5.7. Until 2011, did you implement the requirement concerning the time interval between two inspections (Art. 7.3.)? | Yes |
| 5.8. How many TEs were inspected at least twice between 2008-2011 (01/01/2008-31/12/2011)? | 1 |
| 5.9. Did you perform/conduct inspections of procurement sites outside tissue establishments? | Yes |
| 5.9.1. If yes, how many? | > 1 |
| 5.10. Did you carry out inspections of third parties? | No |
| 5.10.2. If no, why not? | not appropriate |
| 5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)? | Yes |
| 5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)? | No |
| 5.12.2. Why not? | not possible |
| 5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))? | No |
| 5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))? | No |
| 5.15. Did you organise any inspections of procurement centres or tissue establishments in third countries from which tissues and/or cells were imported in your country (as recorded by 31/12/2011)? | No |
| 5.16. Have you asked another MS, or have you been requested by any other MS, on the results and control measures of your inspections, as part of an enquiry/investigation? | No |
| 5.17. Would you be interested in developing joint inspections? Joint inspections should be understood as inspections of tissue establishments conducted jointly by two or more Member States' Competent Authorities on their territory or in third countries. | No |
| 5.17.1. Could you please explain why not? | no time |
| 5.18. Do you have any additional comments on inspections? | / |

| **6. Import/export (Article 9 Directive 2004/23/EC)** | |
|---|---|
| 6.1. Do you have a register of authorised tissue establishments that are explicitly authorised to perform import/export of tissues and celles from/to third countries? | No |
| 6.2. Please specify the number of tissue establishments authorised to import tissues and cells from third countries (recorded by 31/12/2011). | 0 |
| 6.3. Please specify the number of tissue establishments authorised to export tissues and cells from third countries (recorded by 31/12/2011). | 0 |
| 6.4. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of skin from third countries. | / |
| 6.5. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of musculo-skeletal (bone, tendons, fascia etc.) tissues from third countries. | / |
| 6.6. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of ophtalmic (cornea, sclera, etc) tissues from third countries. | / |
| 6.7. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cardio vascular tissues from third countries. | / |
| 6.8. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) (other than cord blood) from third countries. | / |
| 6.9. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cord blood from third countries. | / |
| 6.10. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of reproductive cells (sperm, egg cells) from third countries. | / |
| 6.11. Did you import tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | No |
| 6.12. Did you export tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | No |
| 6.13. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on imports/exports of tissues/cells between your country and other third countries? | No |
| 6.14. What is the relation between import/export of tissues and cells and self-sufficiency? (more than 1 answer possible) | F. Other |
| Please specify 'other': | no import/export |
| 6.15. Did you authorise direct imports of tissues/cells to hospitals/clinics in your country? | No |
| 6.16. Do you have any additional comments on import/export? | |
| **7. Distribution/intra community exchanges (Article 23 Directive 2004/23/EC)** | |
| 7.1. Do you have intra-community exchanges of tissues and cells? | No |
| 7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify. | audit |
| 7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible). | Yes, no restrictions apply |
| 7.4. Have you authorised direct distribution to the recipient of specific tissues and cells (Art. 6, Directive 2006/17/EC)? | No |
| 7.5. Do you collect data regarding the cross-border exchange of tissue/cells between your country and other EU MS? | No |
| 7.6. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on cross-border exchanges of tissues/cells | No |

| | |
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| between your country and other EU MS? | |
| 7.7. Do you allow brokerage companies for either distribution in EU and/or import/export of tissues/cells? In this context, a brokerage company means a body that arranges transactions between a supplier (tissue establishment/company selling tissues or cells) and a buyer (a tissue establishment/a hospital or clinic/an individual) without undertaking activities of processing, preservation or storage. | No |
| 7.8. Are brokers actively supplying health professionals/establishments in your country? | No |
| 7.9. Do you have any additional comments on distribution? | |
| **8. Register of tissue establishments and reporting obligations (Article 10, Directive 2004/23/EC)** | |
| 8.1. Do you have an annual report model/template on the activities of tissue establishments in your Member State? (Article 10(1)). If yes, please upload the template. | No |
| 8.1.1. If no, why not? | / |
| 8.2. How many tissue establishments submitted annual reports of their activities during 2011. Please provide an estimation. (1 answer possible) | 100% (all) |
| 8.3. Are these reports publicly available? (Article 10(1)) | No |
| 8.4. Do you publish a national annual report of the consolidated activities of all tissue establishments in your country? | No |
| 8.4.2. If no, why not? | / |
| 8.5. Is there a publicly accessible register of authorised tissue establishements in place? (Article 10(2)) | No |
| 8.5.2. If no, why not? | information given on demand |
| 8.6. Do you provide data regarding tissues and cells activities to the EUROCET registry (non-mandatory reporting)? | Yes |
| 8.6.1. If yes, what data are provided to EUROCET? Please specify. | ART |
| 8.7. Do you have any additional comments on reporting? | |
| **9. Traceability (Article 8, Directive 2004/23/EC; and Directive 2006/86/EC)** | |
| 9.1. Was the donor identification system (Art. 8(2)) implemented in your country? | Yes |
| 9.2. Who assigns the unique code for each donation? (only 1 answer possible) | Tissue establishment |
| 9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible) | Both paper records and electronic forms |
| 9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify. | / |
| 9.5. Do you have any additional comments on traceability? | |
| **10. Notification of serious adverse events and reactions (Article 11 Directive 2004/23, Article 6 Directive 2006/76)** | |
| 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))? | Yes |
| 10.1.1. If yes, which CA/institution is responsible? | Direction de la Santé |
| 10.1.2. If yes, please provide a short description of its organisation. | / |
| 10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use the SAR/E (to the CA (2006/76 art 6.4)) templates developed to the Annual reporting ot the EC also at national level? | Yes |
| 10.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level? | Yes |
| 10.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all TEs? | No |
| 10.4.1. Why not? | not enough personnal |
| 10.5. How many tissue establishments provided in 2011 the SAR/SAE data as requested (please provide the % from the total number of TEs authorised in your country). | 100% |
| 10.6. Do you have a mandatory procedure for the transplantation centres when reporting SAR/SAE to the TEs which distributed the tissues/cells (Art 11.2)? | No |
| 10.6.2. If no, how do you ensure that SAR/SAE are reported to the TEs? | on case by case |

| | |
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| 10.7. Do you give feedback to the TEs regarding SAR/SAE recorded at national level? | Yes |
| 10.7.1. Please specify. | case by case |
| 10.8. Do you give feedback to the TEs regarding SAR/SAE recorded at EU level? | Yes |
| 10.8.1. Please specify. | case by case |
| 10.9. Do you require your TEs to have a recall procedure? | Yes |
| 10.10. How many recalls related to safety and quality of tissues/cells were issued in your country in 2011? Please specify the number and which tissues were recalled and why (e.g. missing consent, quality defects etc). | 0 |
| 10.11. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites in case of a national rapid alert? | Yes |
| 10.11.1. If yes, please give a short description of the system/procedure. | email - fax - telephone |
| 10.12. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites when a rapid alert is issued via the EU RATC platform? | Yes |
| 10.12.1. If yes, please give a short description of the system/procedure. | email - fax - telephone |
| 10.13. Do you provide data regarding SAR/SAE to the EUROCET registry (non-mandatory reporting)? | Yes |
| 10.13.1. If yes, please specify what data. | if then ART |
| 10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems? | No |
| 10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S? | No |
| 10.15.2. If no, please specify why not. | no time |
| 10.16. Do you have any additional comments on SARE reporting? | |
| **11. Consent and personal data protection (Article 13 and 14, Directive 2004/23/EC)** | |
| 11.1. What consent system for living tissue/cell donation do you have in place within your Member State? | Explicit consent (opt-in) |
| 11.1.1. Please specify your choice of consent system for living tissue/cell donation. | the person must give his or hers authorization |
| 11.2. What consent system for deceased tissue/cell donation do you have in place within your Member State? | Explicit consent (opt-in) |
| 11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible) | First degree relatives (including spouse) |
| 11.4. Is the consent system for deceased tissue donation the same as for organs? | No |
| 11.4.1. If no, please describe the difference. | organs = opt out system |
| 11.5. How is this consent verified during inspections? (more than 1 answer possible) | Analysis of documentation |
| 11.6. What measures are in place to ensure that donors/relatives/authorising persons on behalf of donors are provided with the appropriate information, as requested by Art. 13(2)? (more than 1 answer possible) | Only trained personnel is allowed to provide such information |
| 11.7. What measures are in place to ensure that both donors and recipients remain unidentifiable when access is given to third parties (Art. 14(1)). Please specify. | coding |
| 11.8. Please specify what measures are in place to ensure that the identity of the receipient is not disclosed to the donor and vice versa. | coding |
| 11.9. Does your national legislation allows disclosure of donor data in case of gametes donation? | Yes |
| 11.10. Do you have any additional comments on consent and data protection? | |
| **12. Selection, evaluation and procurement (Article 15 Directive 2004/23; Annexes I-IV Directive 2006/17)** | |

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|---|---|
| 12.1. How do you ensure that all requirements related to the evaluation and selection of donors (except donors of reproductive cells) are respected in your country (Art. 15(1), Annex I Directive 2006/17/EC)? (more than 1 answer possible) | Inspections of TEs and procurement sites<br>Audit of documentation |
| 12.2. How do you ensure that all requirements related to the evaluation and selection of donors of reproductive cells are respected in your country (Art 15 (1), Annex III of Directive 2006/17/EC)? (more than 1 answer possible) | Inspections of ART centres<br>Audit documentation |
| 12.3. Do you have more stringent criteria for donor selection than those listed in Annex I of the Directive 2006/17/EC? | No |
| 12.4. What sources are required in your MS for the evaluation of a deceased donor of tissues/cells? (more than 1 answer possible) | Interview with the donor's family or a person who knew the donor well<br>Medical records of the donor |
| 12.5. Do you have more stringent criteria for selection of donors of reproductive cells than those listed in Annex III of the Directive 2006/17/EC? | No |
| 12.6. Do you have more stringent criteria for autologous donation than those listed in Annex I of the Directive 2006/17/EC? | No |
| 12.7. Do you require more information on the donation of tissues/cells than the mandatory one as laid down in the Annex of Directive 2004/23/EC (Art 15(3)? | No |
| 12.8. How do you ensure that all requirements regarding tissues and cells' procurement, packaging and transport are complied with by tissue establishments in your country (Art 15(1), Annex IV of Directive 2006/17/EC? (more than 1 answer possible)(For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)) | Inspection of tissue establishment<br>Audit of tissue establishment |
| 12.9. Do you have any additional comments on selection, evaluation and procurement? | |
| **13. Quality management, responsible person, personnel (Article 16, 17, 18 Directive 2004/23/EC)** | |
| 13.1. How do you ensure that tissue establishments in your country have in place a quality system respecting the provisions of the Directive 2004/23/EC Art 16.1? (more than 1 answer possible). (For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)). | Authorisation requirement<br>Inspections |
| 13.2. How do you ensure that tissue establishments have a responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible) | Authorisation requirement<br>Inspections |
| 13.3. How do you ensure an appropriate training for the personnel directly involved in the activities of tissue establishments? (more than 1 answer possible) | Authorisation requirement<br>Inspections |
| 13.4. Do you have national/regional/local training programmes for the personnel of tissue establishments? | No |
| 13.4.2. If no, in which country(ies) is your personnel trained? | EU countries |
| 13.4.2.1. Please specify EU-countries. | / |
| 13.5. Any additional comments on quality management, responsible person, personnel? | |
| **14. Reception, processing, storage, labelling and packaging (Art 19-22 Directive 2004/23/EC)** | |
| 14.1. How do you ensure that tissue establishments in your country fulfill the requirments of the Art. 19 (Tissue and cell reception) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | Inspections of tissue establishments<br>Internal audits of tissue establishments |

| | |
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| 14.2. How do you ensure that tissue establishments in your country fulfill the requirements of the Art. 20 (Tissue and cell processing) of Directive 2004/23/EC? (more than 1 answer possible) | SOPs for all processes affecting quality and safety are mandatory for authorisation<br>Inspections of tissue establishments |
| 14.3. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 21 (tissue and cell storage conditions) of Directive 2004/23/EC? (more than 1 answer possible) | SOPs for procedures associated with storage of tissues and cells are mandatory for authorisation<br>Inspections of tissue establishments |
| 14.4. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | SOPs for procedures associated with labelling and packaging are mandatory for authorisation<br>Inspections of tissue establishments |
| 14.5. Any additional comments on reception, processing, storage, labelling and packaging? | |
| **15. Third party agreements (Art. 24 Directive 2004/23/EC)** | |
| 15.1. Are third party agreements foreseen/allowed in your national legislation? | No |
| 15.2. Any additional comments on third party agreements? | |
| **16. General comments - implementation** | |
| 16.1. Do you have at national level more stringent quality and safety requirements than those requested by the EU legislation in this field (e.g. restrictions concerning the donation/use of certain tissues/cells, mandatory unpaid donation etc.)? | No |
| 16.2. Has your Member State encountered any difficulties in implementing the requirements in the EU Tissues and Cells Directives? Please choose from the options below. | No difficulties |
| 16.2.1. For all selected options in question 16.2., please provide a short description. | / |
| 16.3. In your opinion, in which of the following Directives are there shortcomings (if any)? (more than 1 answer possible) | No shortcomings |

## *A.1.20. Survey response Malta*

| **1. Public information** | |
|---|---|
| 1.1. Name of National Competent Authority (NCA) 1: | Superintendence of Public Health, Ministry for Health, Malta |
| 1.1.2. Address of NCA 1: | SLH-OPD- Level 1 St. Lukes Square, Gwardamangia PTA1010 |
| 1.1.3. Telephone (central access point): | (+00356) 25953326/8 |
| 1.1.4. E-mail (central access point): | healthstandards.sph@gov.mt |
| 1.1.5. Website: | https://ehealth.gov.mt/HealthPortal/public_health/publichealthregulation/introduction.aspx and https://ehealth.gov.mt/HealthPortal/public_health/healthcare_serv_standards/tissues_cells_organs.aspx |
| 1.1.6. The NCA is responsible for? (more than 1 answer possible) | Non-reproductive tissues and cells<br>Reproductive tissues and cells<br>Blood and blood components<br>Human organs<br>Pharmaceuticals<br>Other |
| Please specify 'other': | Public Health Regulation, Health Care Standards, Health Promotion/Disease Prevention and Environmental Health |
| 1.1.7. What are the role/tasks of the NCA? (more than 1 answer possible) | Accreditation, authorisation, licensing of TEs<br>Inspection<br>Vigilance |
| 1.2. National Competent Authority 2? | No |
| 1.5. Please give a short description of the legal status and organisation of the National Competent Authority(ies) (e.g. departments, staffing, number of senior and junior inspectors, staff working on EU affairs and legal matters, vigilance officers, budget, independence from government etc.). | The National Competent Authority is the Superintendent of Public Health. The Superintendence has three directorates under its remit- 1.The Health Care Standards Directorate which is accountable to the Superintendent of Public Health in managing issues related to the regulation of subtances of Human Origin. There is just one person responsible for this area, the Director who is a consultant in Public Health and is responsible for regulatory matters related to SOHO, inspections, authorisations, related EU and legal matters and SOHO vigilance. 2. The Health Promotion/Disease Prevention Directorate 3. The Environmental Health Directorate. The Medicines Authority also falls under the Superintendence from the technical point of view |
| 1.6. In case of MS with federal or decentralised systems, please indicate the roles/tasks of the Regional Competent Authority(ies). (more than 1 answer possible) | Not applicable |
| 1.7. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies) for tissues and cells: | Not applicable- There are no regional Competent Authorities. |
| **2. Procurement (Article 5 Directive 2004/23/EC)** | |
| 2.1. Do you authorise the "conditions of procurement"? | Yes |
| 2.1.1. How do you authorise the "conditions of procurement"? (more than 1 answer possible) | By inspecting all procurement centres<br>By inspecting the documentation associated with procurement that is available in the tissue establishment working with procurement centres |
| 2.1.2. How many such authorisations were granted in 2011 (01/01-31/12/2011)? | Provisional Authorisations were given to two cord blood companies in 2011. These have now been fully authorised in 2013 together with another new cord blood procurement organisation. |
| 2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011). | 0 |
| 2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011). | 2 |
| 2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues were carried out in 2011 (01/01-31/12/2011). | 0 |
| 2.2.4. Please provide the number of procurement centers in which | 0 |

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| procurement of tissues/cells for ATMP manufacturing were carried out in 2011 (01/01-31/12/2011). | |
| 2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC and its implementing Directive 2006/17/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) ? (more than 1 answer possible) | Inspections of the site/centre<br>Analysis of the mandatory documentation |
| 2.4. Are you also responsible for the accreditation, designation, authorisation or licensing of laboratories performing donor testing? | Yes |
| 2.4.1. Please provide the number of the laboratories performing donor testing. | Cord blood procurement organisations in Malta store cord blood in tissue/cell establishments abroad and in such cases the testing is done by the mother company abroad |
| 2.5. How do you ensure, as CA for T&C, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art. 5(2))? (more than 1 answer possible) | Analysis of the mandatory documentation requested from the tissue establishment |
| 2.6. Please provide data on qualified laboratories accredited, authorised or licensed in your country (e.g. number, year of accreditation/authorisation/license, which donor tests are performed etc.). | 0 |
| 2.7. Do you have any additional comments on procurement? | Nil |
| **3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)** | |
| 3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>HBs AG<br>Anti HBc<br>Anti HCV-Ab<br>Treponema Pallidum |
| 3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>HBs AG<br>Anti HBc<br>Anti HCV-Ab<br>Treponema Pallidum |
| 3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to encourage its use? Please specify why or why not (e.g. number of additional cases detected, cost-benefit etc.). | There is no intention to make it mandatory. The prevalence of HIV/Hep B etc in Malta is low and a cost-benefit analysis does not warrant its introduction |
| 3.4. Do you have concerns on accuracy of the available tests and test procedures for deceased donors? | No |
| 3.5. Are any other laboratory tests required for donors of non-reproductive tissues and cells in your Member State? | No |
| 3.6. Are any other laboratory tests required for donors of reproductive tissues and cells in your Member State? | No |
| 3.7. Do you request/use international accreditation systems for testing laboratories? | No |
| 3.8. Do you have any additional comments on testing? | Nil |
| **4. Accreditation, designation, authorisation or licensing of tissue establishments (Article 6, Directive 2004/23/EC)** | |
| 4.1. Do you have a system of designation, authorisation, accreditation or licensing for all types of tissue establishments under your responsability? | Yes |
| 4.2. Is inspection a prerequisite for the designation, authorisation, accreditation or licensing of tissue establishments? | Yes |
| 4.2.1. How many inspections were performed in 2011 for authorising/accrediting/licensing/designating TEs? | 2 |
| 4.3. Are preparation processes authorised? | Yes |
| 4.3.1. How are they authorised? (more than 1 answer possible) | During routine inspections<br>During inspections organised for this purpose<br>By review of a submitted application with supporting documentation |
| 4.4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), | Nil |

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| how many authorisations/accreditation/licenses were suspended in 2011? | |
| 4.5. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011? | Nil |
| 4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)? | No |
| **4bis. Overview of tissue/cells establishments authorised by the NCA** | |
| 4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible): | Cord blood tissue establishments |
| 4.7.6. How many cord blood tissue establishments? | 2 procurement organisations |
| 4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible): | Other tissue establishments |
| 4.8.9. Please specify the type of tissues/cells and how many. | Two cord blood procurement organisations |
| 4.9. Tissue establishments first time authorised between 01/01/2011 and 31/12/2011 (more than 1 answer possible): | Other tissue establishments |
| 4.9.9. Please specify the type of tissues/cells and how many. | Two cord blood procurement organisations which have now been authorised. |
| 4.10. All tissue establishments authorised by 31/12/2011 (more than 1 answer possible): | Other tissue establishments |
| 4.10.9.1. Please specify the type of 'other' public tissues/cells establishements and how many. | Nil |
| 4.10.9.2. Please specify the type of 'other' private tissues/cells establishements and how many. | 2 cord blood procurement organisations which were in the process of being authorised and were then authorised in 2012 |
| 4.11. How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Art. 6(5) during 2011? Please provide number(s) per type tissues/cells. | Nil |
| **4ter. Sanctions** | |
| 4.16. Have penalties for infringements of the national provisions pursuant to the Directive been defined (Article 27)? | Yes |
| 4.16.1. Have penalties already been imposed? | No |
| 4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing? | Nil |
| **5. Inspections (Article 7, Directive 2004/23/EC)** | |
| 5.1. Is a system in place for organising inspections and control measures of tissue establishments? | Yes |
| 5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections. | The Superintendence of Public Health |
| 5.1.2. If yes, please specify staffing (how many inspectors). | 1 expert on tissues and Cells and two GMP inspectors |
| 5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible) | Yes |
| 5.2.1. If yes, please specify. (more than 1 answer possible) | Blood<br>Organs<br>Advanced therapies<br>Hospitals |
| 5.3. How many routine inspections of tissue establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011)? | Nil |
| 5.3.1. How many inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) following serious adverse events or reactions, or suspicion thereof ? | Nil |
| 5.3.2. How many other type of inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | nil |
| 5.3.3. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What | 0 |

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| was the number of inspections carried out where no shortcomings were observed? | |
| 5.3.4. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where minor shortcomings were noted? | 2 cord blood procurement organisations |
| 5.3.5. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where major shortcomings were noted? | 0 |
| 5.3.6. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by suspension of authorisation? | Nil |
| 5.3.7. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by closure? | Nil |
| 5.3.8. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of other inspections carried out? Please specify. | Not applicable |
| 5.4. How many routine inspections were conducted in ART establishments (from 1/1/2011 to 31/12/2011)? | 0 |
| 5.4.1. How many inspections were conducted in ART establishments following serious adverse events or reactions, or suspicion thereof (from 1/1/2011 to 31/12/2011)? | 0 |
| 5.4.2. How many other type of inspections were conducted on ART establishments (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | 0 |
| 5.4.3. Outcome of inspections of ART tissue establishments carried out in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | 0 |
| 5.4.4. What was the number of inspections carried out in ART establishments where minor shortcomings were noted? | 0 |
| 5.4.5. What was the number of inspections carried out in ART establishments where major shortcomings were noted? | 0 |
| 5.4.6. What was the number of inspections carried out in ART establishments followed by suspension of authorisation? | 0 |
| 5.4.7. What was the number of inspections carried out in ART establishments followed by closure of respective establishements? | 0 |
| 5.4.8. What was the number of other inspections of ART establishments? Please specify. | 0 |
| 5.5. Which type of routine inspections do you conduct? (more than 1 answer possible) | General system-oriented inspections<br>Desk based reviews |
| 5.6. How do you decide which type of routine inspection to conduct? | Depending on the nature of the organisation- whetehr it is a procurment organisation with storage of tissues/cells in establishments in Eu or EEA Member States, the nature of tissues and cells collected and the nature of processes. |
| 5.7. Until 2011, did you implement the requirement concerning the time interval between two inspections (Art. 7.3.)? | Yes |
| 5.8. How many TEs were inspected at least twice between 2008-2011 (01/01/2008-31/12/2011)? | 0 |
| 5.9. Did you perform/conduct inspections of procurement sites outside tissue establishments? | Yes |
| 5.9.1. If yes, how many? | 2 |
| 5.10. Did you carry out inspections of third parties? | Yes |
| 5.10.1. If yes, how many? | 1 |
| 5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)? | Yes |

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| 5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)? | Yes |
| 5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)? | 5 |
| 5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))? | No |
| 5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))? | No |
| 5.15. Did you organise any inspections of procurement centres or tissue establishments in third countries from which tissues and/or cells were imported in your country (as recorded by 31/12/2011)? | No |
| 5.16. Have you asked another MS, or have you been requested by any other MS, on the results and control measures of your inspections, as part of an enquiry/investigation? | No |
| 5.17. Would you be interested in developing joint inspections? Joint inspections should be understood as inspections of tissue establishments conducted jointly by two or more Member States' Competent Authorities on their territory or in third countries. | Yes |
| 5.18. Do you have any additional comments on inspections? | Malta has to rely on the help of other inspectors from EU member states to assist the local inspectors during the inspections |
| **6. Import/export (Article 9 Directive 2004/23/EC)** | |
| 6.1. Do you have a register of authorised tissue establishments that are explicitly authorised to perform import/export of tissues and celles from/to third countries? | No |
| 6.2. Please specify the number of tissue establishments authorised to import tissues and cells from third countries (recorded by 31/12/2011). | 0 |
| 6.3. Please specify the number of tissue establishments authorised to export tissues and cells from third countries (recorded by 31/12/2011). | 0 |
| 6.4. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of skin from third countries. | Notification of the import to the Competent Authority who verifies the equivalence of standards and a requirement of cerification by the responsible person of the exporting tissue establishment stating the equivalence of standards |
| 6.5. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of musculo-skeletal (bone, tendons, fascia etc.) tissues from third countries. | Notification of the import to the Competent Authority who verifies the equivalence of standards and a requirement of cerification by the responsible person of the exporting tissue establishment stating the equivalence of standards |
| 6.6. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of ophtalmic (cornea, sclera, etc) tissues from third countries. | Notification of the import to the Competent Authority who verifies the equivalence of standards and a requirement of cerification by the responsible person of the exporting tissue establishment stating the equivalence of standards. No such importations have as yet taken place. |
| 6.7. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cardio vascular tissues from third countries. | Notification of the import to the Competent Authority who verifies the equivalence of standards and a requirement of cerification by the responsible person of the exporting tissue establishment stating the equivalence of standards. No such imporations have as yet taken place. |
| 6.8. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) (other than cord blood) from third countries. | Notification of the import to the Competent Authority who verifies the equivalence of standards and a requirement cerification of the responsible person of the exporting tissue establishment stating the equivalence of standards. No such imporations have as yet taken place. |
| 6.9. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cord blood from third countries. | Notification of the import to the Competent Authority who verifies the equivalence of standards and a requirement cerification of the responsible person of the exporting tissue establishment stating the equivalence of standards. No such importations have as yet taken |

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| | place. |
| 6.10. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of reproductive cells (sperm, egg cells) from third countries. | Not applicable. Importation of gametes is not allowed in Malta |
| 6.11. Did you import tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | Yes |
| 6.11.1. If yes, please provide the data concerning the number/volume of imported tissues and cells by country of origin. | Skin- from Netherlands |
| 6.12. Did you export tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | No |
| 6.13. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on imports/exports of tissues/cells between your country and other third countries? | No |
| 6.14. What is the relation between import/export of tissues and cells and self-sufficiency? (more than 1 answer possible) | F. Other |
| Please specify 'other': | Import is considered when the tissues/cells are not avalable locally at all. |
| 6.15. Did you authorise direct imports of tissues/cells to hospitals/clinics in your country? | Yes |
| 6.15.1. If yes, please specify the number of cases and for which type of tissues/cells. | Demineralised bone matrix |
| 6.16. Do you have any additional comments on import/export? | Nil |
| **7. Distribution/intra community exchanges (Article 23 Directive 2004/23/EC)** | |
| 7.1. Do you have intra-community exchanges of tissues and cells? | No |
| 7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify. | They have to be certified by the responsible person of the tissue establishment distributing them. |
| 7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible). | Other |
| Please specify 'other'. | Direct distribution to hospitals/clinics through brokers after notification of the Competent Authority who authorises the import if the relevant documentation shows equivalence of standards |
| 7.4. Have you authorised direct distribution to the recipient of specific tissues and cells (Art. 6, Directive 2006/17/EC)? | Yes |
| 7.4.1. If yes, how many authorisations were given in 2011 (01/01/2011 to 31/12/2011)? | One |
| 7.4.2. If yes, for which tissues/cells? | Demineralised bone martix |
| 7.5. Do you collect data regarding the cross-border exchange of tissue/cells between your country and other EU MS? | No |
| 7.6. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on cross-border exchanges of tissues/cells between your country and other EU MS? | No |
| 7.7. Do you allow brokerage companies for either distribution in EU and/or import/export of tissues/cells? In this context, a brokerage company means a body that arranges transactions between a supplier (tissue establishment/company selling tissues or cells) and a buyer (a tissue establishment/a hospital or clinic/an individual) without undertaking activities of processing, preservation or storage. | Yes |
| 7.7.1. Please describe the legal requirements and your role (if any) as a Competent Authority, in their authorisation/monitoring or inspection. | The Competent Authority has to be notified regarding each and every importation, requests further information, analyses the information provided and only gives authorisation for importaion after equivalence of standards is verified |
| 7.8. Are brokers actively supplying health professionals/establishments in your country? | Yes |
| 7.8.1. Where are the brokers located? | Your country |
| 7.9. Do you have any additional comments on distribution? | Nil |
| **8. Register of tissue establishments and reporting obligations (Article 10, Directive 2004/23/EC)** | |
| 8.1. Do you have an annual report model/template on the activities of tissue establishments in your Member State? (Article 10(1)). If | Yes |

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| yes, please upload the template. | |
| 8.2. How many tissue establishments submitted annual reports of their activities during 2011. Please provide an estimation. (1 answer possible) | 100% (all) |
| 8.3. Are these reports publicly available? (Article 10(1)) | Yes |
| 8.3.1. If yes, please insert the link(s) to the report(s). | https://ehealth.gov.mt/HealthPortal/public_health/healthcare_serv_standards/tissues_cells_organs.aspx |
| 8.4. Do you publish a national annual report of the consolidated activities of all tissue establishments in your country? | Yes |
| 8.4.1. Please insert the link to the published national annual report. | https://ehealth.gov.mt/HealthPortal/public_health/healthcare_serv_standards/tissues_cells_organs.aspx |
| 8.5. Is there a publicly accessible register of authorised tissue establishements in place? (Article 10(2)) | Yes |
| 8.5.1. If yes, please provide us with the link to the register's web site. | https://ehealth.gov.mt/HealthPortal/public_health/healthcare_serv_standards/tissues_cells_organs.aspx |
| 8.6. Do you provide data regarding tissues and cells activities to the EUROCET registry (non-mandatory reporting)? | Yes |
| 8.6.1. If yes, what data are provided to EUROCET? Please specify. | Data on procurement of cord blood and distribution of any imported tissues (such as imported skin or bone matrix for clinical application in Malta). |
| 8.7. Do you have any additional comments on reporting? | Nil |
| **9. Traceability (Article 8, Directive 2004/23/EC; and Directive 2006/86/EC)** | |
| 9.1. Was the donor identification system (Art. 8(2)) implemented in your country? | Yes |
| 9.2. Who assigns the unique code for each donation? (only 1 answer possible) | Procurement centre |
| 9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible) | Both paper records and electronic forms |
| 9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify. | By randomly checking that donations till now can be traced and overseeing that procurement organisations have adequate data backup sytems and checking that they also have in place a system wherby data can be stored even in case of closure of the establishment. |
| 9.5. Do you have any additional comments on traceability? | Nil |
| **10. Notification of serious adverse events and reactions (Article 11 Directive 2004/23, Article 6 Directive 2006/76)** | |
| 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))? | Yes |
| 10.1.1. If yes, which CA/institution is responsible? | The Superintendence of Public Health |
| 10.1.2. If yes, please provide a short description of its organisation. | The Superintendence of Public Health is made up of three directorates- (1) The Directorate for Health Care Standards (2) the Health Promotion and Disease Surveillnace Directortyae and the Environmental Health Directorate. The Vigilance sytem is taken care of by the Health Care Standards Directorate. The same directorate also takes care of the haemovigilance system and vigilance and surveillnce related to organ transplants. |
| 10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use the SAR/E (to the CA (2006/76 art 6.4)) templates developed to the Annual reporting ot the EC also at national level? | Yes |
| 10.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level? | Yes |
| 10.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all TEs? | Yes |
| 10.5. How many tissue establishments provided in 2011 the SAR/SAE data as requested (please provide the % from the total number of TEs authorised in your country). | 100% |
| 10.6. Do you have a mandatory procedure for the transplantation centres when reporting SAR/SAE to the TEs which distributed the tissues/cells (Art 11.2)? | Yes |
| 10.6.1. If yes, please provide a brief description. | Transplantation centres have to report to the Tissue establishments which distributed the tissues/cells. The tissue/cell establishments |

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| | then investigate the issue and report to the Competent Authority. Transplantation centres are also obliged to inform the Competent Authority when such SAR/SAEs occur. |
| 10.7. Do you give feedback to the TEs regarding SAR/SAE recorded at national level? | Yes |
| 10.7.1. Please specify. | An annual report consolidated report is posted on the website |
| 10.8. Do you give feedback to the TEs regarding SAR/SAE recorded at EU level? | Yes |
| 10.8.1. Please specify. | An annual report consolidated report is posted on the website |
| 10.9. Do you require your TEs to have a recall procedure? | Yes |
| 10.10. How many recalls related to safety and quality of tissues/cells were issued in your country in 2011? Please specify the number and which tissues were recalled and why (e.g. missing consent, quality defects etc). | Nil |
| 10.11. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites in case of a national rapid alert? | Yes |
| 10.11.1. If yes, please give a short description of the system/procedure. | The same directorate responsible for Vigilance and Surveilance system for Tissues/Cell is also responsible for the national rapid alert sytem. The system also communicates with rapid alert sytems for blood and other substances of human origin. It can also send alerts to the Malta Medicines Authority whhich is responsible for Pharmacovigilance and to the MCCAA which is the Competent Authority responsible for Medical Devices. |
| 10.12. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites when a rapid alert is issued via the EU RATC platform? | Yes |
| 10.12.1. If yes, please give a short description of the system/procedure. | The same directorate responsible for Vigilance and Surveilance system for Tissues/Cell is the Directorate that receives the alerts through the RATC platform and is also responsible for the national rapid alert sytem. The system also communicates with rapid alert sytems for blood and other substances of human origin. It can also send alerts to the Malta Medicines Authority whhich is responsible for Pharmacovigilance and to the MCCAA which is the Competent Authority responsible for Medical Devices. The alert can be also cascaded to tissue establishments and procurement sites and also to end users like hospitals and transplantation centres. |
| 10.13. Do you provide data regarding SAR/SAE to the EUROCET registry (non-mandatory reporting)? | Yes |
| 10.13.1. If yes, please specify what data. | Cord blood procurement data. |
| 10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems? | Yes |
| 10.14.1. If yes, please specify which of the following systems are usually contacted. (more than 1 answer possible) | Haemovigilance<br>Pharmacovilance<br>Medical devices<br>Other |
| Please specify 'other'. | End users, transpnt centres including the organ tranplant centre. |
| 10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S? | Yes |
| 10.15.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (insufficient) - 2 (sufficient) 3 (good) - 4 (very good) to 5 (essential)? | 5 |
| 10.16. Do you have any additional comments on SARE reporting? | Nil |
| **11. Consent and personal data protection (Article 13 and 14, Directive 2004/23/EC)** | |
| 11.1. What consent system for living tissue/cell donation do you have in place within your Member State? | Explicit consent (opt-in) |
| 11.1.1. Please specify your choice of consent system for living tissue/cell donation. | It is considered that the donor has a right to decide whether to donate or not. |
| 11.2. What consent system for deceased tissue/cell donation do you | Explicit consent (opt-in) |

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| have in place within your Member State? | |
| 11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible) | First degree relatives (including spouse)<br>Other relatives |
| 11.4. Is the consent system for deceased tissue donation the same as for organs? | Yes |
| 11.5. How is this consent verified during inspections? (more than 1 answer possible) | Analysis of documentation |
| 11.6. What measures are in place to ensure that donors/relatives/authorising persons on behalf of donors are provided with the appropriate information, as requested by Art. 13(2)? (more than 1 answer possible) | Only trained personnel is allowed to provide such information |
| 11.7. What measures are in place to ensure that both donors and recipients remain unidentifiable when access is given to third parties (Art. 14(1)). Please specify. | The donors and recipients are given a unique identifier number. |
| 11.8. Please specify what measures are in place to ensure that the identity of the receipient is not disclosed to the donor and vice versa. | The identity of the donor is not revealed to the recipient and all precautions are taken so that any material is given a unique identifier number that can only be traced back by the procurement organisation or tissue establishment as the the traceability requrements dictate and in the case of a need for look-back procedures in investigations or by the Competent Authority during investigations. |
| 11.9. Does your national legislation allows disclosure of donor data in case of gametes donation? | No |
| 11.9.1. If no, please specify the circumstances and measures in place. | Not applicable as gamete donation is not permitted in Malta. |
| 11.10. Do you have any additional comments on consent and data protection? | Data Protection is ensured through the Data Protection Act of 2001. |
| **12. Selection, evaluation and procurement (Article 15 Directive 2004/23; Annexes I-IV Directive 2006/17)** | |
| 12.1. How do you ensure that all requirements related to the evaluation and selection of donors (except donors of reproductive cells) are respected in your country (Art. 15(1), Annex I Directive 2006/17/EC)? (more than 1 answer possible) | Audit of documentation |
| 12.2. How do you ensure that all requirements related to the evaluation and selection of donors of reproductive cells are respected in your country (Art 15 (1), Annex III of Directive 2006/17/EC)? (more than 1 answer possible) | Audit documentation |
| 12.3. Do you have more stringent criteria for donor selection than those listed in Annex I of the Directive 2006/17/EC? | No |
| 12.4. What sources are required in your MS for the evaluation of a deceased donor of tissues/cells? (more than 1 answer possible) | Interview with the donor's family or a person who knew the donor well<br>Medical records of the donor<br>Interview with the treating physician<br>Interview with the general practitioner<br>Autopsy report |
| 12.5. Do you have more stringent criteria for selection of donors of reproductive cells than those listed in Annex III of the Directive 2006/17/EC? | No |
| 12.6. Do you have more stringent criteria for autologous donation than those listed in Annex I of the Directive 2006/17/EC? | No |
| 12.7. Do you require more information on the donation of tissues/cells than the mandatory one as laid down in the Annex of Directive 2004/23/EC (Art 15(3)? | No |
| 12.8. How do you ensure that all requirements regarding tissues and cells' procurement, packaging and transport are complied with by tissue establishments in your country (Art 15(1), Annex IV of Directive 2006/17/EC? (more than 1 answer possible)(For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to | Inspection of tissue establishment<br>Inspection of the centre of human application (e.g. transplantation centre, ART centre)<br>Other |

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| the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)) | |
| 12.8.1. Please specify. | Related information is also requested in the Tissue Establishment Dossier that is requested prior to inspections. This dossier and the documentation therein is inspected by the Licensing Authority prior to the onsite inspection. |
| 12.9. Do you have any additional comments on selection, evaluation and procurement? | Nil |
| **13. Quality management, responsible person, personnel (Article 16, 17, 18 Directive 2004/23/EC)** | |
| 13.1. How do you ensure that tissue establishments in your country have in place a quality system respecting the provisions of the Directive 2004/23/EC Art 16.1? (more than 1 answer possible). (For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)). | Authorisation requirement<br>Inspections |
| 13.2. How do you ensure that tissue establishments have a responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible) | Authorisation requirement<br>Inspections |
| 13.3. How do you ensure an appropriate training for the personnel directly involved in the activities of tissue establishments? (more than 1 answer possible) | Authorisation requirement<br>Inspections<br>Other |
| Please specify 'other'. | At inspection, the inspectorate team asks for documentation of training for the personnel directly involved in the activities of tissue establishments. |
| 13.4. Do you have national/regional/local training programmes for the personnel of tissue establishments? | Yes |
| 13.4.1. If yes, please specify. | The training undergone depends on the type of personnel. The Tissue Establishment has to have a Quality Manual that defines the job description and the qualifications and training required by the personnel. It has to define how the training is to be provided, the proficiency testing of the personnel and the documentation of such training/proficiency tests and competencies of the personnel. |
| 13.5. Any additional comments on quality management, responsible person, personnel? | Nil |
| **14. Reception, processing, storage, labelling and packaging (Art 19-22 Directive 2004/23/EC)** | |
| 14.1. How do you ensure that tissue establishments in your country fulfill the requirments of the Art. 19 (Tissue and cell reception) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | National regulation/policy for reception of tissues/cells<br>Inspections of tissue establishments |
| 14.2. How do you ensure that tissue establishments in your country fulfill the requirements of the Art. 20 (Tissue and cell processing) of Directive 2004/23/EC? (more than 1 answer possible) | SOPs for all processes affecting quality and safety are mandatory for authorisation<br>Inspections of tissue establishments |
| 14.3. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 21 (tissue and cell storage conditions) of Directive 2004/23/EC? (more than 1 answer possible) | SOPs for procedures associated with storage of tissues and cells are mandatory for authorisation<br>Inspections of tissue establishments |
| 14.4. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | SOPs for procedures associated with labelling and packaging are mandatory for authorisation<br>Inspections of tissue establishments |
| 14.5. Any additional comments on reception, processing, storage, labelling and packaging? | Nil |
| **15. Third party agreements (Art. 24 Directive 2004/23/EC)** | |
| 15.1. Are third party agreements foreseen/allowed in your national legislation? | Yes |
| 15.1.1. If yes, have tissue establishments in your Member State notified third party agreements? | Yes |
| 15.1.1.1. Under which circumstances and for which responsibilities? | Cord blood procurement organisations have third party agreements |

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| | with clinical teams responsible for procurement. |
| 15.1.1.2. How are third party agreements controlled (Art 6.2) by the Competent Auhtority(ies) in your MS? Please specify. | The procurement organisation/tissue establishment has to have a documented list of third parties with which it has agreements and has to have documented copied of the agreement. The agreements have to define the responsibilities of both parties with definition of SOPs for all the processes and control measures that could affect the quality and safety of the tissues and cells. |
| 15.2. Any additional comments on third party agreements? | Nil |
| **16. General comments - implementation** | |
| 16.1. Do you have at national level more stringent quality and safety requirements than those requested by the EU legislation in this field (e.g. restrictions concerning the donation/use of certain tissues/cells, mandatory unpaid donation etc.)? | No |
| 16.2. Has your Member State encountered any difficulties in implementing the requirements in the EU Tissues and Cells Directives? Please choose from the options below. | No difficulties |
| 16.2.1. For all selected options in question 16.2., please provide a short description. | Not applicable |
| 16.3. In your opinion, in which of the following Directives are there shortcomings (if any)? (more than 1 answer possible) | No shortcomings |

## *A.1.21. Survey response Netherlands*

| **1. Public information** | |
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| 1.1. Name of National Competent Authority (NCA) 1: | Ministry of Health, Welfare and Sport (Ministerie voor Volksgezondheid, Welzijn en Sport, VWS) |
| 1.1.2. Address of NCA 1: | P.O. Box 20350 2500 EJ Den Haag The Netherlands |
| 1.1.3. Telephone (central access point): | + 31 70 340 7911 |
| 1.1.4. E-mail (central access point): | - |
| 1.1.5. Website: | www.minvws.nl |
| 1.1.6. The NCA is responsible for? (more than 1 answer possible) | Non-reproductive tissues and cells<br>Reproductive tissues and cells<br>Blood and blood components<br>Human organs<br>Pharmaceuticals<br>Medical devices |
| 1.1.7. What are the role/tasks of the NCA? (more than 1 answer possible) | Accreditation, authorisation, licensing of TEs<br>Other |
| Please specify 'other': | policy making |
| 1.2. National Competent Authority 2? | Yes |
| 1.2.1. Name of National Competent Authority 2: | Health Care Inspectorate (Inspectie voor de Gezondheidszorg, IGZ) |
| 1.2.2. Address of NCA 2: | P.O Box 2680 3500 GR Utrecht The Netherlands |
| 1.2.3. Telephone (central access point): | + 31 (0)88-120 5000 |
| 1.2.4. E-mail (central access point): | meldpunt@igz.nl |
| 1.2.5. Website: | www.igz.nl |
| 1.2.6. The NCA is responsible for? (more than 1 answer possible) | Non-reproductive tissues and cells<br>Reproductive tissues and cells<br>Blood and blood components<br>Human organs<br>Pharmaceuticals<br>Medical devices |
| 1.2.7. What are the role/tasks of the NCA? (more than 1 answer possible) | Inspection<br>Vigilance |
| 1.3. National Competent Authority 3? | Yes |
| 1.3.1. Name of National Competent Authority 3: | Dutch Transplantation Foundation (Nederlandse Transplantatie Stichting, NTS) |
| 1.3.2. Address of NCA 3: | P.O.Box 2304 2301 CH Leiden The Netherlands |
| 1.3.3. Telephone (central access point): | + 31 (0)71 5795 777 |
| 1.3.4. E-mail (central access point): | info@transplantatiestichting.nl |
| 1.3.5. Website: | http://www.transplantatiestichting.nl/ |
| 1.3.6. The NCA is responsible for? (more than 1 answer possible) | Non-reproductive tissues and cells<br>Reproductive tissues and cells<br>Human organs |
| 1.3.7. What are the role/tasks of the NCA? (more than 1 answer possible) | Other |
| Please specify 'other': | donor registry, patient waiting list, allocation of organs and tissues. |
| 1.4. National Competent Authority 4? | No |
| 1.5. Please give a short description of the legal status and organisation of the National Competent Authority(ies) (e.g. departments, staffing, number of senior and junior inspectors, staff working on EU affairs and legal matters, vigilance officers, budget, independence from government etc.). | NCA1 Ministerie van Volksgezondheid, Welzijn en Sport ( VWS, Ministry of Health, Welfare and Sport); responsible for policy making; divisions Public Health, Curative Care, Long-term Care; staffing: total 4200 fte's, 8 dedicated to EU (legal) affairs; budget ca € 18 billion; NCA2 Inspectie voor de GezondheidsZorg (IGZ, Health Care Inspectorate); independent part of ministry of Health, Welfare and Sport; departements: Cure, care, pharmaceutical products (including organs, tissues, cells, and blood); budget € 60 million; staffing: total 500, 300 dedicated to inspections, specific tissues and cells; staff for international/European inspection and vigilance: 2 senior, 1 junior, 1 support, 1 legal. NCA3 Nederlandse TransplantatieStichting (NTS, Dutch Transplantation Foundation); legally assigned as Organcenter, in charge of donor registry, patient waiting list, allocation of organs and tissues; budget € 30 million; staffing: total 65; |

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| 1.6. In case of MS with federal or decentralised systems, please indicate the roles/tasks of the Regional Competent Authority(ies). (more than 1 answer possible) | Not applicable |
| 1.7. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies) for tissues and cells: | N/a |
| **2. Procurement (Article 5 Directive 2004/23/EC)** | |
| 2.1. Do you authorise the "conditions of procurement"? | Yes |
| 2.1.1. How do you authorise the "conditions of procurement"? (more than 1 answer possible) | By inspecting the documentation associated with procurement that is available in the tissue establishment working with procurement centres |
| 2.1.2. How many such authorisations were granted in 2011 (01/01-31/12/2011)? | 18 TE; Conditions of procurement were inspected and granted at each inspection of TE, except when at inspections for authorisations for import and distributions. |
| 2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011). | 38 |
| 2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011). | 11 |
| 2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues were carried out in 2011 (01/01-31/12/2011). | 80 |
| 2.2.4. Please provide the number of procurement centers in which procurement of tissues/cells for ATMP manufacturing were carried out in 2011 (01/01-31/12/2011). | 1 |
| 2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC and its implementing Directive 2006/17/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) ? (more than 1 answer possible) | Inspections of the site/centre<br>Analysis of the mandatory documentation |
| 2.4. Are you also responsible for the accreditation, designation, authorisation or licensing of laboratories performing donor testing? | Yes |
| 2.4.1. Please provide the number of the laboratories performing donor testing. | 51 |
| 2.5. How do you ensure, as CA for T&C, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art. 5(2))? (more than 1 answer possible) | Inspections of the laboratories<br>Analysis of the mandatory documentation requested from the tissue establishment |
| 2.6. Please provide data on qualified laboratories accredited, authorised or licensed in your country (e.g. number, year of accreditation/authorisation/license, which donor tests are performed etc.). | 43 donor test labs for 2006/17 tests; 8 donor test labs for 2006/17 tests plus HLA typing. In the Netherlands accreditation of donor test labs started in 2011. |
| 2.7. Do you have any additional comments on procurement? | no |
| **3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)** | |
| 3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>HBs AG<br>Anti HBc<br>Anti HCV-Ab<br>Treponema Pallidum |
| 3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>HBs AG<br>Anti HBc<br>Anti HCV-Ab<br>NAT Chlamydia<br>Treponema Pallidum |

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| 3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to encourage its use? Please specify why or why not (e.g. number of additional cases detected, cost-benefit etc.). | We do not plan to make NAT mandatory; 180 days quarantaine in case of living donors is regarded sufficient. |
| 3.4. Do you have concerns on accuracy of the available tests and test procedures for deceased donors? | No |
| 3.5. Are any other laboratory tests required for donors of non-reproductive tissues and cells in your Member State? | Yes |
| 3.5.1. Please specify. | Donor is tested for HTLV, depending on the country of origine. |
| 3.6. Are any other laboratory tests required for donors of reproductive tissues and cells in your Member State? | Yes |
| 3.6.1. Please specify. | The non-partner donor is tested for HTLV, depending on the country of origine. |
| 3.7. Do you request/use international accreditation systems for testing laboratories? | No |
| 3.8. Do you have any additional comments on testing? | no |
| **4. Accreditation, designation, authorisation or licensing of tissue establishments (Article 6, Directive 2004/23/EC)** | |
| 4.1. Do you have a system of designation, authorisation, accreditation or licensing for all types of tissue establishments under your responsability? | Yes |
| 4.2. Is inspection a prerequisite for the designation, authorisation, accreditation or licensing of tissue establishments? | Yes |
| 4.2.1. How many inspections were performed in 2011 for authorising/accrediting/licensing/designating TEs? | 18 |
| 4.3. Are preparation processes authorised? | Yes |
| 4.3.1. How are they authorised? (more than 1 answer possible) | During routine inspections<br>During inspections organised for this purpose |
| 4.4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were suspended in 2011? | 0 |
| 4.5. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011? | 0 |
| 4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)? | Yes |
| 4.6.1. What is the relation between the indpendent certification(s) (e.g. ISO, JACIE, FACT) and the CA authorisation of the tissue establishments? (more than 1 answer possible) | Mandatory for authorisation |
| **4bis. Overview of tissue/cells establishments authorised by the NCA** | |
| 4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible): | Other tissue establishments |
| 4.7.9. Please specify the type of tissues/cells and how many. | 0; no authorisations pending approval at 01/01/2011. |
| 4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible): | Other tissue establishments |
| 4.8.9. Please specify the type of tissues/cells and how many. | 0; no authorisations pending approval at 31/12/2011. |
| 4.9. Tissue establishments first time authorised between 01/01/2011 and 31/12/2011 (more than 1 answer possible): | Musculo-skeletal tissue establishments<br>HSC tissue establishments<br>ART tissue establishments |
| 4.9.2. How many musculo-skeletal tissue establishments? | 1 |
| 4.9.5. How many HSC tissue establishments? | 1 |
| 4.9.7. How many ART tissue establishments? | 16 |
| 4.10. All tissue establishments authorised by 31/12/2011 (more than 1 answer possible): | Skin tissue establishments<br>Musculo-skeletal tissue establishments<br>Cardiovascular tissue establishments<br>HSC tissue establishments<br>Cord blood tissue establishments<br>ART tissue establishments<br>Multi-tissue establishments |
| 4.10.1.1. How many public skin tissue establishments? | 0 |
| 4.10.1.2. How many private skin tissue establishments? | 1 |

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| 4.10.2.1. How many public musculo-skeletal tissue establishments? | 0 |
| 4.10.2.2. How many private musculo-skeletal tissue establishments? | 15 |
| 4.10.4.1. How many public cardiovascular tissue establishments? | 0 |
| 4.10.4.2. How many private cardiovascular tissue establishments? | 1 |
| 4.10.5.1. How many public HSC tissue establishments? | 0 |
| 4.10.5.2. How many private HSC tissue establishments? | 11 |
| 4.10.6.1. How many public cord blood tissue establishments? | 0 |
| 4.10.6.2. How many private cord blood tissue establishments? | 3 |
| 4.10.7.1. How many public ART tissue establishments? | 0 |
| 4.10.7.2. How many private ART tissue establishments? | 79 |
| 4.10.8.1. How many public multi-tissue establishments? | 0 |
| 4.10.8.2. How many private multi-tissue establishments? | 5 |
| 4.11. How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Art. 6(5) during 2011? Please provide number(s) per type tissues/cells. | 0 |
| **4ter. Sanctions** | |
| 4.16. Have penalties for infringements of the national provisions pursuant to the Directive been defined (Article 27)? | Yes |
| 4.16.1. Have penalties already been imposed? | Yes |
| 4.16.1.1. How many penalties have been imposed in 2011 (from 01/01/2011-31/12/2011)? | 0 |
| 4.16.1.2. What were the reasons for imposing the penalties? Please describe. | N/a |
| 4.16.1.3. What kind of penalties were imposed? Please describe (e.g. suspension of authorisation, criminal penalty etc.) | N/a |
| 4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing? | 4.6, 4.6.1: JACIE, FACT, only for (HP)stemcells; |
| **5. Inspections (Article 7, Directive 2004/23/EC)** | |
| 5.1. Is a system in place for organising inspections and control measures of tissue establishments? | Yes |
| 5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections. | Health Care Inspectorate |
| 5.1.2. If yes, please specify staffing (how many inspectors). | 2 senior inspectors,1 junior inspector, 1 supporting staff member |
| 5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible) | Yes |
| 5.2.1. If yes, please specify. (more than 1 answer possible) | Blood<br>Organs<br>Advanced therapies |
| 5.3. How many routine inspections of tissue establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011)? | 11 |
| 5.3.1. How many inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) following serious adverse events or reactions, or suspicion thereof ? | 0 |
| 5.3.2. How many other type of inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | 1; due to a whistle-blower. |
| 5.3.3. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | 0 |
| 5.3.4. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where minor | 13 |

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| shortcomings were noted? | |
| 5.3.5. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where major shortcomings were noted? | 10 |
| 5.3.6. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by suspension of authorisation? | 0 |
| 5.3.7. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by closure? | 0 |
| 5.3.8. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of other inspections carried out? Please specify. | 0 |
| 5.4. How many routine inspections were conducted in ART establishments (from 1/1/2011 to 31/12/2011)? | 24 |
| 5.4.1. How many inspections were conducted in ART establishments following serious adverse events or reactions, or suspicion thereof (from 1/1/2011 to 31/12/2011)? | 0 |
| 5.4.2. How many other type of inspections were conducted on ART establishments (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | 0 |
| 5.4.3. Outcome of inspections of ART tissue establishments carried out in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | 0 |
| 5.4.4. What was the number of inspections carried out in ART establishments where minor shortcomings were noted? | 24 |
| 5.4.5. What was the number of inspections carried out in ART establishments where major shortcomings were noted? | 20 |
| 5.4.6. What was the number of inspections carried out in ART establishments followed by suspension of authorisation? | 0 |
| 5.4.7. What was the number of inspections carried out in ART establishments followed by closure of respective establishements? | 0 |
| 5.4.8. What was the number of other inspections of ART establishments? Please specify. | 0 |
| 5.5. Which type of routine inspections do you conduct? (more than 1 answer possible) | General system-oriented inspections |
| 5.6. How do you decide which type of routine inspection to conduct? | N/a |
| 5.7. Until 2011, did you implement the requirement concerning the time interval between two inspections (Art. 7.3.)? | No |
| 5.7.1. Why not? | Understaffed. |
| 5.7.2. How do you prioritise tissue establishments to be inspected? | Criteria: - external certification; - previous shortcomings (type and numer); -notifications (events, reactions, alerts, and field signals); - size of TE (numer of tissues distributed or processed); - type of activity |
| 5.8. How many TEs were inspected at least twice between 2008-2011 (01/01/2008-31/12/2011)? | 33 |
| 5.9. Did you perform/conduct inspections of procurement sites outside tissue establishments? | No |
| 5.9.2. If no, why not? | This is regarded the responsibility of the TE. See 2.1.1: documentation associated with (conditions of) procurement is inspected at the TE working with the procurement centres. |
| 5.10. Did you carry out inspections of third parties? | Yes |
| 5.10.1. If yes, how many? | 2 |
| 5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for | Yes |

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| inspections (Commission Decision 2010/453/EU)? | |
| 5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)? | Yes |
| 5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)? | 3 |
| 5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))? | Yes |
| 5.13.1. Could you please explain why? | In case of shipment of tissues to the Netherlands. |
| 5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))? | No |
| 5.15. Did you organise any inspections of procurement centres or tissue establishments in third countries from which tissues and/or cells were imported in your country (as recorded by 31/12/2011)? | No |
| 5.16. Have you asked another MS, or have you been requested by any other MS, on the results and control measures of your inspections, as part of an enquiry/investigation? | Yes |
| 5.16.1. If yes, please specify. | NL requested clarifications of a license issued in another MS. |
| 5.17. Would you be interested in developing joint inspections? Joint inspections should be understood as inspections of tissue establishments conducted jointly by two or more Member States' Competent Authorities on their territory or in third countries. | Yes |
| 5.18. Do you have any additional comments on inspections? | no |
| **6. Import/export (Article 9 Directive 2004/23/EC)** | |
| 6.1. Do you have a register of authorised tissue establishments that are explicitly authorised to perform import/export of tissues and celles from/to third countries? | No |
| 6.2. Please specify the number of tissue establishments authorised to import tissues and cells from third countries (recorded by 31/12/2011). | 12 |
| 6.3. Please specify the number of tissue establishments authorised to export tissues and cells from third countries (recorded by 31/12/2011). | Unknown |
| 6.4. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of skin from third countries. | Aide-memoire for importing. |
| 6.5. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of musculo-skeletal (bone, tendons, fascia etc.) tissues from third countries. | Aide-memoire for importing. |
| 6.6. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of ophtalmic (cornea, sclera, etc) tissues from third countries. | Aide-memoire for importing. |
| 6.7. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cardio vascular tissues from third countries. | Aide-memoire for importing. |
| 6.8. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) (other than cord blood) from third countries. | Aide-memoire for importing. |
| 6.9. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cord blood from third countries. | Aide-memoire for importing. |
| 6.10. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of reproductive cells (sperm, egg cells) from third | Aide-memoire for importing. |

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| countries. | |
| 6.11. Did you import tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | Yes |
| 6.11.1. If yes, please provide the data concerning the number/volume of imported tissues and cells by country of origin. | No data. |
| 6.12. Did you export tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | Yes |
| 6.12.1. If yes, please provide the data concerning the number/volume of exported tissues and cells by country of destination. | skin 5453, bone 4830, cornea 48, HPSC unrelated 1 (bonemarrow) 14 (periphere blood), 4 (cord blood), embryo 8. ART 2011 not available yet. |
| 6.13. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on imports/exports of tissues/cells between your country and other third countries? | No |
| 6.14. What is the relation between import/export of tissues and cells and self-sufficiency? (more than 1 answer possible) | F. Other |
| Please specify 'other': | Export of post-mortal tissues and scarce tissues is restricted. |
| 6.15. Did you authorise direct imports of tissues/cells to hospitals/clinics in your country? | Yes |
| 6.15.1. If yes, please specify the number of cases and for which type of tissues/cells. | One (1) case of direct import of an embryo. |
| 6.16. Do you have any additional comments on import/export? | See activities and conclusions of the Working Group Import of Tissues and Cells. |
| **7. Distribution/intra community exchanges (Article 23 Directive 2004/23/EC)** | |
| 7.1. Do you have intra-community exchanges of tissues and cells? | Yes |
| 7.1.1. If yes, how do you address the possible more stringent quality and safety measures established by other Member States? Please specify. | This is responsibility of the authorised distributor/TE. |
| 7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States? | Yes |
| 7.1.2.1. How do you address this difference for tissues and cells coming from a MS with minimum quality requirements? Please specify. | For safety reasons more stringent measures are regulated in The Netherlands in order to control the distribution of unprocessed tissues from other MS. |
| 7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify. | On site inspections of TE's. |
| 7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible). | Other |
| Please specify 'other'. | Yes, but FOR UNPROCESSED TISSUES only via an authorised TE in our MS. |
| 7.4. Have you authorised direct distribution to the recipient of specific tissues and cells (Art. 6, Directive 2006/17/EC)? | No |
| 7.5. Do you collect data regarding the cross-border exchange of tissue/cells between your country and other EU MS? | Yes |
| 7.5.1. Please provide us with data (country of destination, type of tissue/cell and number of units distributed) concerning distribution to other MS in 2011 (01/01/2011-31/12/2011). | Distributed to EU (none NL; no data on country of destination): skin 9830, bone 16821, tendon 99, cornea 182, sclera 15, amnion 10, heart valve 27, blood vessel 5, HPSC 4 (bone marow), 15 (periphere blood), 7 (cord blood), lymfocyt 1, semen (donor) 156, semen (partner) 963, oocyt (autologeous) 745, embryo 8. |
| 7.5.2. Please provide us with data (country of origin, type of tissue/cell and number of units distributed) concerning distribution to other MS in 2011 (01/01/2011-31/12/2011) | Not available. |
| 7.6. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on cross-border exchanges of tissues/cells between your country and other EU MS? | No |
| 7.7. Do you allow brokerage companies for either distribution in EU and/or import/export of tissues/cells? In this context, a brokerage company means a body that arranges transactions between a supplier (tissue establishment/company selling tissues or cells) and a buyer (a tissue establishment/a hospital or clinic/an individual) without undertaking activities of processing, | Yes |

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| preservation or storage. | |
| 7.7.1. Please describe the legal requirements and your role (if any) as a Competent Authority, in their authorisation/monitoring or inspection. | In the Netherlands, a broker is a legal entity, in the field of tissues only allowed to make financial and logistic arrangents between seller and buyer without handling the tissues. Handling the tissues is only allowed to authorised TE's. |
| 7.8. Are brokers actively supplying health professionals/establishments in your country? | Yes |
| 7.8.1. Where are the brokers located? | Another country |
| 7.8.2. If the broker is located in another country, how easy/difficult is it to ensure that safety and quality requirements are met? | Unknown, yet to be determined. |
| 7.9. Do you have any additional comments on distribution? | no |
| **8. Register of tissue establishments and reporting obligations (Article 10, Directive 2004/23/EC)** | |
| 8.1. Do you have an annual report model/template on the activities of tissue establishments in your Member State? (Article 10(1)). If yes, please upload the template. | No |
| 8.1.1. If no, why not? | This is the responsibility of the TE. |
| 8.2. How many tissue establishments submitted annual reports of their activities during 2011. Please provide an estimation. (1 answer possible) | <50% |
| 8.3. Are these reports publicly available? (Article 10(1)) | No |
| 8.4. Do you publish a national annual report of the consolidated activities of all tissue establishments in your country? | No |
| 8.4.2. If no, why not? | Following from the Act of Freedom of Information, annual reports from TE's are already publicly available. |
| 8.5. Is there a publicly accessible register of authorised tissue establishements in place? (Article 10(2)) | Yes |
| 8.5.1. If yes, please provide us with the link to the register's web site. | http://www.farmatec.nl/doc/pdf/Internetoverzicht%20Wvkl-erkenningen%20en%20-vergunningen%20afgegeven%20vanaf%201%20juni%202007_18122.pdf |
| 8.6. Do you provide data regarding tissues and cells activities to the EUROCET registry (non-mandatory reporting)? | No |
| 8.6.2. If no, why not? | no raw data readily accessible; |
| 8.7. Do you have any additional comments on reporting? | No |
| **9. Traceability (Article 8, Directive 2004/23/EC; and Directive 2006/86/EC)** | |
| 9.1. Was the donor identification system (Art. 8(2)) implemented in your country? | Yes |
| 9.2. Who assigns the unique code for each donation? (only 1 answer possible) | National Competent Authority |
| 9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible) | Both paper records and electronic forms |
| 9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify. | On site inspections. |
| 9.5. Do you have any additional comments on traceability? | No |
| **10. Notification of serious adverse events and reactions (Article 11 Directive 2004/23, Article 6 Directive 2006/76)** | |
| 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))? | Yes |
| 10.1.1. If yes, which CA/institution is responsible? | Health Care Inspectorate (IGZ) |
| 10.1.2. If yes, please provide a short description of its organisation. | See question 1.5. |
| 10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use the SAR/E (to the CA (2006/76 art 6.4)) templates developed to the Annual reporting ot the EC also at national level? | No |
| 10.2.1. If no, what template do you use? You are welcome to upload the template if you wish. | For annual SAR/E - report we use descriptive set-up (text, tables and figures) instead of a specific template. |
| 10.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level? | Yes |
| 10.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all TEs? | Yes |

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| 10.5. How many tissue establishments provided in 2011 the SAR/SAE data as requested (please provide the % from the total number of TEs authorised in your country). | 70-99% |
| 10.6. Do you have a mandatory procedure for the transplantation centres when reporting SAR/SAE to the TEs which distributed the tissues/cells (Art 11.2)? | No |
| 10.6.2. If no, how do you ensure that SAR/SAE are reported to the TEs? | 1. The reporting of SAR/E's are incorporated in the instructions for use of the tissue-product. 2. On-site inspections. |
| 10.7. Do you give feedback to the TEs regarding SAR/SAE recorded at national level? | Yes |
| 10.7.1. Please specify. | Feedback is given for single notifications if necessary, and on a general level in the national annual report for SAR/E. |
| 10.8. Do you give feedback to the TEs regarding SAR/SAE recorded at EU level? | No |
| 10.8.2. Please specify why not. | Already publicly available on SANCO website. |
| 10.9. Do you require your TEs to have a recall procedure? | Yes |
| 10.10. How many recalls related to safety and quality of tissues/cells were issued in your country in 2011? Please specify the number and which tissues were recalled and why (e.g. missing consent, quality defects etc). | 0 |
| 10.11. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites in case of a national rapid alert? | Yes |
| 10.11.1. If yes, please give a short description of the system/procedure. | Part of specific standard operating procedure of the Health Care Inspectorate. |
| 10.12. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites when a rapid alert is issued via the EU RATC platform? | Yes |
| 10.12.1. If yes, please give a short description of the system/procedure. | Part of specific standard operatnig procedure of the Health Care Inspectorate. |
| 10.13. Do you provide data regarding SAR/SAE to the EUROCET registry (non-mandatory reporting)? | No |
| 10.13.2. If no, please specify why not. | This is not deemed necessary. |
| 10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems? | Yes |
| 10.14.1. If yes, please specify which of the following systems are usually contacted. (more than 1 answer possible) | Haemovigilance<br>Medical devices<br>Other |
| Please specify 'other'. | Organs, clinical trials. |
| 10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S? | Yes |
| 10.15.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (insufficient) - 2 (sufficient) 3 (good) - 4 (very good) to 5 (essential)? | 3 |
| 10.16. Do you have any additional comments on SARE reporting? | No |
| **11. Consent and personal data protection (Article 13 and 14, Directive 2004/23/EC)** | |
| 11.1. What consent system for living tissue/cell donation do you have in place within your Member State? | Explicit consent (opt-in) |
| 11.1.1. Please specify your choice of consent system for living tissue/cell donation. | Political decision. |
| 11.2. What consent system for deceased tissue/cell donation do you have in place within your Member State? | Explicit consent (opt-in) |
| 11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible) | First degree relatives (including spouse)<br>Other relatives<br>Non-marital partners<br>Other |
| Please specify 'other'. | Guardian, in case of child of 12 years of age or older. |
| 11.4. Is the consent system for deceased tissue donation the same as for organs? | Yes |

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| 11.5. How is this consent verified during inspections? (more than 1 answer possible) | Analysis of documentation<br>Interviews with personnel |
| 11.6. What measures are in place to ensure that donors/relatives/authorising persons on behalf of donors are provided with the appropriate information, as requested by Art. 13(2)? (more than 1 answer possible) | Only trained personnel is allowed to provide such information |
| 11.7. What measures are in place to ensure that both donors and recipients remain unidentifiable when access is given to third parties (Art. 14(1)). Please specify. | Legally regulated in Dutch Act on Safety and Quality of SoHO (WVKL). |
| 11.8. Please specify what measures are in place to ensure that the identity of the receipient is not disclosed to the donor and vice versa. | Legally regulated in Dutch Act on Safety and Quality of SoHO (WVKL). |
| 11.9. Does your national legislation allows disclosure of donor data in case of gametes donation? | Yes |
| 11.10. Do you have any additional comments on consent and data protection? | No |
| **12. Selection, evaluation and procurement (Article 15 Directive 2004/23; Annexes I-IV Directive 2006/17)** | |
| 12.1. How do you ensure that all requirements related to the evaluation and selection of donors (except donors of reproductive cells) are respected in your country (Art. 15(1), Annex I Directive 2006/17/EC)? (more than 1 answer possible) | Stadardised questionnaires at national levels<br>Inspections of TEs and procurement sites<br>Audit of documentation<br>Regular evaluation of medical personnel |
| 12.2. How do you ensure that all requirements related to the evaluation and selection of donors of reproductive cells are respected in your country (Art 15 (1), Annex III of Directive 2006/17/EC)? (more than 1 answer possible) | Standardised questionnaires at national level<br>Inspections of ART centres<br>Audit documentation<br>Regular evaluation of medical personnel |
| 12.3. Do you have more stringent criteria for donor selection than those listed in Annex I of the Directive 2006/17/EC? | No |
| 12.4. What sources are required in your MS for the evaluation of a deceased donor of tissues/cells? (more than 1 answer possible) | Interview with the donor's family or a person who knew the donor well<br>Medical records of the donor<br>Interview with the treating physician<br>Interview with the general practitioner<br>Autopsy report |
| 12.5. Do you have more stringent criteria for selection of donors of reproductive cells than those listed in Annex III of the Directive 2006/17/EC? | No |
| 12.6. Do you have more stringent criteria for autologous donation than those listed in Annex I of the Directive 2006/17/EC? | No |
| 12.7. Do you require more information on the donation of tissues/cells than the mandatory one as laid down in the Annex of Directive 2004/23/EC (Art 15(3)? | No |
| 12.8. How do you ensure that all requirements regarding tissues and cells' procurement, packaging and transport are complied with by tissue establishments in your country (Art 15(1), Annex IV of Directive 2006/17/EC? (more than 1 answer possible)(For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)) | Inspection of tissue establishment<br>Inspection of the centre of human application (e.g. transplantation centre, ART centre) |
| 12.9. Do you have any additional comments on selection, evaluation and procurement? | No |
| **13. Quality management, responsible person, personnel (Article 16, 17, 18 Directive 2004/23/EC)** | |
| 13.1. How do you ensure that tissue establishments in your country have in place a quality system respecting the provisions of the Directive 2004/23/EC Art 16.1? (more than 1 answer possible). (For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for | Authorisation requirement<br>Inspections |

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| the Transplantation of Organs, Tissues and Cells, 2011)). | |
| 13.2. How do you ensure that tissue establishments have a responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible) | Authorisation requirement<br>Inspections |
| 13.3. How do you ensure an appropriate training for the personnel directly involved in the activities of tissue establishments? (more than 1 answer possible) | Authorisation requirement<br>Inspections |
| 13.4. Do you have national/regional/local training programmes for the personnel of tissue establishments? | No |
| 13.4.2. If no, in which country(ies) is your personnel trained? | EU countries<br>Non-EU countries |
| 13.4.2.1. Please specify EU-countries. | Unknown; location of training of the personnel of TE's is not notified or registred at the level of national competent authority. |
| 13.4.2.2. Please specify non EU-countries. | Unknown; location of training of the personnel of TE's is not notified or registred at the level of national competent authority. |
| 13.5. Any additional comments on quality management, responsible person, personnel? | No |
| **14. Reception, processing, storage, labelling and packaging (Art 19-22 Directive 2004/23/EC)** | |
| 14.1. How do you ensure that tissue establishments in your country fulfill the requirments of the Art. 19 (Tissue and cell reception) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | National regulation/policy for reception of tissues/cells<br>Inspections of tissue establishments |
| 14.2. How do you ensure that tissue establishments in your country fulfill the requirements of the Art. 20 (Tissue and cell processing) of Directive 2004/23/EC? (more than 1 answer possible) | SOPs for all processes affecting quality and safety are mandatory for authorisation<br>Inspections of tissue establishments |
| 14.3. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 21 (tissue and cell storage conditions) of Directive 2004/23/EC? (more than 1 answer possible) | SOPs for procedures associated with storage of tissues and cells are mandatory for authorisation<br>Inspections of tissue establishments |
| 14.4. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | SOPs for procedures associated with labelling and packaging are mandatory for authorisation<br>Inspections of tissue establishments |
| 14.5. Any additional comments on reception, processing, storage, labelling and packaging? | No |
| **15. Third party agreements (Art. 24 Directive 2004/23/EC)** | |
| 15.1. Are third party agreements foreseen/allowed in your national legislation? | Yes |
| 15.1.1. If yes, have tissue establishments in your Member State notified third party agreements? | Yes |
| 15.1.1.1. Under which circumstances and for which responsibilities? | One case in 2012 concerning storage. |
| 15.1.1.2. How are third party agreements controlled (Art 6.2) by the Competent Auhtority(ies) in your MS? Please specify. | - agreements between TE and third parties are requirement for authorisation of TE. - on-site inspection of TE or third party. |
| 15.2. Any additional comments on third party agreements? | No |
| **16. General comments - implementation** | |
| 16.1. Do you have at national level more stringent quality and safety requirements than those requested by the EU legislation in this field (e.g. restrictions concerning the donation/use of certain tissues/cells, mandatory unpaid donation etc.)? | Yes |
| 16.1.1. Please specify. | Distribution of unprocessed tissue from other MS to the Netherlands. |
| 16.2. Has your Member State encountered any difficulties in implementing the requirements in the EU Tissues and Cells Directives? Please choose from the options below. | Inspections |
| 16.2.1. For all selected options in question 16.2., please provide a short description. | - inspection interval; selection of sites to be inspected. |
| 16.3. In your opinion, in which of the following Directives are there shortcomings (if any)? (more than 1 answer possible) | Directive 2004/23/EC<br>Directive 2006/17/EC |

| | Directive 2006/86/EC |
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| 16.3.1. How would you suggest to solve these issues in Directive 2004/23/EC? | We refer to the outcome and report of the PCAM in Vienna, November 2012. |
| 16.3.2. How would you suggest to solve these issues in Directive 2006/17/EC? | We refer to the outcome and report of the PCAM in Vienna, November 2012. |
| 16.3.3. How would you suggest to solve these issues in Directive 2006/86/EC? | We refer to the outcome and report of the PCAM in Vienna, November 2012. |

## *A.1.22. Survey response Norway*

| **1. Public information** | |
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| 1.1. Name of National Competent Authority (NCA) 1: | Norwegian directorate of health |
| 1.1.2. Address of NCA 1: | Norwegian directorate of health P.b 7000 St.Olavs plass NO-0130 Oslo Norway |
| 1.1.3. Telephone (central access point): | +47 81020050 |
| 1.1.4. E-mail (central access point): | postmottak@helsedir.no |
| 1.1.5. Website: | www.helsedirektoratet.no |
| 1.1.6. The NCA is responsible for? (more than 1 answer possible) | Non-reproductive tissues and cells<br>Reproductive tissues and cells<br>Blood and blood components<br>Human organs<br>Medical devices<br>Other |
| Please specify 'other': | Gene modified micro organisms |
| 1.1.7. What are the role/tasks of the NCA? (more than 1 answer possible) | Accreditation, authorisation, licensing of TEs<br>Inspection<br>Vigilance |
| 1.2. National Competent Authority 2? | Yes |
| 1.2.1. Name of National Competent Authority 2: | Norwegian board of health supervision |
| 1.2.2. Address of NCA 2: | Calmeyers gate 1 P.b 8128 NO-0032 Oslo Norway |
| 1.2.3. Telephone (central access point): | +47 21529900 |
| 1.2.4. E-mail (central access point): | postmottak@helsetilsynet.no |
| 1.2.5. Website: | www.helsetilsynet.no |
| 1.2.6. The NCA is responsible for? (more than 1 answer possible) | Non-reproductive tissues and cells<br>Reproductive tissues and cells<br>Blood and blood components<br>Human organs |
| 1.2.7. What are the role/tasks of the NCA? (more than 1 answer possible) | Inspection |
| 1.3. National Competent Authority 3? | Yes |
| 1.3.1. Name of National Competent Authority 3: | Norwegian medicines agency |
| 1.3.2. Address of NCA 3: | pb. 63 Kaldbakken NO-0901 Oslo Norway |
| 1.3.3. Telephone (central access point): | +47 22897700 |
| 1.3.4. E-mail (central access point): | post@legemiddelverket.no |
| 1.3.5. Website: | www.legemiddelverket.no |
| 1.3.6. The NCA is responsible for? (more than 1 answer possible) | Non-reproductive tissues and cells<br>Pharmaceuticals |
| 1.3.7. What are the role/tasks of the NCA? (more than 1 answer possible) | Accreditation, authorisation, licensing of TEs<br>Inspection |
| 1.4. National Competent Authority 4? | No |
| 1.5. Please give a short description of the legal status and organisation of the National Competent Authority(ies) (e.g. departments, staffing, number of senior and junior inspectors, staff working on EU affairs and legal matters, vigilance officers, budget, independence from government etc.). | The national competent authorities are organised under the norwegian ministry og health and care services. The inspectors are independent from govermental control. |
| 1.6. In case of MS with federal or decentralised systems, please indicate the roles/tasks of the Regional Competent Authority(ies). (more than 1 answer possible) | Not applicable |
| 1.7. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies) for tissues and cells: | There are no regional competent authorities for TE |
| **2. Procurement (Article 5 Directive 2004/23/EC)** | |
| 2.1. Do you authorise the "conditions of procurement"? | Yes |
| 2.1.1. How do you authorise the "conditions of procurement"? (more than 1 answer possible) | By inspecting the documentation associated with procurement that is available in the tissue establishment working with procurement centres |
| 2.1.2. How many such authorisations were granted in 2011 (01/01-31/12/2011)? | 14 |

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| 2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011). | 11 |
| 2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011). | 0 |
| 2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues were carried out in 2011 (01/01-31/12/2011). | 10 |
| 2.2.4. Please provide the number of procurement centers in which procurement of tissues/cells for ATMP manufacturing were carried out in 2011 (01/01-31/12/2011). | 1 |
| 2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC and its implementing Directive 2006/17/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) ? (more than 1 answer possible) | Inspections of the site/centre<br>Analysis of the mandatory documentation |
| 2.4. Are you also responsible for the accreditation, designation, authorisation or licensing of laboratories performing donor testing? | Yes |
| 2.4.1. Please provide the number of the laboratories performing donor testing. | 15 |
| 2.5. How do you ensure, as CA for T&C, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art. 5(2))? (more than 1 answer possible) | Inspections of the laboratories<br>Analysis of the mandatory documentation requested from the tissue establishment |
| 2.6. Please provide data on qualified laboratories accredited, authorised or licensed in your country (e.g. number, year of accreditation/authorisation/license, which donor tests are performed etc.). | Number: 15, Year of accreditiation: 2008-2013, tests: HCV, HBV, Tp, HIV, HTLV-1, HTLV-2 |
| 2.7. Do you have any additional comments on procurement? | |
| **3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)** | |
| 3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>HBs AG<br>Anti HBc<br>Anti HCV-Ab<br>Treponema Pallidum<br>HTLV-2 |
| 3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>HBs AG<br>Anti HBc<br>Anti HCV-Ab<br>HTLV-2<br>NAT Chlamydia<br>Treponema Pallidum |
| 3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to encourage its use? Please specify why or why not (e.g. number of additional cases detected, cost-benefit etc.). | NAT is not mandatory according to cost-benefit analysis and epidemiological situation in Norway. |
| 3.4. Do you have concerns on accuracy of the available tests and test procedures for deceased donors? | Yes |
| 3.4.1. Please specify why: | Shortcomings of available tests for deseased donors |
| 3.5. Are any other laboratory tests required for donors of non-reproductive tissues and cells in your Member State? | No |
| 3.6. Are any other laboratory tests required for donors of reproductive tissues and cells in your Member State? | Yes |
| 3.6.1. Please specify. | required tests for gonorrhea and chlamydia for non partner donation |
| 3.7. Do you request/use international accreditation systems for | No |

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| testing laboratories? | |
| 3.8. Do you have any additional comments on testing? | |
| **4. Accreditation, designation, authorisation or licensing of tissue establishments (Article 6, Directive 2004/23/EC)** | |
| 4.1. Do you have a system of designation, authorisation, accreditation or licensing for all types of tissue establishments under your responsability? | Yes |
| 4.2. Is inspection a prerequisite for the designation, authorisation, accreditation or licensing of tissue establishments? | No |
| 4.3. Are preparation processes authorised? | Yes |
| 4.3.1. How are they authorised? (more than 1 answer possible) | By review of a submitted application with supporting documentation |
| 4.4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were suspended in 2011? | 0 |
| 4.5. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011? | 0 |
| 4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)? | No |
| **4bis. Overview of tissue/cells establishments authorised by the NCA** | |
| 4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible): | Other tissue establishments |
| 4.7.9. Please specify the type of tissues/cells and how many. | Approvals given in Norway are not time limited |
| 4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible): | Other tissue establishments |
| 4.8.9. Please specify the type of tissues/cells and how many. | Approvals given in Norway are not time limited |
| 4.9. Tissue establishments first time authorised between 01/01/2011 and 31/12/2011 (more than 1 answer possible): | Other tissue establishments |
| 4.9.9. Please specify the type of tissues/cells and how many. | Approvals given in Norway are not time limited |
| 4.10. All tissue establishments authorised by 31/12/2011 (more than 1 answer possible): | Other tissue establishments |
| 4.10.9.1. Please specify the type of 'other' public tissues/cells establishements and how many. | Approvals given in Norway are not time limited |
| 4.10.9.2. Please specify the type of 'other' private tissues/cells establishements and how many. | Approvals given in Norway are not time limited |
| 4.11. How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Art. 6(5) during 2011? Please provide number(s) per type tissues/cells. | 0 |
| **4ter. Sanctions** | |
| 4.16. Have penalties for infringements of the national provisions pursuant to the Directive been defined (Article 27)? | Yes |
| 4.16.1. Have penalties already been imposed? | No |
| 4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing? | |
| **5. Inspections (Article 7, Directive 2004/23/EC)** | |
| 5.1. Is a system in place for organising inspections and control measures of tissue establishments? | Yes |
| 5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections. | Nowregian board of health supervision |
| 5.1.2. If yes, please specify staffing (how many inspectors). | 2 |
| 5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible) | Yes |
| 5.2.1. If yes, please specify. (more than 1 answer possible) | Blood<br>Pharmaceuticals<br>Advanced therapies<br>Medical devices<br>Accreditation organisations (e.g. JACIE) |
| 5.3. How many routine inspections of tissue establishments for non-reproductive tissues/cells were conducted in 2011 (from | 0 |

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| 1/1/2011 to 31/12/2011)? | |
| 5.3.1. How many inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) following serious adverse events or reactions, or suspicion thereof ? | 0 |
| 5.3.2. How many other type of inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | 0 |
| 5.3.3. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | 0 |
| 5.3.4. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where minor shortcomings were noted? | 0 |
| 5.3.5. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where major shortcomings were noted? | 0 |
| 5.3.6. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by suspension of authorisation? | 0 |
| 5.3.7. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by closure? | 0 |
| 5.3.8. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of other inspections carried out? Please specify. | 0 |
| 5.4. How many routine inspections were conducted in ART establishments (from 1/1/2011 to 31/12/2011)? | 9 |
| 5.4.1. How many inspections were conducted in ART establishments following serious adverse events or reactions, or suspicion thereof (from 1/1/2011 to 31/12/2011)? | 0 |
| 5.4.2. How many other type of inspections were conducted on ART establishments (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | 0 |
| 5.4.3. Outcome of inspections of ART tissue establishments carried out in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | 2 |
| 5.4.4. What was the number of inspections carried out in ART establishments where minor shortcomings were noted? | 7 |
| 5.4.5. What was the number of inspections carried out in ART establishments where major shortcomings were noted? | 0 |
| 5.4.6. What was the number of inspections carried out in ART establishments followed by suspension of authorisation? | 0 |
| 5.4.7. What was the number of inspections carried out in ART establishments followed by closure of respective establishements? | 0 |
| 5.4.8. What was the number of other inspections of ART establishments? Please specify. | 0 |
| 5.5. Which type of routine inspections do you conduct? (more than 1 answer possible) | General system-oriented inspections<br>Thematic inspections |
| 5.6. How do you decide which type of routine inspection to conduct? | Based on review of documentation, risk assessement and history of deficiencies |
| 5.7. Until 2011, did you implement the requirement concerning the time interval between two inspections (Art. 7.3.)? | Yes |
| 5.8. How many TEs were inspected at least twice between 2008-2011 (01/01/2008-31/12/2011)? | 0 |

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| 5.9. Did you perform/conduct inspections of procurement sites outside tissue establishments? | No |
| 5.9.2. If no, why not? | Not relevant |
| 5.10. Did you carry out inspections of third parties? | No |
| 5.10.2. If no, why not? | Not relevant |
| 5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)? | Yes |
| 5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)? | Yes |
| 5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)? | 4 |
| 5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))? | No |
| 5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))? | No |
| 5.15. Did you organise any inspections of procurement centres or tissue establishments in third countries from which tissues and/or cells were imported in your country (as recorded by 31/12/2011)? | No |
| 5.16. Have you asked another MS, or have you been requested by any other MS, on the results and control measures of your inspections, as part of an enquiry/investigation? | No |
| 5.17. Would you be interested in developing joint inspections? Joint inspections should be understood as inspections of tissue establishments conducted jointly by two or more Member States' Competent Authorities on their territory or in third countries. | Yes |
| 5.18. Do you have any additional comments on inspections? | |
| **6. Import/export (Article 9 Directive 2004/23/EC)** | |
| 6.1. Do you have a register of authorised tissue establishments that are explicitly authorised to perform import/export of tissues and celles from/to third countries? | Yes |
| 6.2. Please specify the number of tissue establishments authorised to import tissues and cells from third countries (recorded by 31/12/2011). | 5 |
| 6.3. Please specify the number of tissue establishments authorised to export tissues and cells from third countries (recorded by 31/12/2011). | 0 |
| 6.4. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of skin from third countries. | National regulation of quality and standards equivalent to EU standards |
| 6.5. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of musculo-skeletal (bone, tendons, fascia etc.) tissues from third countries. | National regulation of quality and standards equivalent to EU standards |
| 6.6. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of ophtalmic (cornea, sclera, etc) tissues from third countries. | National regulation of quality and standards equivalent to EU standards |
| 6.7. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cardio vascular tissues from third countries. | National regulation of quality and standards equivalent to EU standards |
| 6.8. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) (other than cord blood) from third countries. | National regulation of quality and standards equivalent to EU standards |

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| 6.9. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cord blood from third countries. | National regulation of quality and standards equivalent to EU standards |
| 6.10. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of reproductive cells (sperm, egg cells) from third countries. | National regulation of quality and standards equivalent to EU standards |
| 6.11. Did you import tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | Yes |
| 6.11.1. If yes, please provide the data concerning the number/volume of imported tissues and cells by country of origin. | Not available |
| 6.12. Did you export tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | No |
| 6.13. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on imports/exports of tissues/cells between your country and other third countries? | No |
| 6.14. What is the relation between import/export of tissues and cells and self-sufficiency? (more than 1 answer possible) | D. Import of tissues/cells is authorised only after checking that local/national needs are not fulfilled<br>E. Import of tissues/cells is authorised based on estimations showing that there is chronic deficiency of those tissues/cells |
| 6.14.1. If A or D were selected, please explain how you quantify local/national needs. | National list of patients in need of tissues and cells or transplantation |
| 6.15. Did you authorise direct imports of tissues/cells to hospitals/clinics in your country? | Yes |
| 6.15.1. If yes, please specify the number of cases and for which type of tissues/cells. | 1, tendonse |
| 6.16. Do you have any additional comments on import/export? | |
| **7. Distribution/intra community exchanges (Article 23 Directive 2004/23/EC)** | |
| 7.1. Do you have intra-community exchanges of tissues and cells? | Yes |
| 7.1.1. If yes, how do you address the possible more stringent quality and safety measures established by other Member States? Please specify. | Distribution conditions shall comply with national regulations. |
| 7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States? | Yes |
| 7.1.2.1. How do you address this difference for tissues and cells coming from a MS with minimum quality requirements? Please specify. | TE with import license must ensure, and document, comliance with national regulations. |
| 7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify. | Licensing and inspection |
| 7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible). | Yes, but only via an authorised TE in my MS |
| 7.4. Have you authorised direct distribution to the recipient of specific tissues and cells (Art. 6, Directive 2006/17/EC)? | No |
| 7.5. Do you collect data regarding the cross-border exchange of tissue/cells between your country and other EU MS? | No |
| 7.6. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on cross-border exchanges of tissues/cells between your country and other EU MS? | No |
| 7.7. Do you allow brokerage companies for either distribution in EU and/or import/export of tissues/cells? In this context, a brokerage company means a body that arranges transactions between a supplier (tissue establishment/company selling tissues or cells) and a buyer (a tissue establishment/a hospital or clinic/an individual) without undertaking activities of processing, preservation or storage. | Yes |
| 7.7.1. Please describe the legal requirements and your role (if any) as a Competent Authority, in their authorisation/monitoring or inspection. | Distribution license for DBX |
| 7.8. Are brokers actively supplying health | No |

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| professionals/establishments in your country? | |
| 7.9. Do you have any additional comments on distribution? | |
| **8. Register of tissue establishments and reporting obligations (Article 10, Directive 2004/23/EC)** | |
| 8.1. Do you have an annual report model/template on the activities of tissue establishments in your Member State? (Article 10(1)). If yes, please upload the template. | Yes |
| 8.2. How many tissue establishments submitted annual reports of their activities during 2011. Please provide an estimation. (1 answer possible) | 50-69% |
| 8.3. Are these reports publicly available? (Article 10(1)) | Yes |
| 8.3.1. If yes, please insert the link(s) to the report(s). | By contacting Norwegian directorate of health |
| 8.4. Do you publish a national annual report of the consolidated activities of all tissue establishments in your country? | Yes |
| 8.4.1. Please insert the link to the published national annual report. | http://www.helsedirektoratet.no/kvalitet-planlegging/bio-genteknologi/celler-og-vev/Documents/ÅRSRAPPORT%20celler%20og%20vev%202011.pdf |
| 8.5. Is there a publicly accessible register of authorised tissue establishements in place? (Article 10(2)) | Yes |
| 8.5.1. If yes, please provide us with the link to the register's web site. | http://www.helsedirektoratet.no/kvalitet-planlegging/bio-genteknologi/celler-og-vev/Sider/default.aspx |
| 8.6. Do you provide data regarding tissues and cells activities to the EUROCET registry (non-mandatory reporting)? | No |
| 8.6.2. If no, why not? | Lack of accordance with eurocet scheme |
| 8.7. Do you have any additional comments on reporting? | |
| **9. Traceability (Article 8, Directive 2004/23/EC; and Directive 2006/86/EC)** | |
| 9.1. Was the donor identification system (Art. 8(2)) implemented in your country? | No |
| 9.1.1. If no, why not? | Identification of donor is determined by national unique personal number identification system |
| 9.2. Who assigns the unique code for each donation? (only 1 answer possible) | Tissue establishment |
| 9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible) | Both paper records and electronic forms |
| 9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify. | License and inspections |
| 9.5. Do you have any additional comments on traceability? | |
| **10. Notification of serious adverse events and reactions (Article 11 Directive 2004/23, Article 6 Directive 2006/76)** | |
| 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))? | Yes |
| 10.1.1. If yes, which CA/institution is responsible? | Norwegian directorate of health |
| 10.1.2. If yes, please provide a short description of its organisation. | www.cellerogvev.no |
| 10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use the SAR/E (to the CA (2006/76 art 6.4)) templates developed to the Annual reporting ot the EC also at national level? | No |
| 10.2.1. If no, what template do you use? You are welcome to upload the template if you wish. | We use ordinary mail. |
| 10.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level? | No |
| 10.3.1. If no, please specify what guidelines you use. | National regulations |
| 10.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all TEs? | Yes |
| 10.5. How many tissue establishments provided in 2011 the SAR/SAE data as requested (please provide the % from the total number of TEs authorised in your country). | <50% |
| 10.6. Do you have a mandatory procedure for the transplantation centres when reporting SAR/SAE to the TEs which distributed the tissues/cells (Art 11.2)? | Yes |
| 10.6.1. If yes, please provide a brief description. | Procedures according to national regulations |
| 10.7. Do you give feedback to the TEs regarding SAR/SAE | Yes |

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| recorded at national level? | |
| 10.7.1. Please specify. | Feedback are given to TE who reports. |
| 10.8. Do you give feedback to the TEs regarding SAR/SAE recorded at EU level? | Yes |
| 10.8.1. Please specify. | Feedback are given to relevant TE's |
| 10.9. Do you require your TEs to have a recall procedure? | Yes |
| 10.10. How many recalls related to safety and quality of tissues/cells were issued in your country in 2011? Please specify the number and which tissues were recalled and why (e.g. missing consent, quality defects etc). | 0 |
| 10.11. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites in case of a national rapid alert? | Yes |
| 10.11.1. If yes, please give a short description of the system/procedure. | Rapid alert information are sendt to relevant TE's |
| 10.12. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites when a rapid alert is issued via the EU RATC platform? | Yes |
| 10.12.1. If yes, please give a short description of the system/procedure. | Rapid alert information are sendt to relevant TE's |
| 10.13. Do you provide data regarding SAR/SAE to the EUROCET registry (non-mandatory reporting)? | No |
| 10.13.2. If no, please specify why not. | Not yet implemented |
| 10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems? | No |
| 10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S? | Yes |
| 10.15.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (insufficient) - 2 (sufficient) 3 (good) - 4 (very good) to 5 (essential)? | 4 |
| 10.16. Do you have any additional comments on SARE reporting? | |
| **11. Consent and personal data protection (Article 13 and 14, Directive 2004/23/EC)** | |
| 11.1. What consent system for living tissue/cell donation do you have in place within your Member State? | Explicit consent (opt-in) |
| 11.1.1. Please specify your choice of consent system for living tissue/cell donation. | Written conscent |
| 11.2. What consent system for deceased tissue/cell donation do you have in place within your Member State? | Presumed consent (opt-out) |
| 11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible) | First degree relatives (including spouse)<br>Other relatives<br>Non-marital partners<br>Friends |
| 11.4. Is the consent system for deceased tissue donation the same as for organs? | Yes |
| 11.5. How is this consent verified during inspections? (more than 1 answer possible) | Analysis of documentation<br>Interviews with personnel |
| 11.6. What measures are in place to ensure that donors/relatives/authorising persons on behalf of donors are provided with the appropriate information, as requested by Art. 13(2)? (more than 1 answer possible) | Only trained personnel is allowed to provide such information |
| 11.7. What measures are in place to ensure that both donors and recipients remain unidentifiable when access is given to third parties (Art. 14(1)). Please specify. | National regulations |
| 11.8. Please specify what measures are in place to ensure that the identity of the receipient is not disclosed to the donor and vice versa. | Personal identification is replaced with donor code |
| 11.9. Does your national legislation allows disclosure of donor data in case of gametes donation? | No |
| 11.9.1. If no, please specify the circumstances and measures in | IVF children have right to know identification of donor |

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| place. | |
| 11.10. Do you have any additional comments on consent and data protection? | |
| **12. Selection, evaluation and procurement (Article 15 Directive 2004/23; Annexes I-IV Directive 2006/17)** | |
| 12.1. How do you ensure that all requirements related to the evaluation and selection of donors (except donors of reproductive cells) are respected in your country (Art. 15(1), Annex I Directive 2006/17/EC)? (more than 1 answer possible) | Inspections of TEs and procurement sites<br>Audit of documentation |
| 12.2. How do you ensure that all requirements related to the evaluation and selection of donors of reproductive cells are respected in your country (Art 15 (1), Annex III of Directive 2006/17/EC)? (more than 1 answer possible) | Inspections of ART centres<br>Audit documentation |
| 12.3. Do you have more stringent criteria for donor selection than those listed in Annex I of the Directive 2006/17/EC? | No |
| 12.4. What sources are required in your MS for the evaluation of a deceased donor of tissues/cells? (more than 1 answer possible) | Interview with the donor's family or a person who knew the donor well<br>Medical records of the donor<br>Autopsy report |
| 12.5. Do you have more stringent criteria for selection of donors of reproductive cells than those listed in Annex III of the Directive 2006/17/EC? | No |
| 12.6. Do you have more stringent criteria for autologous donation than those listed in Annex I of the Directive 2006/17/EC? | No |
| 12.7. Do you require more information on the donation of tissues/cells than the mandatory one as laid down in the Annex of Directive 2004/23/EC (Art 15(3)? | No |
| 12.8. How do you ensure that all requirements regarding tissues and cells' procurement, packaging and transport are complied with by tissue establishments in your country (Art 15(1), Annex IV of Directive 2006/17/EC? (more than 1 answer possible)(For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)) | Inspection of tissue establishment<br>Audit of tissue establishment |
| 12.9. Do you have any additional comments on selection, evaluation and procurement? | |
| **13. Quality management, responsible person, personnel (Article 16, 17, 18 Directive 2004/23/EC)** | |
| 13.1. How do you ensure that tissue establishments in your country have in place a quality system respecting the provisions of the Directive 2004/23/EC Art 16.1? (more than 1 answer possible). (For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)). | Authorisation requirement<br>Inspections<br>Internal audits |
| 13.2. How do you ensure that tissue establishments have a responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible) | Authorisation requirement<br>Inspections<br>Regular evaluation of personnel<br>Mandatory trainings |
| 13.3. How do you ensure an appropriate training for the personnel directly involved in the activities of tissue establishments? (more than 1 answer possible) | Authorisation requirement<br>Inspections<br>Regular evaluation of personnel<br>Mandatory trainings |
| 13.4. Do you have national/regional/local training programmes for the personnel of tissue establishments? | Yes |
| 13.4.1. If yes, please specify. | Sentralised competence centres |
| 13.5. Any additional comments on quality management, | |

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| responsible person, personnel? | |
| **14. Reception, processing, storage, labelling and packaging (Art 19-22 Directive 2004/23/EC)** | |
| 14.1. How do you ensure that tissue establishments in your country fulfill the requirments of the Art. 19 (Tissue and cell reception) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | National regulation/policy for reception of tissues/cells<br>Inspections of tissue establishments<br>Internal audits of tissue establishments |
| 14.2. How do you ensure that tissue establishments in your country fulfill the requirements of the Art. 20 (Tissue and cell processing) of Directive 2004/23/EC? (more than 1 answer possible) | SOPs for all processes affecting quality and safety are mandatory for authorisation<br>Inspections of tissue establishments<br>Internal audits of tissue establishments |
| 14.3. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 21 (tissue and cell storage conditions) of Directive 2004/23/EC? (more than 1 answer possible) | SOPs for procedures associated with storage of tissues and cells are mandatory for authorisation<br>Inspections of tissue establishments<br>Internal audits of tissue establishments |
| 14.4. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | SOPs for procedures associated with labelling and packaging are mandatory for authorisation<br>Inspections of tissue establishments<br>Internal audits of tissue establishments |
| 14.5. Any additional comments on reception, processing, storage, labelling and packaging? | |
| **15. Third party agreements (Art. 24 Directive 2004/23/EC)** | |
| 15.1. Are third party agreements foreseen/allowed in your national legislation? | Yes |
| 15.1.1. If yes, have tissue establishments in your Member State notified third party agreements? | Yes |
| 15.1.1.1. Under which circumstances and for which responsibilities? | Documention of third party agreement |
| 15.1.1.2. How are third party agreements controlled (Art 6.2) by the Competent Auhtority(ies) in your MS? Please specify. | Licensing and inspection |
| 15.2. Any additional comments on third party agreements? | |
| **16. General comments - implementation** | |
| 16.1. Do you have at national level more stringent quality and safety requirements than those requested by the EU legislation in this field (e.g. restrictions concerning the donation/use of certain tissues/cells, mandatory unpaid donation etc.)? | No |
| 16.2. Has your Member State encountered any difficulties in implementing the requirements in the EU Tissues and Cells Directives? Please choose from the options below. | No difficulties |
| 16.2.1. For all selected options in question 16.2., please provide a short description. | TE's mainly comply with national regulations |
| 16.3. In your opinion, in which of the following Directives are there shortcomings (if any)? (more than 1 answer possible) | Directive 2004/23/EC |
| 16.3.1. How would you suggest to solve these issues in Directive 2004/23/EC? | The required interval between two inspections are to short. We would prefer intervals of three/four years. |

## *A.1.23. Survey response Poland*

| **1. Public information** | |
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| 1.1. Name of National Competent Authority (NCA) 1: | National Centre for Tissue and Cell Banking |
| 1.1.2. Address of NCA 1: | ul. Chalubinskiego 5, 02-004 Warsaw, Poland |
| 1.1.3. Telephone (central access point): | +48 22 621 75 43 |
| 1.1.4. E-mail (central access point): | sekretariat@kcbtik.pl; artur.kaminski@wum.edu.pl; |
| 1.1.5. Website: | www.kcbtik.pl |
| 1.1.6. The NCA is responsible for? (more than 1 answer possible) | Non-reproductive tissues and cells |
| 1.1.7. What are the role/tasks of the NCA? (more than 1 answer possible) | Inspection<br>Vigilance |
| 1.2. National Competent Authority 2? | Yes |
| 1.2.1. Name of National Competent Authority 2: | Polish Transplant Coordinating Center - Poltransplant |
| 1.2.2. Address of NCA 2: | Al. Jerozolimskie 87, 02-001 Warsaw, Poland |
| 1.2.3. Telephone (central access point): | + 48 22 622 58 06 |
| 1.2.4. E-mail (central access point): | transpl@poltransplant.org.pl |
| 1.2.5. Website: | www.poltransplant.org.pl |
| 1.2.6. The NCA is responsible for? (more than 1 answer possible) | Non-reproductive tissues and cells<br>Human organs |
| 1.2.7. What are the role/tasks of the NCA? (more than 1 answer possible) | Inspection<br>Vigilance |
| 1.3. National Competent Authority 3? | Yes |
| 1.3.1. Name of National Competent Authority 3: | Department of Mother and Child, Ministry of Health |
| 1.3.2. Address of NCA 3: | ul. Długa 38/40, 00-241 Warsaw, Poland |
| 1.3.3. Telephone (central access point): | +48 22 53 00 383 |
| 1.3.4. E-mail (central access point): | dep-md@mz.gov.pl |
| 1.3.5. Website: | www.mz.gov.pl |
| 1.3.6. The NCA is responsible for? (more than 1 answer possible) | Reproductive tissues and cells |
| 1.3.7. What are the role/tasks of the NCA? (more than 1 answer possible) | Vigilance |
| 1.4. National Competent Authority 4? | No |
| 1.5. Please give a short description of the legal status and organisation of the National Competent Authority(ies) (e.g. departments, staffing, number of senior and junior inspectors, staff working on EU affairs and legal matters, vigilance officers, budget, independence from government etc.). | National Centre for Tissue and Cell Banking (KCBTiK – Krajowe Centrum Bankowania Tkanek i Komorek) is a budgetary unit submitted to the minister competent to do with health matters. The tasks of the National Centre for Tissue and Cell Banking include, in particular: 1) organization of a co-operation between tissue and cell banks; 2) performance of reference and consultative functions; 3) supervision and inspection of tissue and cell banks in respect of the merits; 4) keeping a register of tissue and cell banks; 5) organizing the trainings with regard to recovery, collection, testing, processing, sterilization, storage and distribution of cells and tissues; 6) keeping the list of persons who completed the trainings with regard to recovery, collection, testing, processing, sterilization, storage and distribution of cells and tissues; 7) exercising substantive supervision over the activity of recovery teams; 8) management of SAREs. Polish Transplant Coordinating Center is responsible for: 1) procurement and transplant centers of biovital tissues and cells , 2) HSC import and export, 3) management of SAREs in the field of HSC. Department of Mother and Child has no assigned status of the NCA. However it deals with matters related to ART in Poland. |
| 1.6. In case of MS with federal or decentralised systems, please indicate the roles/tasks of the Regional Competent Authority(ies). (more than 1 answer possible) | Not applicable |
| 1.7. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies) for tissues and cells: | There are no Regional CAs in Poland. |
| **2. Procurement (Article 5 Directive 2004/23/EC)** | |
| 2.1. Do you authorise the "conditions of procurement"? | Yes |
| 2.1.1. How do you authorise the "conditions of procurement"? (more than 1 answer possible) | By inspecting some procurement centres<br>By inspecting the documentation associated with procurement that is |

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| | available in the tissue establishment working with procurement centres |
| 2.1.2. How many such authorisations were granted in 2011 (01/01-31/12/2011)? | 3 |
| 2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011). | 154 |
| 2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011). | 120 |
| 2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues were carried out in 2011 (01/01-31/12/2011). | no data |
| 2.2.4. Please provide the number of procurement centers in which procurement of tissues/cells for ATMP manufacturing were carried out in 2011 (01/01-31/12/2011). | 27 |
| 2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC and its implementing Directive 2006/17/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) ? (more than 1 answer possible) | Inspections of the site/centre<br>Analysis of the mandatory documentation |
| 2.4. Are you also responsible for the accreditation, designation, authorisation or licensing of laboratories performing donor testing? | No |
| 2.4.2. Which National Authority is in charge of this activity? | National Chamber of Diagnostic Laboratories |
| 2.5. How do you ensure, as CA for T&C, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art. 5(2))? (more than 1 answer possible) | Analysis of the mandatory documentation requested from the tissue establishment |
| 2.6. Please provide data on qualified laboratories accredited, authorised or licensed in your country (e.g. number, year of accreditation/authorisation/license, which donor tests are performed etc.). | 59 |
| 2.7. Do you have any additional comments on procurement? | In 2012 there were 15 on site inspections of procurement centers. |
| **3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)** | |
| 3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>HBs AG<br>Anti HBc<br>Anti HCV-Ab<br>Treponema Pallidum |
| 3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>HBs AG<br>Anti HBc<br>Anti HCV-Ab<br>Treponema Pallidum |
| 3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to encourage its use? Please specify why or why not (e.g. number of additional cases detected, cost-benefit etc.). | NAT testing is used for verification of doubtfull serological results |
| 3.4. Do you have concerns on accuracy of the available tests and test procedures for deceased donors? | No |
| 3.5. Are any other laboratory tests required for donors of non-reproductive tissues and cells in your Member State? | No |
| 3.6. Are any other laboratory tests required for donors of reproductive tissues and cells in your Member State? | No |
| 3.7. Do you request/use international accreditation systems for testing laboratories? | No |
| 3.8. Do you have any additional comments on testing? | Due to the lack of the regulation regarding ART in Poland the panel |

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| | of obligatory laboratory tests required for donors of reproductive tissues and cells is not formally established. |
| **4. Accreditation, designation, authorisation or licensing of tissue establishments (Article 6, Directive 2004/23/EC)** | |
| 4.1. Do you have a system of designation, authorisation, accreditation or licensing for all types of tissue establishments under your responsability? | No |
| 4.1.1. Why not? | Designation of tissue and cell establishments is done by Minister of Health |
| 4.2. Is inspection a prerequisite for the designation, authorisation, accreditation or licensing of tissue establishments? | Yes. Review of submitted documentation and on-site inspection is always required. |
| 4.2.1. How many inspections were performed in 2011 for authorising/accrediting/licensing/designating TEs? | 5 |
| 4.3. Are preparation processes authorised? | Yes |
| 4.3.1. How are they authorised? (more than 1 answer possible) | During routine on-site inspections and by review of a submitted application with supporting documentation |
| 4.4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were suspended in 2011? | 0 |
| 4.5. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011? | 0 |
| 4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)? | No |
| **4bis. Overview of tissue/cells establishments authorised by the NCA** | |
| 4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible): | Ocular tissue establishments<br>HSC tissue establishments |
| 4.7.3. How many ocular tissue establishments? | 1 |
| 4.7.5. How many HSC tissue establishments? | 4 |
| 4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible): | HSC tissue establishments |
| 4.8.5. How many HSC tissue establishments? | 1 |
| 4.9. Tissue establishments first time authorised between 01/01/2011 and 31/12/2011 (more than 1 answer possible): | Ocular tissue establishments<br>HSC tissue establishments |
| 4.9.3. How many ocular tissue establishments? | 1 |
| 4.9.5. How many HSC tissue establishments? | 4 |
| 4.10. All tissue establishments authorised by 31/12/2011 (more than 1 answer possible): | Skin tissue establishments<br>Musculo-skeletal tissue establishments<br>Ocular tissue establishments<br>Cardiovascular tissue establishments<br>HSC tissue establishments<br>Cord blood tissue establishments<br>Multi-tissue establishments<br>Other tissue establishments |
| 4.10.1.1. How many public skin tissue establishments? | 2 |
| 4.10.1.2. How many private skin tissue establishments? | 1 |
| 4.10.2.1. How many public musculo-skeletal tissue establishments? | 1 |
| 4.10.2.2. How many private musculo-skeletal tissue establishments? | 0 |
| 4.10.3.1. How many public ocular tissue establishments? | 4 |
| 4.10.3.2. How many private ocular tissue establishments? | 0 |
| 4.10.4.1. How many public cardiovascular tissue establishments? | 2 |
| 4.10.4.2. How many private cardiovascular tissue establishments? | 0 |
| 4.10.5.1. How many public HSC tissue establishments? | 18 |
| 4.10.5.2. How many private HSC tissue establishments? | 0 |
| 4.10.6.1. How many public cord blood tissue establishments? | 3 |
| 4.10.6.2. How many private cord blood tissue establishments? | 6 |
| 4.10.8.1. How many public multi-tissue establishments? | 2 |
| 4.10.8.2. How many private multi-tissue establishments? | 1 |
| 4.10.9.1. Please specify the type of 'other' public tissues/cells establishements and how many. | - pancreatic islets bank - 1 |
| 4.10.9.2. Please specify the type of 'other' private tissues/cells | - chondocytes and osteoblasts bank - 1 |

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| establishements and how many. | |
| 4.11. How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Art. 6(5) during 2011? Please provide number(s) per type tissues/cells. | 0 |
| **4ter. Sanctions** | |
| 4.16. Have penalties for infringements of the national provisions pursuant to the Directive been defined (Article 27)? | Yes |
| 4.16.1. Have penalties already been imposed? | No |
| 4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing? | Tissue and cell establishments are authorised every five years (the Designation of the Minister of Health is valid for 5 years). Inspections for designation follows application prepared by applying tissue establishment. At least every two years each tissue establishment is subjected to on-site inspection. |
| **5. Inspections (Article 7, Directive 2004/23/EC)** | |
| 5.1. Is a system in place for organising inspections and control measures of tissue establishments? | Yes |
| 5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections. | National Centre for Tissue and Cell Banking |
| 5.1.2. If yes, please specify staffing (how many inspectors). | 6 |
| 5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible) | No |
| 5.3. How many routine inspections of tissue establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011)? | 11 |
| 5.3.1. How many inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) following serious adverse events or reactions, or suspicion thereof ? | 3 |
| 5.3.2. How many other type of inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | 0 |
| 5.3.3. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | 0 |
| 5.3.4. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where minor shortcomings were noted? | 3 |
| 5.3.5. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where major shortcomings were noted? | 3 |
| 5.3.6. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by suspension of authorisation? | 0 |
| 5.3.7. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by closure? | 0 |
| 5.3.8. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of other inspections carried out? Please specify. | 0 |
| 5.4. How many routine inspections were conducted in ART establishments (from 1/1/2011 to 31/12/2011)? | 0 |
| 5.4.1. How many inspections were conducted in ART establishments | 0 |

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| following serious adverse events or reactions, or suspicion thereof (from 1/1/2011 to 31/12/2011)? | |
| 5.4.2. How many other type of inspections were conducted on ART establishments (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | 0 |
| 5.4.3. Outcome of inspections of ART tissue establishments carried out in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | 0 |
| 5.4.4. What was the number of inspections carried out in ART establishments where minor shortcomings were noted? | 0 |
| 5.4.5. What was the number of inspections carried out in ART establishments where major shortcomings were noted? | 0 |
| 5.4.6. What was the number of inspections carried out in ART establishments followed by suspension of authorisation? | 0 |
| 5.4.7. What was the number of inspections carried out in ART establishments followed by closure of respective establishements? | 0 |
| 5.4.8. What was the number of other inspections of ART establishments? Please specify. | 0 |
| 5.5. Which type of routine inspections do you conduct? (more than 1 answer possible) | General system-oriented inspections<br>Thematic inspections<br>Desk based reviews |
| 5.6. How do you decide which type of routine inspection to conduct? | On-site inspections are always carried out in 2-year period sheme and after SARE reporting. |
| 5.7. Until 2011, did you implement the requirement concerning the time interval between two inspections (Art. 7.3.)? | Yes |
| 5.8. How many TEs were inspected at least twice between 2008-2011 (01/01/2008-31/12/2011)? | 23 |
| 5.9. Did you perform/conduct inspections of procurement sites outside tissue establishments? | Yes |
| 5.9.1. If yes, how many? | 2 |
| 5.10. Did you carry out inspections of third parties? | Yes |
| 5.10.1. If yes, how many? | 3 |
| 5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)? | Yes |
| 5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)? | Yes |
| 5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)? | 5 |
| 5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))? | No |
| 5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))? | No |
| 5.15. Did you organise any inspections of procurement centres or tissue establishments in third countries from which tissues and/or cells were imported in your country (as recorded by 31/12/2011)? | No |
| 5.16. Have you asked another MS, or have you been requested by any other MS, on the results and control measures of your inspections, as part of an enquiry/investigation? | No |
| 5.17. Would you be interested in developing joint inspections? Joint inspections should be understood as inspections of tissue establishments conducted jointly by two or more Member States' Competent Authorities on their territory or in third countries. | Yes |
| 5.18. Do you have any additional comments on inspections? | |
| **6. Import/export (Article 9 Directive 2004/23/EC)** | |

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| 6.1. Do you have a register of authorised tissue establishments that are explicitly authorised to perform import/export of tissues and celles from/to third countries? | No |
| 6.2. Please specify the number of tissue establishments authorised to import tissues and cells from third countries (recorded by 31/12/2011). | 0 |
| 6.3. Please specify the number of tissue establishments authorised to export tissues and cells from third countries (recorded by 31/12/2011). | 0 |
| 6.4. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of skin from third countries. | Regulation of Minister of Health on exportation and importation of cells tissues and organs (Dz.U. 2010, Nr 75, poz. 485) : - donation procedure, donor selection criteria, laboratory testing, processing, storage, distribution and transportation conditions |
| 6.5. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of musculo-skeletal (bone, tendons, fascia etc.) tissues from third countries. | Regulation of Minister of Health on exportation and importation of cells tissues and organs (Dz.U. 2010, Nr 75, poz. 485) : - donation procedure, donor selection criteria, laboratory testing, processing, storage, distribution and transportation conditions |
| 6.6. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of ophtalmic (cornea, sclera, etc) tissues from third countries. | Regulation of Minister of Health on exportation and importation of cells tissues and organs (Dz.U. 2010, Nr 75, poz. 485) : - donation procedure, donor selection criteria, laboratory testing, processing, storage, distribution and transportation conditions |
| 6.7. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cardio vascular tissues from third countries. | Regulation of Minister of Health on exportation and importation of cells tissues and organs (Dz.U. 2010, Nr 75, poz. 485) : - donation procedure, donor selection criteria, laboratory testing, processing, storage, distribution and transportation conditions |
| 6.8. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) (other than cord blood) from third countries. | Regulation of Minister of Health on exportation and importation of cells tissues and organs (Dz.U. 2010, Nr 75, poz. 485) : - donation procedure, donor selection criteria, laboratory testing, processing, storage, distribution and transportation conditions |
| 6.9. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cord blood from third countries. | Regulation of Minister of Health on exportation and importation of cells tissues and organs (Dz.U. 2010, Nr 75, poz. 485) : - donation procedure, donor selection criteria, laboratory testing, processing, storage, distribution and transportation conditions |
| 6.10. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of reproductive cells (sperm, egg cells) from third countries. | There is no regulation regarding ART in Poland |
| 6.11. Did you import tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | Yes |
| 6.11.1. If yes, please provide the data concerning the number/volume of imported tissues and cells by country of origin. | HSC: 9 (USA), 2 (Australia) |
| 6.12. Did you export tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | Yes |
| 6.12.1. If yes, please provide the data concerning the number/volume of exported tissues and cells by country of destination. | HSC: 1 (Australia), 1 (Croatia) |
| 6.13. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on imports/exports of tissues/cells between your country and other third countries? | No |
| 6.14. What is the relation between import/export of tissues and cells and self-sufficiency? (more than 1 answer possible) | A. Export of tissues/cells is authorised only after checking that local/national needs are fulfilled.<br>C. Export of tissues/cells is authorised irrespective of national needs<br>E. Import of tissues/cells is authorised based on estimations showing that there is chronic deficiency of those tissues/cells |
| 6.14.1. If A or D were selected, please explain how you quantify local/national needs. | Based on current request for particular type of tissue graft from hospitals in Poland. |
| 6.15. Did you authorise direct imports of tissues/cells to hospitals/clinics in your country? | No |
| 6.16. Do you have any additional comments on import/export? | According to law regulations each procedure of crossing of Polish border of tissues and cells is recognised as import or export. In general there is no differences between other member states and |

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| | third countries. |
| **7. Distribution/intra community exchanges (Article 23 Directive 2004/23/EC)** | |
| 7.1. Do you have intra-community exchanges of tissues and cells? | Yes |
| 7.1.1. If yes, how do you address the possible more stringent quality and safety measures established by other Member States? Please specify. | No in general. According to law regulations each procedure of crossing of Polish border of tissues and cells is recognised as import or export. In general there is no differences between other member states and third countries. The authorisation of tiissue establishment by adequate CA is an important part of verification. Each tissue or cel graft is distibuted to Polish hospitals with the involment of designated by Polish Minister of Health tiissue establishment. |
| 7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States? | Yes |
| 7.1.2.1. How do you address this difference for tissues and cells coming from a MS with minimum quality requirements? Please specify. | - document of accredidation, designation, licencing of tissue establishment by adequate CA; - direct contact with CA from other MS (t.e. country of origin); - procedures of donation, donor selection criteria, laboratory testing, procurement, processing, storage, distribution and transportation conditions. |
| 7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify. | Verification of document of accredidation, designation, licencing of tissue establishment by adequate CA; - direct contact with CA from other MS (t.e. country of origin); - procedures of donation, donor selection criteria, laboratory testing, procurement, processing, storage, distribution and transportation conditions. |
| 7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible). | Yes, but only via an authorised TE in my MS |
| 7.4. Have you authorised direct distribution to the recipient of specific tissues and cells (Art. 6, Directive 2006/17/EC)? | No |
| 7.5. Do you collect data regarding the cross-border exchange of tissue/cells between your country and other EU MS? | Yes |
| 7.5.1. Please provide us with data (country of destination, type of tissue/cell and number of units distributed) concerning distribution to other MS in 2011 (01/01/2011-31/12/2011). | - ocular tissue: 1 (Germany) - heart valves: 20 (Germany) - HSC: 126 (Germany), 8 (Great Britain), 1 (Cyprus), 2 (Czech Republik), 2 (France), 1 (Spain), 1 (Italy) |
| 7.5.2. Please provide us with data (country of origin, type of tissue/cell and number of units distributed) concerning distribution to other MS in 2011 (01/01/2011-31/12/2011) | 0 |
| 7.6. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on cross-border exchanges of tissues/cells between your country and other EU MS? | No |
| 7.7. Do you allow brokerage companies for either distribution in EU and/or import/export of tissues/cells? In this context, a brokerage company means a body that arranges transactions between a supplier (tissue establishment/company selling tissues or cells) and a buyer (a tissue establishment/a hospital or clinic/an individual) without undertaking activities of processing, preservation or storage. | No |
| 7.8. Are brokers actively supplying health professionals/establishments in your country? | No |
| 7.9. Do you have any additional comments on distribution? | |
| **8. Register of tissue establishments and reporting obligations (Article 10, Directive 2004/23/EC)** | |
| 8.1. Do you have an annual report model/template on the activities of tissue establishments in your Member State? (Article 10(1)). If yes, please upload the template. | Yes |
| 8.2. How many tissue establishments submitted annual reports of their activities during 2011. Please provide an estimation. (1 answer possible) | 100% (all) |
| 8.3. Are these reports publicly available? (Article 10(1)) | Yes |
| 8.3.1. If yes, please insert the link(s) to the report(s). | http://www.kcbtik.pl/?Zestawienia |
| 8.4. Do you publish a national annual report of the consolidated activities of all tissue establishments in your country? | Yes |
| 8.4.1. Please insert the link to the published national annual report. | http://www.kcbtik.pl/?Zestawienia |
| 8.5. Is there a publicly accessible register of authorised tissue establishements in place? (Article 10(2)) | Yes |

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| 8.5.1. If yes, please provide us with the link to the register's web site. | http://www.kcbtik.pl/?Banki_Tkanek |
| 8.6. Do you provide data regarding tissues and cells activities to the EUROCET registry (non-mandatory reporting)? | Yes |
| 8.6.1. If yes, what data are provided to EUROCET? Please specify. | - consolidated activities for tissue and cells regarding donation, procurement, processing, storage and distribution |
| 8.7. Do you have any additional comments on reporting? | |
| **9. Traceability (Article 8, Directive 2004/23/EC; and Directive 2006/86/EC)** | |
| 9.1. Was the donor identification system (Art. 8(2)) implemented in your country? | Yes |
| 9.2. Who assigns the unique code for each donation? (only 1 answer possible) | Tissue establishment |
| 9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible) | Both paper records and electronic forms |
| 9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify. | Based on review of writen procedure in place regarding set of data and adequate (30 years) period of storage. Procedures and data archivisation is reviewed during each on-site inspection. |
| 9.5. Do you have any additional comments on traceability? | Poland has implemented ISBT 128 coding system in tissue and cell establishments. |
| **10. Notification of serious adverse events and reactions (Article 11 Directive 2004/23, Article 6 Directive 2006/76)** | |
| 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))? | Yes |
| 10.1.1. If yes, which CA/institution is responsible? | Both National Centre for Tissue and Cell Banking and Polish Transplant Coordinating Center |
| 10.1.2. If yes, please provide a short description of its organisation. | National Centre for Tissue and Cell Banking for tissue establishments, Poltransplant and National Centre for Tissue and Cell Banking for procurement and transplantation. System is based on EUSTITE project deliverables. Management of SAREs by tissue bank was discussed during training courses organised in Poland. Each tissue establishment by implementing quality system managment is responsible for implementation SARE SOP. National Centre for Tissue Banking receives SARE notificantions from tissue establishments. If described case is scored as serious inspection is mandatory. NCTCB is involved in investigation and corrective actions. SAREs related to procurement and clinical use of tissues and cells are magaged together by NCTCB and Poltransplant |
| 10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use the SAR/E (to the CA (2006/76 art 6.4)) templates developed to the Annual reporting ot the EC also at national level? | Yes |
| 10.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level? | Yes |
| 10.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all TEs? | No |
| 10.4.1. Why not? | All tissue and cells establishments inspectors are responsible for managing of SAREs. They are all trained during EUSTITE or SOHOV7S projects and during internal trainings. |
| 10.5. How many tissue establishments provided in 2011 the SAR/SAE data as requested (please provide the % from the total number of TEs authorised in your country). | 100% |
| 10.6. Do you have a mandatory procedure for the transplantation centres when reporting SAR/SAE to the TEs which distributed the tissues/cells (Art 11.2)? | Yes |
| 10.6.1. If yes, please provide a brief description. | Tissue establishments are responsible to send SARE notification form to each transplant centers where they distribute tissues and cells. Poland started implementation of electronic notification of SAREs from transplant centers via "Registry" platform administered by Poltransplant. SARE cases are immidiately reported to the Ministry of Health. Minister of Health designates adequate CA for inspection according to writen procedure describing CA's competency. |
| 10.7. Do you give feedback to the TEs regarding SAR/SAE recorded | Yes |

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| at national level? | |
| 10.7.1. Please specify. | Annonimous data are analysed for educational reasons during training courses organised by National Centre for Tissue and Cell Banking. |
| 10.8. Do you give feedback to the TEs regarding SAR/SAE recorded at EU level? | Yes |
| 10.8.1. Please specify. | Annonimous data are analysed for educational reasons during training courses organised by National Centre for Tissue and Cell Banking |
| 10.9. Do you require your TEs to have a recall procedure? | Yes |
| 10.10. How many recalls related to safety and quality of tissues/cells were issued in your country in 2011? Please specify the number and which tissues were recalled and why (e.g. missing consent, quality defects etc). | 0 |
| 10.11. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites in case of a national rapid alert? | Yes |
| 10.11.1. If yes, please give a short description of the system/procedure. | Notification is dane via e-mail and/or fax communication. |
| 10.12. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites when a rapid alert is issued via the EU RATC platform? | Yes |
| 10.12.1. If yes, please give a short description of the system/procedure. | Notification is dane via e-mail and/or fax communication. |
| 10.13. Do you provide data regarding SAR/SAE to the EUROCET registry (non-mandatory reporting)? | No |
| 10.13.2. If no, please specify why not. | Data are provided directly to the European Comission. |
| 10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems? | Yes |
| 10.14.1. If yes, please specify which of the following systems are usually contacted. (more than 1 answer possible) | Haemovigilance<br>Pharmacovilance<br>Medical devices |
| 10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S? | Yes |
| 10.15.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (insufficient) - 2 (sufficient) 3 (good) - 4 (very good) to 5 (essential)? | 5 |
| 10.16. Do you have any additional comments on SARE reporting? | |
| **11. Consent and personal data protection (Article 13 and 14, Directive 2004/23/EC)** | |
| 11.1. What consent system for living tissue/cell donation do you have in place within your Member State? | Explicit consent (opt-in) |
| 11.1.1. Please specify your choice of consent system for living tissue/cell donation. | - potental donor was informed about the riscs related to donation (in written form); - potential donor agreed to became a donor (written agreement for procedurę of donation); - potential donor has full competency for legal actions; - in case when potential donor has no full competency for legal actions the decission of legal representative or a court is required. |
| 11.2. What consent system for deceased tissue/cell donation do you have in place within your Member State? | Presumed consent (opt-out) |
| 11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible) | No further authorisation is needed |
| 11.4. Is the consent system for deceased tissue donation the same as for organs? | Yes |
| 11.5. How is this consent verified during inspections? (more than 1 answer possible) | Analysis of documentation<br>Interviews with personnel |
| 11.6. What measures are in place to ensure that donors/relatives/authorising persons on behalf of donors are provided with the appropriate information, as requested by Art. | Only trained personnel is allowed to provide such information<br>Information for donors are standardised at national/regional level |

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| 13(2)? (more than 1 answer possible) | |
| 11.7. What measures are in place to ensure that both donors and recipients remain unidentifiable when access is given to third parties (Art. 14(1)). Please specify. | - Act of 6 November 2008 on the rights of the patient and the patient's Ombudsman (art.13) - Implementation of coding system for tissues and cells (ISBT 128); - Only codes appear on tissue grafts labels; - Legal requirement of anonimity between donor and recipient. |
| 11.8. Please specify what measures are in place to ensure that the identity of the receipient is not disclosed to the donor and vice versa. | - Act of 6 November 2008 on the rights of the patient and the patient's Ombudsman (art.13) - Implementation of coding system for tissues and cells (ISBT 128); - Only codes appear on tissue grafts labels; - Legal requirement of anonimity between donor and recipient. |
| 11.9. Does your national legislation allows disclosure of donor data in case of gametes donation? | No |
| 11.9.1. If no, please specify the circumstances and measures in place. | Act of 6 November 2008 on the rights of the patient and the patient's Ombudsman (art.13) |
| 11.10. Do you have any additional comments on consent and data protection? | |
| **12. Selection, evaluation and procurement (Article 15 Directive 2004/23; Annexes I-IV Directive 2006/17)** | |
| 12.1. How do you ensure that all requirements related to the evaluation and selection of donors (except donors of reproductive cells) are respected in your country (Art. 15(1), Annex I Directive 2006/17/EC)? (more than 1 answer possible) | Inspections of TEs and procurement sites<br>Audit of documentation<br>Regular evaluation of medical personnel |
| 12.2. How do you ensure that all requirements related to the evaluation and selection of donors of reproductive cells are respected in your country (Art 15 (1), Annex III of Directive 2006/17/EC)? (more than 1 answer possible) | Other |
| Please specify 'other'. | There is no regulation regarding ART in Poland. |
| 12.3. Do you have more stringent criteria for donor selection than those listed in Annex I of the Directive 2006/17/EC? | No |
| 12.4. What sources are required in your MS for the evaluation of a deceased donor of tissues/cells? (more than 1 answer possible) | Interview with the donor's family or a person who knew the donor well<br>Medical records of the donor<br>Interview with the treating physician<br>Interview with the general practitioner<br>Autopsy report |
| 12.5. Do you have more stringent criteria for selection of donors of reproductive cells than those listed in Annex III of the Directive 2006/17/EC? | No |
| 12.6. Do you have more stringent criteria for autologous donation than those listed in Annex I of the Directive 2006/17/EC? | No |
| 12.7. Do you require more information on the donation of tissues/cells than the mandatory one as laid down in the Annex of Directive 2004/23/EC (Art 15(3)? | No |
| 12.8. How do you ensure that all requirements regarding tissues and cells' procurement, packaging and transport are complied with by tissue establishments in your country (Art 15(1), Annex IV of Directive 2006/17/EC? (more than 1 answer possible)(For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)) | Inspection of tissue establishment<br>Inspection of the centre of human application (e.g. transplantation centre, ART centre) |
| 12.9. Do you have any additional comments on selection, evaluation and procurement? | |
| **13. Quality management, responsible person, personnel (Article 16, 17, 18 Directive 2004/23/EC)** | |
| 13.1. How do you ensure that tissue establishments in your country have in place a quality system respecting the provisions of the Directive 2004/23/EC Art 16.1? (more than 1 answer possible). (For this question "audit" means a documented review of procedures, | Authorisation requirement<br>Inspections<br>Internal audits<br>External audits |

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| records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)). | |
| 13.2. How do you ensure that tissue establishments have a responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible) | Authorisation requirement<br>Inspections<br>Regular evaluation of personnel<br>Mandatory trainings |
| 13.3. How do you ensure an appropriate training for the personnel directly involved in the activities of tissue establishments? (more than 1 answer possible) | Authorisation requirement<br>Inspections<br>Regular evaluation of personnel<br>Mandatory trainings |
| 13.4. Do you have national/regional/local training programmes for the personnel of tissue establishments? | Yes |
| 13.4.1. If yes, please specify. | There are traininng programmes for responsible persons and personel of tissue establishments, procurement and transplantation medical personel created and developed during realisation of Transition Facility 2004 project dedicated to National Centre for Tissue and Cell Banking. Trainings (6-7 courses) are organised every year since 2006. Trainigs are free of charge for participants and financed from National Programme for Development of Transplantation Medicine for years: 2010-2020. |
| 13.5. Any additional comments on quality management, responsible person, personnel? | Except of responisible person, each tissue establishment designates quality manager. |
| **14. Reception, processing, storage, labelling and packaging (Art 19-22 Directive 2004/23/EC)** | |
| 14.1. How do you ensure that tissue establishments in your country fulfill the requirments of the Art. 19 (Tissue and cell reception) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | National regulation/policy for reception of tissues/cells<br>Inspections of tissue establishments<br>Internal audits of tissue establishments<br>External audits of tissue establishments (e.g. ISO) |
| 14.2. How do you ensure that tissue establishments in your country fulfill the requirements of the Art. 20 (Tissue and cell processing) of Directive 2004/23/EC? (more than 1 answer possible) | SOPs for all processes affecting quality and safety are mandatory for authorisation<br>Inspections of tissue establishments<br>Internal audits of tissue establishments<br>External audits of tissue establishments (e.g. ISO) |
| 14.3. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 21 (tissue and cell storage conditions) of Directive 2004/23/EC? (more than 1 answer possible) | SOPs for procedures associated with storage of tissues and cells are mandatory for authorisation<br>Inspections of tissue establishments<br>Internal audits of tissue establishments<br>External audits of tissue establishments (e.g. ISO) |
| 14.4. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | SOPs for procedures associated with labelling and packaging are mandatory for authorisation<br>Inspections of tissue establishments<br>Internal audits of tissue establishments<br>External audits of tissue establishments(e.g. ISO) |
| 14.5. Any additional comments on reception, processing, storage, labelling and packaging? | External audits are not obligatory, but some of tissue establishments applied for and received ISO accreditaion. JACIE accreditaion programme of procurement and transplantation centers as well as tissue establishments in the field of HSC starts this (2013) year. |
| **15. Third party agreements (Art. 24 Directive 2004/23/EC)** | |
| 15.1. Are third party agreements foreseen/allowed in your national legislation? | Yes |
| 15.1.1. If yes, have tissue establishments in your Member State notified third party agreements? | Yes |
| 15.1.1.1. Under which circumstances and for which responsibilities? | - the list of third party agreements is a mandatory part of a documentation provided by tissue establishment during application for designation, - third party agreements and related documents (see below) are reviewed during on site inspections, - the responsibility lies on tissue establishment and if such activity of third party is accredited in Poland (eg. laboratory testig, radiation-sterilisation) the certifficate of such accreditaion document is required. |

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| 15.1.1.2. How are third party agreements controlled (Art 6.2) by the Competent Auhtority(ies) in your MS? Please specify. | - obligatory part of application for designation for tissue establishment activities, - third party agreements and related documents are reviewed during on-site inspections. |
| 15.2. Any additional comments on third party agreements? | |
| **16. General comments - implementation** | |
| 16.1. Do you have at national level more stringent quality and safety requirements than those requested by the EU legislation in this field (e.g. restrictions concerning the donation/use of certain tissues/cells, mandatory unpaid donation etc.)? | No |
| 16.2. Has your Member State encountered any difficulties in implementing the requirements in the EU Tissues and Cells Directives? Please choose from the options below. | ART provisions |
| 16.2.1. For all selected options in question 16.2., please provide a short description. | There is no consesus in the Parliament to transpose and then implement regulatiuons regarding ART. |
| 16.3. In your opinion, in which of the following Directives are there shortcomings (if any)? (more than 1 answer possible) | No shortcomings |

### *A.1.24. Survey response Portugal*

| **1. Public information** | |
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| 1.1. Name of National Competent Authority (NCA) 1: | Instituto Português do Sangue e da Transplantação, IP (IPST) |
| 1.1.2. Address of NCA 1: | Avenida Miguel Bombarda, n.º 6; 1000-208 Lisboa |
| 1.1.3. Telephone (central access point): | +351 210 063 063 |
| 1.1.4. E-mail (central access point): | transplantacao@ipst.min-saude.pt |
| 1.1.5. Website: | http://ipsangue.org/ipsangue2011/index.php |
| 1.1.6. The NCA is responsible for? (more than 1 answer possible) | Non-reproductive tissues and cells<br>Blood and blood components<br>Human organs |
| 1.1.7. What are the role/tasks of the NCA? (more than 1 answer possible) | Accreditation, authorisation, licensing of TEs<br>Other |
| Please specify 'other': | IPST is responsible for the biovigilance system and the authorization of import/export and circulation activities |
| 1.2. National Competent Authority 2? | Yes |
| 1.2.1. Name of National Competent Authority 2: | Direção-Geral de Saúde |
| 1.2.2. Address of NCA 2: | Alameda Dom Afonso Henriques, 45 - 1049-005 Lisboa |
| 1.2.3. Telephone (central access point): | -+351 21 843 05 00 |
| 1.2.4. E-mail (central access point): | sanguetransplantacao@dgs.pt |
| 1.2.5. Website: | www.dgs.pt |
| 1.2.6. The NCA is responsible for? (more than 1 answer possible) | Non-reproductive tissues and cells<br>Blood and blood components<br>Human organs |
| 1.2.7. What are the role/tasks of the NCA? (more than 1 answer possible) | Accreditation, authorisation, licensing of TEs<br>Inspection<br>Vigilance |
| 1.3. National Competent Authority 3? | Yes |
| 1.3.1. Name of National Competent Authority 3: | Conselho Nacional de Procriação Medicamente Assistida (CNPMA) |
| 1.3.2. Address of NCA 3: | Assembleia da República Palácio de São Bento 1249-068 LISBOA |
| 1.3.3. Telephone (central access point): | +351 21 391 93 03 |
| 1.3.4. E-mail (central access point): | cnpma.correio@ar.parlamento.pt |
| 1.3.5. Website: | http://www.cnpma.org.pt |
| 1.3.6. The NCA is responsible for? (more than 1 answer possible) | Reproductive tissues and cells |
| 1.3.7. What are the role/tasks of the NCA? (more than 1 answer possible) | Accreditation, authorisation, licensing of TEs<br>Inspection<br>Vigilance |
| 1.4. National Competent Authority 4? | No |
| 1.5. Please give a short description of the legal status and organisation of the National Competent Authority(ies) (e.g. departments, staffing, number of senior and junior inspectors, staff working on EU affairs and legal matters, vigilance officers, budget, independence from government etc.). | IPST is a public institute directly dependent of Ministry of Health, responsible for: - Coordination of procurement and transplant of organs, tissues, cells and blood (and blood components); - National System of Biovigilance and haemovigilance; - Monitoring the national activity with organs, tissues, cells and blood (and blood components); - Authorization of tissue and cells import/export activities; - Proposal of new regulations to the CA (DGS), based on the analysis of national activity. Staff of IPST Transplant department (central services): 1 – IPST Director (PhD, MD) |

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| | 1 – Transplant National Coordinator (MD.) 2 – Biologists (with 4 years experience in the field of inspections and national coordination) 1 –Jurist/legal advisor IPST, IP is also responsible for: - Public Tissue Bank (amniotic membrane; bone; cardiac valves; blood vessels; skin) - Public Cord Blood Bank; - Histocompatibiity centers - Regional Blood Establishments. Diretorate-General of Health is a central organism directly dependent of Ministry of Health, responsible for: - Quality and safety of organs, tissues, cells and blood; - Monitoring the quality and safety of national activity with organs, tissues, cells and blood; - Authorization of services and activities with organs, tissues, cells and blood and inspections; - Proposal of new regulations to the CA, based on the analysis of national activity Staff of DGS (Central service) Quality and Safety Department (QSD) for cells, tissues and organs: 1 – QSD Director (MD) 1 – Medical Doctor 1 – Manager Hospital/Jurist 1 – Pharmacist and veterinary doctor 1 - Architect DGS is also responsible for the authorization and monitoring of quality and safety of: - Public Tissue Banks (amniotic membrane; bone; cardiac valves; blood vessels; skin) - Public Cord Blood Bank; - Private Cord Blood Banks - Regional Public Blood Establishments CNPMA (National Council for Assisted Reproduction Technologies) was created in 2006, under the Law 32/2006, of 26 July. CNPMA is an independent authority that functions under the aegis of the Portuguese Assembly of the Republic, with powers, in general, to pronounce on ethical, social and legal questions of assisted reproduction technologies. Among others, the Council is responsible for: a) establishing the terms for authorization of centres where assisted reproduction techniques are administered, and of centres where gametes or embryos are preserved and monitoring the activities of those centres; b) updating scientific information on assisted reproduction technologies; c) issuing opinions on the implementation of assisted reproduction techniques within the National Health Service; d) centralizing all relevant information on the application of assisted reproduction techniques, namely registers of donors, beneficiaries and children born, as well as providing information related to donors, within the limited framework permitted by law. National Council for Assisted Reproduction Technologies comprises nine distinguished persons of recognized merit who are especially qualified in the field of the ethical, scientific, social and legal issues raised by assisted reproduction technologies: a) Five members are elected by the Assembly of the Republic; and b) Four members are appointed by the members of Government responsible for health and science. Staff: two policy officers. Regarding inspections and auditing, it is the Ministry of Health administrative body for Health Inspections that is responsible for monitoring public and private ART TE, under the guidance of the CNPMA, which assures initial and permanent training for clinical and laboratory inspectors. |

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| 1.6. In case of MS with federal or decentralised systems, please indicate the roles/tasks of the Regional Competent Authority(ies). (more than 1 answer possible) | Not applicable |
| 1.7. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies) for tissues and cells: | Not applicable |
| **2. Procurement (Article 5 Directive 2004/23/EC)** | |
| 2.1. Do you authorise the "conditions of procurement"? | Yes |
| 2.1.1. How do you authorise the "conditions of procurement"? (more than 1 answer possible) | By inspecting some procurement centres<br>By inspecting the documentation associated with procurement that is available in the tissue establishment working with procurement centres |
| 2.1.2. How many such authorisations were granted in 2011 (01/01-31/12/2011)? | None (By this new CA, in charge of these field since the end of 2012) |
| 2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011). | None (By this new CA, in charge of these field since the end of 2012) |
| 2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011). | None (By this new CA, in charge of these field since the end of 2012) |
| 2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues were carried out in 2011 (01/01-31/12/2011). | 28 |
| 2.2.4. Please provide the number of procurement centers in which procurement of tissues/cells for ATMP manufacturing were carried out in 2011 (01/01-31/12/2011). | None (By this new CA, in charge of these field since the end of 2012) |
| 2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC and its implementing Directive 2006/17/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) ? (more than 1 answer possible) | Inspections of the site/centre<br>Analysis of the mandatory documentation |
| 2.4. Are you also responsible for the accreditation, designation, authorisation or licensing of laboratories performing donor testing? | No |
| 2.4.2. Which National Authority is in charge of this activity? | CA2 - DGS |
| 2.5. How do you ensure, as CA for T&C, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art. 5(2))? (more than 1 answer possible) | Inspections of the laboratories<br>Analysis of the mandatory documentation requested from the tissue establishment |
| 2.6. Please provide data on qualified laboratories accredited, authorised or licensed in your country (e.g. number, year of accreditation/authorisation/license, which donor tests are performed etc.). | Since this NCA is dealing with this field (end of 2012): 2 . However there are many other being validated by this CA. |
| 2.7. Do you have any additional comments on procurement? | No addicional comments on procurement |
| **3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)** | |
| 3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>NAT HIV 1<br>HBs AG |

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| | Anti HBc<br>NAT HBV<br>Anti HCV-Ab<br>NAT HCV<br>Treponema Pallidum<br>HTLV-2 |
| 3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>HBs AG<br>Anti HBc<br>Anti HCV-Ab<br>HTLV-2<br>NAT Chlamydia<br>Treponema Pallidum |
| 3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to encourage its use? Please specify why or why not (e.g. number of additional cases detected, cost-benefit etc.). | NAT mandatory in Portugal (CNPMA - NCA3): Regarding reproductive cells, NAT is not mandatory for HIV, HBV and HCV (but it requires a second tests on samples collected after quarentine period). |
| 3.4. Do you have concerns on accuracy of the available tests and test procedures for deceased donors? | Yes |
| 3.4.1. Please specify why: | Still under analysis by the new CAs (in charge since the end of 2012) |
| 3.5. Are any other laboratory tests required for donors of non-reproductive tissues and cells in your Member State? | No |
| 3.6. Are any other laboratory tests required for donors of reproductive tissues and cells in your Member State? | No |
| 3.7. Do you request/use international accreditation systems for testing laboratories? | Yes |
| 3.7.1. Please specify. | International Guidelines |
| 3.8. Do you have any additional comments on testing? | No addicional comments on testing. |
| **4. Accreditation, designation, authorisation or licensing of tissue establishments (Article 6, Directive 2004/23/EC)** | |
| 4.1. Do you have a system of designation, authorisation, accreditation or licensing for all types of tissue establishments under your responsability? | Yes |
| 4.2. Is inspection a prerequisite for the designation, authorisation, accreditation or licensing of tissue establishments? | Yes |
| 4.2.1. How many inspections were performed in 2011 for authorising/accrediting/licensing/designating TEs? | None (By this new CA, in charge of these field since the end of 2012) |
| 4.3. Are preparation processes authorised? | Yes |
| 4.3.1. How are they authorised? (more than 1 answer possible) | During routine inspections<br>During inspections organised for this purpose<br>By review of a submitted application with supporting documentation |
| 4.4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were suspended in 2011? | None (By this new CA, in charge of these field since the end of 2012) |
| 4.5. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011? | None (By this new CA, in charge of these field since the end of 2012) |
| 4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)? | No |
| **4bis. Overview of tissue/cells establishments authorised by the NCA** | |

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| 4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible): | Ocular tissue establishments<br>Cord blood tissue establishments<br>Multi-tissue establishments |
| 4.7.3. How many ocular tissue establishments? | Information not yet available by this new CA |
| 4.7.6. How many cord blood tissue establishments? | Information not yet available by this new CA |
| 4.7.8. How many multi-tissue establishments? | Information not yet available by this new CA |
| 4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible): | Ocular tissue establishments<br>Cord blood tissue establishments<br>Multi-tissue establishments |
| 4.8.3. How many ocular tissue establishments? | Information not availble yet by this new CA |
| 4.8.6. How many cord blood tissue establishments? | Information not yet available by this new CA |
| 4.8.8. How many multi-tissue establishments? | Information not yet available by this new CA |
| 4.9. Tissue establishments first time authorised between 01/01/2011 and 31/12/2011 (more than 1 answer possible): | Other tissue establishments |
| 4.9.9. Please specify the type of tissues/cells and how many. | Information not yet available by this new CA |
| 4.10. All tissue establishments authorised by 31/12/2011 (more than 1 answer possible): | ART tissue establishments |
| 4.10.7.1. How many public ART tissue establishments? | 10 |
| 4.10.7.2. How many private ART tissue establishments? | 18 |
| 4.11. How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Art. 6(5) during 2011? Please provide number(s) per type tissues/cells. | Tissues and cells distributed in 2011: Bone Marrow: 36 Peripheral Blood: 555 Cord blood: 11 Heart Valves: 75 Musculoskeletal: NA Amniotic Membrane: 233 units (43385 cm2) ocular tissues: 752 |
| **4ter. Sanctions** | |
| 4.16. Have penalties for infringements of the national provisions pursuant to the Directive been defined (Article 27)? | Yes |
| 4.16.1. Have penalties already been imposed? | No |
| 4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing? | No addicional comments. |
| **5. Inspections (Article 7, Directive 2004/23/EC)** | |
| 5.1. Is a system in place for organising inspections and control measures of tissue establishments? | Yes |
| 5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections. | DGS - Departamento da Qualidade na Saúde (DGS-NCA2). (CNPMA - NCA3): For ART it is the Ministry of Health administrative body for Health Inspections (IGAS) in collaboration with CNPMA. |
| 5.1.2. If yes, please specify staffing (how many inspectors). | (DGS-NCA2): CA team is constituted by 4 elements and 2 of them (one medical doctor and one pharmacist) have done the CATIE's course and 6 designated experts, for the time being; the inspections are also performed by inspectors from the Ministry of Health Inspection Central Department, included in the CA team; (CNPMA - NCA3): Team is constituted by two inspectors and four designated experts (two clinical and two laboratorial). |
| 5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible) | No |
| 5.3. How many routine inspections of tissue establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011)? | None (By this new CA, in charge of these field since the end of 2012) |

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| 5.3.1. How many inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) following serious adverse events or reactions, or suspicion thereof ? | None (By this new CA, in charge of these field since the end of 2012) |
| 5.3.2. How many other type of inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | None (By this new CA, in charge of these field since the end of 2012) |
| 5.3.3. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | None (By this new CA, in charge of these field since the end of 2012) |
| 5.3.4. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where minor shortcomings were noted? | None (By this new CA, in charge of these field since the end of 2012) |
| 5.3.5. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where major shortcomings were noted? | None (By this new CA, in charge of these field since the end of 2012) |
| 5.3.6. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by suspension of authorisation? | None (By this new CA, in charge of these field since the end of 2012) |
| 5.3.7. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by closure? | None (By this new CA, in charge of these field since the end of 2012) |
| 5.3.8. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of other inspections carried out? Please specify. | None (By this new CA, in charge of these field since the end of 2012) |
| 5.4. How many routine inspections were conducted in ART establishments (from 1/1/2011 to 31/12/2011)? | 10 |
| 5.4.1. How many inspections were conducted in ART establishments following serious adverse events or reactions, or suspicion thereof (from 1/1/2011 to 31/12/2011)? | 1 |
| 5.4.2. How many other type of inspections were conducted on ART establishments (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | 1 |
| 5.4.3. Outcome of inspections of ART tissue establishments carried out in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | 0 |
| 5.4.4. What was the number of inspections carried out in ART establishments where minor shortcomings were noted? | 8 |
| 5.4.5. What was the number of inspections carried out in ART establishments where major shortcomings were noted? | 2 |
| 5.4.6. What was the number of inspections carried out in ART establishments followed by suspension of authorisation? | 0 |
| 5.4.7. What was the number of inspections carried out in ART establishments followed by closure of respective establishements? | 0 |

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| 5.4.8. What was the number of other inspections of ART establishments? Please specify. | 0 |
| 5.5. Which type of routine inspections do you conduct? (more than 1 answer possible) | General system-oriented inspections<br>Thematic inspections<br>Desk based reviews |
| 5.6. How do you decide which type of routine inspection to conduct? | (DGS - NCA2): The routine inspections are decided among those urgent pending from the previous CA; the CA also pretend to cover proporcionally public and private establishements and blood/T&C E (CNPMA - NCA3): The first routine inspections is always a general system-oriented inspection; afterwards it may be followed by a thematic inspection (just to check the overcome of the diagnosed shortcomings) or a desk based reviews if the aim is to monitor the implementation of corrective measures. |
| 5.7. Until 2011, did you implement the requirement concerning the time interval between two inspections (Art. 7.3.)? | No |
| 5.7.1. Why not? | Because this new CA only is in charge of these field since the end of 2012 |
| 5.7.2. How do you prioritise tissue establishments to be inspected? | First of all those who are urgent, pending from the previous CA. |
| 5.8. How many TEs were inspected at least twice between 2008-2011 (01/01/2008-31/12/2011)? | Information not yet available by this new CA |
| 5.9. Did you perform/conduct inspections of procurement sites outside tissue establishments? | Yes |
| 5.9.1. If yes, how many? | Information not yet available for this new CA |
| 5.10. Did you carry out inspections of third parties? | No |
| 5.10.2. If no, why not? | Not yet analised and organised by this new CA |
| 5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)? | Yes |
| 5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)? | Yes |
| 5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)? | 5 |
| 5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))? | No |
| 5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))? | No |
| 5.15. Did you organise any inspections of procurement centres or tissue establishments in third countries from which tissues and/or cells were imported in your country (as recorded by 31/12/2011)? | No |
| 5.16. Have you asked another MS, or have you been requested by any other MS, on the results and control measures of your inspections, as part of an enquiry/investigation? | No |
| 5.17. Would you be interested in developing joint | Yes |

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| inspections? Joint inspections should be understood as inspections of tissue establishments conducted jointly by two or more Member States' Competent Authorities on their territory or in third countries. | |
| 5.18. Do you have any additional comments on inspections? | No addicional comments |
| **6. Import/export (Article 9 Directive 2004/23/EC)** | |
| 6.1. Do you have a register of authorised tissue establishments that are explicitly authorised to perform import/export of tissues and celles from/to third countries? | Yes |
| 6.2. Please specify the number of tissue establishments authorised to import tissues and cells from third countries (recorded by 31/12/2011). | 2 cells HSC banks |
| 6.3. Please specify the number of tissue establishments authorised to export tissues and cells from third countries (recorded by 31/12/2011). | 2 cells HSC banks |
| 6.4. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of skin from third countries. | Portugal only receives tissues from other Member States (there are no authorizations for importation tissues from third countries) |
| 6.5. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of musculo-skeletal (bone, tendons, fascia etc.) tissues from third countries. | Portugal only receives tissues from other Member States (there are no authorizations for importation tissues from third countries) |
| 6.6. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of ophtalmic (cornea, sclera, etc) tissues from third countries. | Portugal only receives tissues from other Member States (there are no authorizations for importation tissues from third countries) |
| 6.7. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cardio vascular tissues from third countries. | Portugal only receives tissues from other Member States (there are no authorizations for importation tissues from third countries) |
| 6.8. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) (other than cord blood) from third countries. | There are 2 HSC banks authorized to import/export units. This authorization was given after inspection where the procedures were evaluated. The other HSC banks have to ask authorization every time they need to export/import (through the submission of a documented process) |
| 6.9. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cord blood from third countries. | There are 2 HSC banks authorized to import/export units. This authorization was given after inspection where the procedures were evaluated. The other HSC banks have to ask authorization every time they need to export/import (through the submission of a documented process) |
| 6.10. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of reproductive cells (sperm, egg cells) from third countries. | Portugal only receives reproductive cells from other Member States (there are no authorizations for importation tissues/cells from third countries) |
| 6.11. Did you import tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | Yes |
| 6.11.1. If yes, please provide the data concerning the number/volume of imported tissues and cells by country of origin. | Non Reproductive cell (HSC) imported during 2011: USA: 6 Canada: 1 Swiss: 1 |
| 6.12. Did you export tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | Yes |
| 6.12.1. If yes, please provide the data concerning the number/volume of exported tissues and cells by country of destination. | Non Reproductive cell (HSC) exported during 2011: Swiss: 1; USA: 11; New Zeland: 1; Canada: 4; Brazil: 1; Uruguai: 2; Russia: 1; None reproductive tissues/cells were exported |
| 6.13. Are you aware of any significant changes in 2012 | No |

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| which may invalidate the 2011 data on imports/exports of tissues/cells between your country and other third countries? | |
| 6.14. What is the relation between import/export of tissues and cells and self-sufficiency? (more than 1 answer possible) | A. Export of tissues/cells is authorised only after checking that local/national needs are fulfilled.<br>E. Import of tissues/cells is authorised based on estimations showing that there is chronic deficiency of those tissues/cells |
| 6.14.1. If A or D were selected, please explain how you quantify local/national needs. | Every year Portugal has to import tissues from other MS, in this way is considered that the nationals TE aren't able to respond to the need (of public and private) heath institutions in Portugal |
| 6.15. Did you authorise direct imports of tissues/cells to hospitals/clinics in your country? | No |
| 6.16. Do you have any additional comments on import/export? | |
| **7. Distribution/intra community exchanges (Article 23 Directive 2004/23/EC)** | |
| 7.1. Do you have intra-community exchanges of tissues and cells? | Yes |
| 7.1.1. If yes, how do you address the possible more stringent quality and safety measures established by other Member States? Please specify. | The TE must comply with the requirements imposed by the MS where the products will be distributed. CA should collaborate in order to evaluate the quality and safety of the products distributed in different MS. |
| 7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States? | Yes |
| 7.1.2.1. How do you address this difference for tissues and cells coming from a MS with minimum quality requirements? Please specify. | NAT |
| 7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify. | TE must submit a documented authorization request, also IPST ask for the collaboration of the CA from the MS of origin, in order to determine the compliance of the criteria imposed by the Directives and National Legislation. |
| 7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible). | No |
| 7.4. Have you authorised direct distribution to the recipient of specific tissues and cells (Art. 6, Directive 2006/17/EC)? | No |
| 7.5. Do you collect data regarding the cross-border exchange of tissue/cells between your country and other EU MS? | Yes |
| 7.5.1. Please provide us with data (country of destination, type of tissue/cell and number of units distributed) concerning distribution to other MS in 2011 (01/01/2011-31/12/2011). | HSC distributed in other MS: German: 8 Italy: 15 Spain: 14 Austria: 1 United Kingdom: 2 France: 6 Greece: 1 Belgium: 1 Sweden: 1 Finland: 1 Slovenia: 1 Netherlands: 2 |
| 7.5.2. Please provide us with data (country of origin, type of tissue/cell and number of units distributed) concerning distribution to other MS in 2011 (01/01/2011-31/12/2011) | HSC: German - 41; United Kingdom - 2; Italy - 1; Spain - 1; Netherlands - 1 Ocular Tissues: Italy - 162 Musculoskeletal: Spain - 118 Other tissues: Spain - 21 |
| 7.6. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on cross-border exchanges of tissues/cells between your country and other EU MS? | No |
| 7.7. Do you allow brokerage companies for either distribution in EU and/or import/export of tissues/cells? In this context, a brokerage company means a body that arranges transactions between a supplier (tissue establishment/company selling tissues or cells) and a buyer (a tissue establishment/a hospital or clinic/an individual) without undertaking activities of processing, preservation or storage. | No |

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| 7.8. Are brokers actively supplying health professionals/establishments in your country? | No |
| 7.9. Do you have any additional comments on distribution? | |
| **8. Register of tissue establishments and reporting obligations (Article 10, Directive 2004/23/EC)** | |
| 8.1. Do you have an annual report model/template on the activities of tissue establishments in your Member State? (Article 10(1)). If yes, please upload the template. | Yes |
| 8.2. How many tissue establishments submitted annual reports of their activities during 2011. Please provide an estimation. (1 answer possible) | 60-99% |
| 8.3. Are these reports publicly available? (Article 10(1)) | No |
| 8.4. Do you publish a national annual report of the consolidated activities of all tissue establishments in your country? | Yes |
| 8.4.1. Please insert the link to the published national annual report. | http://ipsangue.org/ipsangue2011/index.php?option=com_content&view=category&layout=blog&id=75&Itemid=118; http://www.cnpma.org.pt/Docs/RELATORIO_ATIVIDADE_PMA2011.pdf |
| 8.5. Is there a publicly accessible register of authorised tissue establishements in place? (Article 10(2)) | Yes |
| 8.5.1. If yes, please provide us with the link to the register's web site. | http://www.dgs.pt/ms/8/default.aspx?pl=&id=5521&acess=0 (DGS); CNPMA: http://www.cnpma.org.pt/centros_lista.aspx |
| 8.6. Do you provide data regarding tissues and cells activities to the EUROCET registry (non-mandatory reporting)? | Yes |
| 8.6.1. If yes, what data are provided to EUROCET? Please specify. | Tissues and cells and HSC forms ART forms |
| 8.7. Do you have any additional comments on reporting? | The annual report form is available on line at: http://ipsangue.org/ipsangue2011/index.php?option=com_content&view=category&layout=blog&id=81&Itemid=124 |
| **9. Traceability (Article 8, Directive 2004/23/EC; and Directive 2006/86/EC)** | |
| 9.1. Was the donor identification system (Art. 8(2)) implemented in your country? | Yes |
| 9.2. Who assigns the unique code for each donation? (only 1 answer possible) | Tissue establishment |
| 9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible) | Both paper records and electronic forms |
| 9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify. | The CA validates it in the inspections, analising the available documentation. |
| 9.5. Do you have any additional comments on traceability? | (CNPMA - NCA3): Until 31.12.2012 assignment of unique code for each donations was assured by ART TE. Since 01.01.2013, it is a centralized registry - National Competent Authority assigns the unique code for each donation. |
| **10. Notification of serious adverse events and reactions (Article 11 Directive 2004/23, Article 6 Directive 2006/76)** | |
| 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))? | Yes |
| 10.1.1. If yes, which CA/institution is responsible? | Instituto Português do Sangue e da Transplantação (IPST) (NCA1); CNPMA (NCA3) |
| 10.1.2. If yes, please provide a short description of its organisation. | On-line form for notification of SAR and SAE; each organization (TE, procurement unit, transplant units) have a |

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| | login and password and can submit notification at anytime; in the begging of every year TE must full fill the annual reports through the form available also on-line at: http://ipsangue.org/ipsangue2011/index.php?option=com_content&view=category&layout=blog&id=81&Itemid=124 Everytime that there are an alert, information is sent to every organizations that have requested authorization. CNPMA (NCA3): there is a form and standardized procedures to report SAE and reactions (urgent notification: within 48 hours or until 15th of every month for non-urgent SAE/SAR) - Everytime that there is an alert, information is sent to the responsible person of each ART TE (notification by email). |
| 10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use the SAR/E (to the CA (2006/76 art 6.4)) templates developed to the Annual reporting ot the EC also at national level? | No |
| 10.2.1. If no, what template do you use? You are welcome to upload the template if you wish. | (IPST NCA1) available at: http://ipsangue.org/ipsangue2011/index.php?option=com_content&view=category&layout=blog&id=81&Itemid=124 (CNPMA NCA3) available at: http://www.cnpma.org.pt/profissionais_notificacao.aspx |
| 10.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level? | Yes |
| 10.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all TEs? | Yes |
| 10.5. How many tissue establishments provided in 2011 the SAR/SAE data as requested (please provide the % from the total number of TEs authorised in your country). | 70-99% |
| 10.6. Do you have a mandatory procedure for the transplantation centres when reporting SAR/SAE to the TEs which distributed the tissues/cells (Art 11.2)? | Yes |
| 10.6.1. If yes, please provide a brief description. | TE are responsible for collecting the follow up notifications of all the recipients of the distributed products |
| 10.7. Do you give feedback to the TEs regarding SAR/SAE recorded at national level? | Yes |
| 10.7.1. Please specify. | Divulgation of EC Annual reporting |
| 10.8. Do you give feedback to the TEs regarding SAR/SAE recorded at EU level? | Yes |
| 10.8.1. Please specify. | the data is presented only through communications on courses and seminars |
| 10.9. Do you require your TEs to have a recall procedure? | Yes |
| 10.10. How many recalls related to safety and quality of tissues/cells were issued in your country in 2011? Please specify the number and which tissues were recalled and why (e.g. missing consent, quality defects etc). | 0 |
| 10.11. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites in case of a national rapid alert? | Yes |
| 10.11.1. If yes, please give a short description of the system/procedure. | e-mail communication with the responsible persons of every organization that have requested authorization |
| 10.12. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites when a rapid alert is issued via the EU RATC platform? | Yes |

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| 10.12.1. If yes, please give a short description of the system/procedure. | e-mail communication with the responsible persons of every organization that have requested authorization |
| 10.13. Do you provide data regarding SAR/SAE to the EUROCET registry (non-mandatory reporting)? | No |
| 10.13.2. If no, please specify why not. | not requested |
| 10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems? | Yes |
| 10.14.1. If yes, please specify which of the following systems are usually contacted. (more than 1 answer possible) | Haemovigilance |
| 10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S? | Yes |
| 10.15.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (insufficient) - 2 (sufficient) 3 (good) - 4 (very good) to 5 (essential)? | 4 |
| 10.16. Do you have any additional comments on SARE reporting? | |
| **11. Consent and personal data protection (Article 13 and 14, Directive 2004/23/EC)** | |
| 11.1. What consent system for living tissue/cell donation do you have in place within your Member State? | Explicit consent (opt-in) |
| 11.1.1. Please specify your choice of consent system for living tissue/cell donation. | Accordingly with the portuguese law |
| 11.2. What consent system for deceased tissue/cell donation do you have in place within your Member State? | Presumed consent (opt-out) |
| 11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible) | No further authorisation is needed |
| 11.4. Is the consent system for deceased tissue donation the same as for organs? | Yes |
| 11.5. How is this consent verified during inspections? (more than 1 answer possible) | Analysis of documentation<br>Interviews with personnel |
| 11.6. What measures are in place to ensure that donors/relatives/authorising persons on behalf of donors are provided with the appropriate information, as requested by Art. 13(2)? (more than 1 answer possible) | Only trained personnel is allowed to provide such information |
| 11.7. What measures are in place to ensure that both donors and recipients remain unidentifiable when access is given to third parties (Art. 14(1)). Please specify. | The CA verifies the acess levels to the information by the HCP and the procedures in place to ensure the confidenciality. |
| 11.8. Please specify what measures are in place to ensure that the identity of the receipient is not disclosed to the donor and vice versa. | The CA validates the procedures in place to ensure the confidenciality levels (inspection/documental analysis) |
| 11.9. Does your national legislation allows disclosure of donor data in case of gametes donation? | No |
| 11.9.1. If no, please specify the circumstances and measures in place. | (CNPMA- NCA3): Donor's identity is kept confidential except if the donor express consent on contrary and only when the children born turns 18. Any other case, disclosure of donor data is only allowed for weighty reasons recognized by a judicial decision. Since 2013 there is a centralized registry with restricted access. |
| 11.10. Do you have any additional comments on consent and data protection? | |
| **12. Selection, evaluation and procurement (Article 15 Directive 2004/23; Annexes I-IV Directive 2006/17)** | |

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| 12.1. How do you ensure that all requirements related to the evaluation and selection of donors (except donors of reproductive cells) are respected in your country (Art. 15(1), Annex I Directive 2006/17/EC)? (more than 1 answer possible) | Stadardised questionnaires at national levels<br>Inspections of TEs and procurement sites<br>Audit of documentation |
| 12.2. How do you ensure that all requirements related to the evaluation and selection of donors of reproductive cells are respected in your country (Art 15 (1), Annex III of Directive 2006/17/EC)? (more than 1 answer possible) | Inspections of ART centres |
| 12.3. Do you have more stringent criteria for donor selection than those listed in Annex I of the Directive 2006/17/EC? | No |
| 12.4. What sources are required in your MS for the evaluation of a deceased donor of tissues/cells? (more than 1 answer possible) | Interview with the donor's family or a person who knew the donor well<br>Medical records of the donor |
| 12.5. Do you have more stringent criteria for selection of donors of reproductive cells than those listed in Annex III of the Directive 2006/17/EC? | Yes |
| 12.5.1. Please specify. | Age criteria: 35 for oocyte donors and 45 for sperm donor<br>For oocyte donation there is only allowence for 3 oocyte pick-ups cycles per donor. For sperm donation, a donor can only originate 8 deliveries. |
| 12.6. Do you have more stringent criteria for autologous donation than those listed in Annex I of the Directive 2006/17/EC? | No |
| 12.7. Do you require more information on the donation of tissues/cells than the mandatory one as laid down in the Annex of Directive 2004/23/EC (Art 15(3)? | No |
| 12.8. How do you ensure that all requirements regarding tissues and cells' procurement, packaging and transport are complied with by tissue establishments in your country (Art 15(1), Annex IV of Directive 2006/17/EC? (more than 1 answer possible)(For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)) | Inspection of tissue establishment<br>Audit of tissue establishment<br>Audit of the centre of human application |
| 12.9. Do you have any additional comments on selection, evaluation and procurement? | |
| **13. Quality management, responsible person, personnel (Article 16, 17, 18 Directive 2004/23/EC)** | |
| 13.1. How do you ensure that tissue establishments in your country have in place a quality system respecting the provisions of the Directive 2004/23/EC Art 16.1? (more than 1 answer possible). (For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)). | Authorisation requirement<br>Inspections |
| 13.2. How do you ensure that tissue establishments have a responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible) | Authorisation requirement<br>Inspections<br>Other |

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| Please specify 'other'. | HCP titulation (Portuguese Professional Associations) |
| 13.3. How do you ensure an appropriate training for the personnel directly involved in the activities of tissue establishments? (more than 1 answer possible) | Authorisation requirement<br>Inspections |
| 13.4. Do you have national/regional/local training programmes for the personnel of tissue establishments? | Yes |
| 13.4.1. If yes, please specify. | The TE do some trainnig programmes for the personnel of TE, in their Activities Plans, accordingly with the law. |
| 13.5. Any additional comments on quality management, responsible person, personnel? | |
| **14. Reception, processing, storage, labelling and packaging (Art 19-22 Directive 2004/23/EC)** | |
| 14.1. How do you ensure that tissue establishments in your country fulfill the requirments of the Art. 19 (Tissue and cell reception) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | Inspections of tissue establishments |
| 14.2. How do you ensure that tissue establishments in your country fulfill the requirements of the Art. 20 (Tissue and cell processing) of Directive 2004/23/EC? (more than 1 answer possible) | Inspections of tissue establishments |
| 14.3. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 21 (tissue and cell storage conditions) of Directive 2004/23/EC? (more than 1 answer possible) | Inspections of tissue establishments |
| 14.4. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | Inspections of tissue establishments |
| 14.5. Any additional comments on reception, processing, storage, labelling and packaging? | |
| **15. Third party agreements (Art. 24 Directive 2004/23/EC)** | |
| 15.1. Are third party agreements foreseen/allowed in your national legislation? | Yes |
| 15.1.1. If yes, have tissue establishments in your Member State notified third party agreements? | Yes |
| 15.1.1.1. Under which circumstances and for which responsibilities? | Each time an external activity takes place which influences the quality and safety of T and C processed in cooperation with a third party, namely the topics under article 24 of the directive, that were included in the portuguese law. |
| 15.1.1.2. How are third party agreements controlled (Art 6.2) by the Competent Auhtority(ies) in your MS? Please specify. | In the inspections and documental analysis |
| 15.2. Any additional comments on third party agreements? | No additional comments |
| **16. General comments - implementation** | |
| 16.1. Do you have at national level more stringent quality and safety requirements than those requested by the EU legislation in this field (e.g. restrictions concerning the donation/use of certain tissues/cells, mandatory unpaid donation etc.)? | Yes |
| 16.1.1. Please specify. | NAT |
| 16.2. Has your Member State encountered any difficulties in implementing the requirements in the EU Tissues and Cells Directives? Please choose from the options below. | ART provisions<br>Import-export<br>Vigilance<br>Authorisation-accreditation-licensing of TEs<br>Other |

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| 16.2.1. For all selected options in question 16.2., please provide a short description. | (CNPMA - NCA3): The specificity of ART are such that would require more adjusted measures and requirements. We welcome the planned introduction of specific chapters regarding this field. (DGS - NCA2): This CA is still in organization process and has not enough resources for the time being. |
| 16.3. In your opinion, in which of the following Directives are there shortcomings (if any)? (more than 1 answer possible) | No shortcomings |

## *A.1.25. Survey response Romania*

| **1. Public information** | |
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| 1.1. Name of National Competent Authority (NCA) 1: | National Transplant Agency |
| 1.1.2. Address of NCA 1: | 2-8 Constantin Caracas street, 4-th floor, sector 1, 011155 Bucharest |
| 1.1.3. Telephone (central access point): | +40317101473, +40317101474, fax +40213130434, |
| 1.1.4. E-mail (central access point): | ant@transplant.ro |
| 1.1.5. Website: | www.transplant.ro |
| 1.1.6. The NCA is responsible for? (more than 1 answer possible) | Non-reproductive tissues and cells<br>Reproductive tissues and cells<br>Human organs |
| 1.1.7. What are the role/tasks of the NCA? (more than 1 answer possible) | Accreditation, authorisation, licensing of TEs |
| 1.2. National Competent Authority 2? | Yes |
| 1.2.1. Name of National Competent Authority 2: | Ministry of Health - Public Health and Control in Public Health Directorate |
| 1.2.2. Address of NCA 2: | 1-3, Cristian Popisteanu street, sector 1 Bucharest |
| 1.2.3. Telephone (central access point): | +40213072557 |
| 1.2.4. E-mail (central access point): | sparvu@ms.ro |
| 1.2.5. Website: | www.ms.ro |
| 1.2.6. The NCA is responsible for? (more than 1 answer possible) | Non-reproductive tissues and cells<br>Reproductive tissues and cells<br>Blood and blood components<br>Human organs<br>Pharmaceuticals<br>Medical devices<br>Other |
| Please specify 'other': | health care etc |
| 1.2.7. What are the role/tasks of the NCA? (more than 1 answer possible) | Inspection<br>Vigilance |
| 1.3. National Competent Authority 3? | No |
| 1.5. Please give a short description of the legal status and organisation of the National Competent Authority(ies) (e.g. departments, staffing, number of senior and junior inspectors, staff working on EU affairs and legal matters, vigilance officers, budget, independence from government etc.). | National Transplant Agency (NTA) is an independent body subordinated to the Ministry of Health. The staff consists in 6,5 positions occupied from 18 approved. NTA does not have inspectors. NTA has 2 experts representing Romania to the European institutions and 1 judicial expert. The budget of NTA is established by the Ministry of Health. Ministry of Health Romania - Public Health and Control in Public Health Directorate The Ministry of Health is a governmental institution, financed from the public budget. According to the Governmental Decision no 144/2010 regarding the organizing and functioning of the Ministry of Health, there are two directorates with responsibilities in the field of transplant: the Public Health and Control in Public Health Directorate (PHCPHD) and the Health Care and Public Polices Department (HCPPD) The main responsibilities in the field of transplant are: - developing of legal acts (HCPPD); - carrying out inspections and control regarding the quality and sanitary safety of human grafts for therapeutic use and for application of art. 7 form the Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cellular (PHCPHD) - organizing and coordinating the vigilance system and taking the necessary measures for food categories in the fields of competence; - carrying out official control according to the annual plans of PHCPHD as well as control thematic actions initiated at the central level and in case of complaints from the population; - coordinating the activity of inspectors from the County Public Health Control The responsibilities of the County Public Health Directorates (CPHCD), are established by the Ministerial Order no. 1078/ 2010 for organizing and functioning of the CPHDs and the Ministerial |

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| | Order no 824/2006 regarding the Norms for functioning and organizing of the sanitary state inspection. We have inspectors how are dedicated to inspect establishments with transplant activities (44 inspectors), but they do inspections in other fields to. They are certificated in the field of medical sciences which was awarded of a university course of study and experience of working within a CA that inspects hospitals, blood establishments, hospital blood banks and tissues and cells establishments. According to the Governmental Decision no. 524/2013 beginning with de the 2nd of September the Ministry of Health is reorganizing. Regarding this decision there will be two other departments: Strategies and Health Policies Department and the Stat Sanitary Inspectorate. |
| 1.6. In case of MS with federal or decentralised systems, please indicate the roles/tasks of the Regional Competent Authority(ies). (more than 1 answer possible) | Not applicable |
| 1.7. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies) for tissues and cells: | No |
| **2. Procurement (Article 5 Directive 2004/23/EC)** | |
| 2.1. Do you authorise the "conditions of procurement"? | Yes |
| 2.1.1. How do you authorise the "conditions of procurement"? (more than 1 answer possible) | Other |
| Please specify 'other': | NTA is not allowed by law to realize inspections but only evaluations. NTA realizes evaluation of the documentation and evaluation of all procurement centers according to the requirements of the EU Directives. |
| 2.1.2. How many such authorisations were granted in 2011 (01/01-31/12/2011)? | 35 |
| 2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011). | 5 (2 skeleletal; 1skin; 2 cornea) |
| 2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011). | 3 |
| 2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues were carried out in 2011 (01/01-31/12/2011). | 30 |
| 2.2.4. Please provide the number of procurement centers in which procurement of tissues/cells for ATMP manufacturing were carried out in 2011 (01/01-31/12/2011). | 0 |
| 2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC and its implementing Directive 2006/17/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) ? (more than 1 answer possible) | Analysis of the mandatory documentation<br>Other |
| Please specify 'other': | Evaluation on the site of the centre |
| 2.4. Are you also responsible for the accreditation, designation, authorisation or licensing of laboratories performing donor testing? | Yes |
| 2.4.1. Please provide the number of the laboratories performing donor testing. | 6 National Transplant Agency being in charge for this activity |
| 2.5. How do you ensure, as CA for T&C, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art. 5(2))? (more than 1 answer possible) | Analysis of the mandatory documentation requested from the tissue establishment |
| 2.6. Please provide data on qualified laboratories accredited, authorised or licensed in your country (e.g. number, year of accreditation/authorisation/license, which donor tests are performed etc.). | 6 accredited laboratories since 2005. Donor tests performed are those in complying with the requirements of the EU Directives. |
| 2.7. Do you have any additional comments on procurement? | No |

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| **3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)** | |
| 3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>Ag HIV<br>NAT HIV 1<br>HBs AG<br>Anti HBc<br>NAT HBV<br>Anti HCV-Ab<br>NAT HCV<br>Treponema Pallidum<br>HTLV-2 |
| 3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>Ag HIV<br>NAT HIV 1<br>HBs AG<br>Anti HBc<br>NAT HBV<br>Anti HCV-Ab<br>NAT HCV<br>HTLV-2<br>NAT HTLV-2<br>Treponema Pallidum |
| 3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to encourage its use? Please specify why or why not (e.g. number of additional cases detected, cost-benefit etc.). | We intend to encourage its use because the superior quality of this test and the shorter period for the validation. |
| 3.4. Do you have concerns on accuracy of the available tests and test procedures for deceased donors? | No |
| 3.5. Are any other laboratory tests required for donors of non-reproductive tissues and cells in your Member State? | No |
| 3.6. Are any other laboratory tests required for donors of reproductive tissues and cells in your Member State? | No |
| 3.7. Do you request/use international accreditation systems for testing laboratories? | Yes |
| 3.7.1. Please specify. | Not requested but used. Some of the accredited laboratories have EFI accreditation. |
| 3.8. Do you have any additional comments on testing? | No |
| **4. Accreditation, designation, authorisation or licensing of tissue establishments (Article 6, Directive 2004/23/EC)** | |
| 4.1. Do you have a system of designation, authorisation, accreditation or licensing for all types of tissue establishments under your responsability? | Yes |
| 4.2. Is inspection a prerequisite for the designation, authorisation, accreditation or licensing of tissue establishments? | Yes |
| 4.2.1. How many inspections were performed in 2011 for authorising/accrediting/licensing/designating TEs? | yes – evaluation performed by NTA, not inspection, 35 evaluations |
| 4.3. Are preparation processes authorised? | No |
| 4.4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were suspended in 2011? | 2 |
| 4.5. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011? | 0 |
| 4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)? | No |
| **4bis. Overview of tissue/cells establishments authorised by the NCA** | |
| 4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible): | Skin tissue establishments<br>Musculo-skeletal tissue establishments<br>Ocular tissue establishments |

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| | HSC tissue establishments<br>Cord blood tissue establishments<br>ART tissue establishments |
| 4.7.1. How many skin tissue establishments? | 0 |
| 4.7.2. How many musculo-skeletal tissue establishments? | 0 |
| 4.7.3. How many ocular tissue establishments? | 0 |
| 4.7.5. How many HSC tissue establishments? | 0 |
| 4.7.6. How many cord blood tissue establishments? | 0 |
| 4.7.7. How many ART tissue establishments? | 0 |
| 4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible): | Skin tissue establishments<br>Musculo-skeletal tissue establishments<br>HSC tissue establishments<br>Cord blood tissue establishments<br>ART tissue establishments |
| 4.8.1. How many skin tissue establishments? | 1 |
| 4.8.2. How many musculo-skeletal tissue establishments? | 2 |
| 4.8.5. How many HSC tissue establishments? | 3 |
| 4.8.6. How many cord blood tissue establishments? | 7 |
| 4.8.7. How many ART tissue establishments? | 28 |
| 4.9. Tissue establishments first time authorised between 01/01/2011 and 31/12/2011 (more than 1 answer possible): | ART tissue establishments |
| 4.9.7. How many ART tissue establishments? | 4 |
| 4.10. All tissue establishments authorised by 31/12/2011 (more than 1 answer possible): | Skin tissue establishments<br>Musculo-skeletal tissue establishments<br>HSC tissue establishments<br>Cord blood tissue establishments<br>ART tissue establishments |
| 4.10.1.1. How many public skin tissue establishments? | 1 |
| 4.10.1.2. How many private skin tissue establishments? | 0 |
| 4.10.2.1. How many public musculo-skeletal tissue establishments? | 2 |
| 4.10.2.2. How many private musculo-skeletal tissue establishments? | 0 |
| 4.10.5.1. How many public HSC tissue establishments? | 3 |
| 4.10.5.2. How many private HSC tissue establishments? | 0 |
| 4.10.6.1. How many public cord blood tissue establishments? | 0 |
| 4.10.6.2. How many private cord blood tissue establishments? | 7 |
| 4.10.7.1. How many public ART tissue establishments? | 2 |
| 4.10.7.2. How many private ART tissue establishments? | 26 |
| 4.11. How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Art. 6(5) during 2011? Please provide number(s) per type tissues/cells. | x |
| **4ter. Sanctions** | |
| 4.16. Have penalties for infringements of the national provisions pursuant to the Directive been defined (Article 27)? | Yes |
| 4.16.1. Have penalties already been imposed? | No |
| 4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing? | No |
| **5. Inspections (Article 7, Directive 2004/23/EC)** | |
| 5.1. Is a system in place for organising inspections and control measures of tissue establishments? | Yes |
| 5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections. | Ministry of Health - Public Health and Control in Public Health Directorate (Stat Sanitary Inspectorate after de 2nd of September.) |
| 5.1.2. If yes, please specify staffing (how many inspectors). | 2 inspectors at the Ministry of health and 42 inspectors at county level. |
| 5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible) | Yes |
| 5.2.1. If yes, please specify. (more than 1 answer possible) | Blood<br>Organs<br>Hospitals |

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| | Others |
| Please specify other. | laboratories, dental offices |
| 5.3. How many routine inspections of tissue establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011)? | 0 |
| 5.3.1. How many inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) following serious adverse events or reactions, or suspicion thereof ? | 0 |
| 5.3.2. How many other type of inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | 0 |
| 5.3.3. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | 0 |
| 5.3.4. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where minor shortcomings were noted? | 0 |
| 5.3.5. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where major shortcomings were noted? | 0 |
| 5.3.6. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by suspension of authorisation? | 0 |
| 5.3.7. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by closure? | 0 |
| 5.3.8. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of other inspections carried out? Please specify. | 0 |
| 5.4. How many routine inspections were conducted in ART establishments (from 1/1/2011 to 31/12/2011)? | 0 |
| 5.4.1. How many inspections were conducted in ART establishments following serious adverse events or reactions, or suspicion thereof (from 1/1/2011 to 31/12/2011)? | 0 |
| 5.4.2. How many other type of inspections were conducted on ART establishments (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | 0 |
| 5.4.3. Outcome of inspections of ART tissue establishments carried out in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | 0 |
| 5.4.4. What was the number of inspections carried out in ART establishments where minor shortcomings were noted? | 0 |
| 5.4.5. What was the number of inspections carried out in ART establishments where major shortcomings were noted? | 0 |
| 5.4.6. What was the number of inspections carried out in ART establishments followed by suspension of authorisation? | 0 |
| 5.4.7. What was the number of inspections carried out in ART establishments followed by closure of respective establishements? | 0 |
| 5.4.8. What was the number of other inspections of ART establishments? Please specify. | In 2011 there were 32 ART establishments |
| 5.5. Which type of routine inspections do you conduct? (more than 1 answer possible) | General system-oriented inspections<br>Thematic inspections<br>Desk based reviews |
| 5.6. How do you decide which type of routine inspection to conduct? | We decide the type of the routine inspection to conduct based on the: |

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| | • type of the establishment (complexity of site operations), • number of deficiencies in a previous inspection and compliance with existing regulations, • number of adverse events/reactions reported or recalls conducted, • volume of activity including significant changes. |
| 5.7. Until 2011, did you implement the requirement concerning the time interval between two inspections (Art. 7.3.)? | Yes |
| 5.8. How many TEs were inspected at least twice between 2008-2011 (01/01/2008-31/12/2011)? | There were 49 TEs inspected at least twice between 2008-2011 |
| 5.9. Did you perform/conduct inspections of procurement sites outside tissue establishments? | Yes |
| 5.9.1. If yes, how many? | We inspected 43 hospitals in 2012, 60 hospitals in 2013. |
| 5.10. Did you carry out inspections of third parties? | Yes |
| 5.10.1. If yes, how many? | 8 |
| 5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)? | Yes |
| 5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)? | Yes |
| 5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)? | 5 |
| 5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))? | No |
| 5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))? | No |
| 5.15. Did you organise any inspections of procurement centres or tissue establishments in third countries from which tissues and/or cells were imported in your country (as recorded by 31/12/2011)? | No |
| 5.16. Have you asked another MS, or have you been requested by any other MS, on the results and control measures of your inspections, as part of an enquiry/investigation? | No |
| 5.17. Would you be interested in developing joint inspections? Joint inspections should be understood as inspections of tissue establishments conducted jointly by two or more Member States' Competent Authorities on their territory or in third countries. | Yes |
| 5.18. Do you have any additional comments on inspections? | No |
| **6. Import/export (Article 9 Directive 2004/23/EC)** | |
| 6.1. Do you have a register of authorised tissue establishments that are explicitly authorised to perform import/export of tissues and celles from/to third countries? | Yes |
| 6.2. Please specify the number of tissue establishments authorised to import tissues and cells from third countries (recorded by 31/12/2011). | 0 |
| 6.3. Please specify the number of tissue establishments authorised to export tissues and cells from third countries (recorded by 31/12/2011). | 0 |
| 6.4. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of skin from third countries. | Asking for documentation to prove that the TE complies with the requiements of the EU Directives and checking this documentation |
| 6.5. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of musculo-skeletal (bone, tendons, fascia etc.) tissues from third countries. | Asking for documentation to prove that the TE complies with the requiements of the EU Directives and checking this documentation |
| 6.6. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of ophtalmic (cornea, sclera, etc) tissues from third countries. | Asking for documentation to prove that the TE complies with the requiements of the EU Directives and checking this documentation |

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| 6.7. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cardio vascular tissues from third countries. | Asking for documentation to prove that the TE complies with the requiements of the EU Directives and checking this documentation |
| 6.8. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) (other than cord blood) from third countries. | Asking for documentation to prove that the TE complies with the requiements of the EU Directives and checking this documentation |
| 6.9. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cord blood from third countries. | Asking for documentation to prove that the TE complies with the requiements of the EU Directives and checking this documentation |
| 6.10. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of reproductive cells (sperm, egg cells) from third countries. | Asking for documentation to prove that the TE complies with the requiements of the EU Directives and checking this documentation |
| 6.11. Did you import tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | No |
| 6.12. Did you export tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | No |
| 6.13. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on imports/exports of tissues/cells between your country and other third countries? | No |
| 6.14. What is the relation between import/export of tissues and cells and self-sufficiency? (more than 1 answer possible) | A. Export of tissues/cells is authorised only after checking that local/national needs are fulfilled.<br>D. Import of tissues/cells is authorised only after checking that local/national needs are not fulfilled |
| 6.14.1. If A or D were selected, please explain how you quantify local/national needs. | Checking the stock of tissues and cells in accreditted TE |
| 6.15. Did you authorise direct imports of tissues/cells to hospitals/clinics in your country? | Yes |
| 6.15.1. If yes, please specify the number of cases and for which type of tissues/cells. | 40 corneas in 2011 |
| 6.16. Do you have any additional comments on import/export? | No |
| **7. Distribution/intra community exchanges (Article 23 Directive 2004/23/EC)** | |
| 7.1. Do you have intra-community exchanges of tissues and cells? | No |
| 7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify. | Asking for documentation |
| 7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible). | Yes, no restrictions apply |
| 7.4. Have you authorised direct distribution to the recipient of specific tissues and cells (Art. 6, Directive 2006/17/EC)? | No |
| 7.5. Do you collect data regarding the cross-border exchange of tissue/cells between your country and other EU MS? | Yes |
| 7.5.1. Please provide us with data (country of destination, type of tissue/cell and number of units distributed) concerning distribution to other MS in 2011 (01/01/2011-31/12/2011). | 0 |
| 7.5.2. Please provide us with data (country of origin, type of tissue/cell and number of units distributed) concerning distribution to other MS in 2011 (01/01/2011-31/12/2011) | 0 |
| 7.6. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on cross-border exchanges of tissues/cells between your country and other EU MS? | No |
| 7.7. Do you allow brokerage companies for either distribution in EU and/or import/export of tissues/cells? In this context, a brokerage company means a body that arranges transactions between a supplier (tissue establishment/company selling tissues or cells) and a buyer (a tissue establishment/a hospital or clinic/an individual) without undertaking activities of processing, preservation or storage. | No |
| 7.8. Are brokers actively supplying health professionals/establishments in your country? | No |

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| 7.9. Do you have any additional comments on distribution? | No |
| **8. Register of tissue establishments and reporting obligations (Article 10, Directive 2004/23/EC)** | |
| 8.1. Do you have an annual report model/template on the activities of tissue establishments in your Member State? (Article 10(1)). If yes, please upload the template. | Yes |
| 8.2. How many tissue establishments submitted annual reports of their activities during 2011. Please provide an estimation. (1 answer possible) | 100% (all) |
| 8.3. Are these reports publicly available? (Article 10(1)) | Yes |
| 8.3.1. If yes, please insert the link(s) to the report(s). | Yes - public by request. They will be soon published on the official site www.transplant.ro |
| 8.4. Do you publish a national annual report of the consolidated activities of all tissue establishments in your country? | Yes |
| 8.4.1. Please insert the link to the published national annual report. | www.transplant.ro |
| 8.5. Is there a publicly accessible register of authorised tissue establishements in place? (Article 10(2)) | Yes |
| 8.5.1. If yes, please provide us with the link to the register's web site. | www.transplant.ro |
| 8.6. Do you provide data regarding tissues and cells activities to the EUROCET registry (non-mandatory reporting)? | Yes |
| 8.6.1. If yes, what data are provided to EUROCET? Please specify. | all data requested by Eurocet |
| 8.7. Do you have any additional comments on reporting? | No |
| **9. Traceability (Article 8, Directive 2004/23/EC; and Directive 2006/86/EC)** | |
| 9.1. Was the donor identification system (Art. 8(2)) implemented in your country? | Yes |
| 9.2. Who assigns the unique code for each donation? (only 1 answer possible) | Other |
| Please specify 'other'. | the unique national code system under construction |
| 9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible) | Both paper records and electronic forms |
| 9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify. | requirement by law |
| 9.5. Do you have any additional comments on traceability? | No |
| **10. Notification of serious adverse events and reactions (Article 11 Directive 2004/23, Article 6 Directive 2006/76)** | |
| 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))? | Yes |
| 10.1.1. If yes, which CA/institution is responsible? | The Ministry of Health – Public Health and Control in Public Health Directorate (Stat Sanitary Inspectorate after de 2nd of September.) |
| 10.1.2. If yes, please provide a short description of its organisation. | Ministry of Health Romania The Ministry of Health is a governmental institution, financed from the public and budget. According to the Governmental Decision no 144/2010 regarding the organizing and functioning of the Ministry of Health, there is one directorate responsible in this field: the Public Health and Control in Public Health Directorate (PHCPHD). The main responsibility is to organize and coordinate the vigilance system at national level. The necessary measures are taken by the sanitary inspectors from the County Public Health Control. The responsibilities of the County Public Health Directorates (CPHCD), are established by the Ministerial Order no 824/2006 regarding the Norms for functioning and organizing of the sanitary state inspection and the Ministerial Order no. 1078/ 2010 for organizing and functioning of the CPHDs. |
| 10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use the SAR/E (to the CA (2006/76 art 6.4)) templates developed to the Annual reporting ot the EC also at national level? | Yes |
| 10.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level? | Yes |
| 10.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all TEs? | No |
| 10.4.1. Why not? | The sanitary inspectors who are responsible for the official control in the transplant field are in charge of collecting SAR/E. |
| 10.5. How many tissue establishments provided in 2011 the | <50% |

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| SAR/SAE data as requested (please provide the % from the total number of TEs authorised in your country). | |
| 10.6. Do you have a mandatory procedure for the transplantation centres when reporting SAR/SAE to the TEs which distributed the tissues/cells (Art 11.2)? | Yes |
| 10.6.1. If yes, please provide a brief description. | We have a V&S system in place covered by the Ministry of Public Health no. 1763/2007, published in the Official Journal no. 698 from 16 october 2007. |
| 10.7. Do you give feedback to the TEs regarding SAR/SAE recorded at national level? | Yes |
| 10.7.1. Please specify. | If the TEs is involved in the recorded SAR/SAE |
| 10.8. Do you give feedback to the TEs regarding SAR/SAE recorded at EU level? | Yes |
| 10.8.1. Please specify. | If the TEs is involved in the recorded SAR/SAE |
| 10.9. Do you require your TEs to have a recall procedure? | Yes |
| 10.10. How many recalls related to safety and quality of tissues/cells were issued in your country in 2011? Please specify the number and which tissues were recalled and why (e.g. missing consent, quality defects etc). | 0 |
| 10.11. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites in case of a national rapid alert? | No |
| 10.11.2. If no, please specify why not. | The system is not yet operational because the national procedure is drafted and has to be approved as a Ministry Order. |
| 10.12. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites when a rapid alert is issued via the EU RATC platform? | No |
| 10.12.2. If no, please specify why not. | There is no procedure but we inform the National Agency of Transplant and the sanitary inspectors form CPHDs |
| 10.13. Do you provide data regarding SAR/SAE to the EUROCET registry (non-mandatory reporting)? | No |
| 10.13.2. If no, please specify why not. | not until now |
| 10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems? | Yes |
| 10.14.1. If yes, please specify which of the following systems are usually contacted. (more than 1 answer possible) | Haemovigilance<br>Pharmacovilance<br>Medical devices |
| 10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S? | Yes |
| 10.15.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (insufficient) - 2 (sufficient) 3 (good) - 4 (very good) to 5 (essential)? | 5 |
| 10.16. Do you have any additional comments on SARE reporting? | No |
| **11. Consent and personal data protection (Article 13 and 14, Directive 2004/23/EC)** | |
| 11.1. What consent system for living tissue/cell donation do you have in place within your Member State? | Explicit consent (opt-in) |
| 11.1.1. Please specify your choice of consent system for living tissue/cell donation. | Explicit informed consent of the donor |
| 11.2. What consent system for deceased tissue/cell donation do you have in place within your Member State? | Explicit consent (opt-in) |
| 11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible) | First degree relatives (including spouse) |
| 11.4. Is the consent system for deceased tissue donation the same as for organs? | Yes |
| 11.5. How is this consent verified during inspections? (more than 1 answer possible) | Analysis of documentation |
| 11.6. What measures are in place to ensure that donors/relatives/authorising persons on behalf of donors are | Only trained personnel is allowed to provide such information |

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| provided with the appropriate information, as requested by Art. 13(2)? (more than 1 answer possible) | |
| 11.7. What measures are in place to ensure that both donors and recipients remain unidentifiable when access is given to third parties (Art. 14(1)). Please specify. | Legal requirement |
| 11.8. Please specify what measures are in place to ensure that the identity of the receipient is not disclosed to the donor and vice versa. | Legal requirement |
| 11.9. Does your national legislation allows disclosure of donor data in case of gametes donation? | No |
| 11.9.1. If no, please specify the circumstances and measures in place. | Only at the specific requirement of the authorities (police, coroner office). |
| 11.10. Do you have any additional comments on consent and data protection? | No |
| **12. Selection, evaluation and procurement (Article 15 Directive 2004/23; Annexes I-IV Directive 2006/17)** | |
| 12.1. How do you ensure that all requirements related to the evaluation and selection of donors (except donors of reproductive cells) are respected in your country (Art. 15(1), Annex I Directive 2006/17/EC)? (more than 1 answer possible) | Inspections of TEs and procurement sites<br>Audit of documentation<br>Regular evaluation of medical personnel |
| 12.2. How do you ensure that all requirements related to the evaluation and selection of donors of reproductive cells are respected in your country (Art 15 (1), Annex III of Directive 2006/17/EC)? (more than 1 answer possible) | Inspections of ART centres<br>Audit documentation<br>Regular evaluation of medical personnel |
| 12.3. Do you have more stringent criteria for donor selection than those listed in Annex I of the Directive 2006/17/EC? | No |
| 12.4. What sources are required in your MS for the evaluation of a deceased donor of tissues/cells? (more than 1 answer possible) | Interview with the donor's family or a person who knew the donor well<br>Medical records of the donor<br>Interview with the treating physician<br>Autopsy report |
| 12.5. Do you have more stringent criteria for selection of donors of reproductive cells than those listed in Annex III of the Directive 2006/17/EC? | No |
| 12.6. Do you have more stringent criteria for autologous donation than those listed in Annex I of the Directive 2006/17/EC? | No |
| 12.7. Do you require more information on the donation of tissues/cells than the mandatory one as laid down in the Annex of Directive 2004/23/EC (Art 15(3)? | No |
| 12.8. How do you ensure that all requirements regarding tissues and cells' procurement, packaging and transport are complied with by tissue establishments in your country (Art 15(1), Annex IV of Directive 2006/17/EC? (more than 1 answer possible)(For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)) | Inspection of tissue establishment<br>Audit of tissue establishment<br>Inspection of the centre of human application (e.g. transplantation centre, ART centre)<br>Audit of the centre of human application |
| 12.9. Do you have any additional comments on selection, evaluation and procurement? | No |
| **13. Quality management, responsible person, personnel (Article 16, 17, 18 Directive 2004/23/EC)** | |
| 13.1. How do you ensure that tissue establishments in your country have in place a quality system respecting the provisions of the Directive 2004/23/EC Art 16.1? (more than 1 answer possible). (For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)). | Authorisation requirement<br>Inspections<br>Internal audits |
| 13.2. How do you ensure that tissue establishments have a | Authorisation requirement |

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| responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible) | Inspections<br>Regular evaluation of personnel<br>Mandatory trainings |
| 13.3. How do you ensure an appropriate training for the personnel directly involved in the activities of tissue establishments? (more than 1 answer possible) | Authorisation requirement<br>Regular evaluation of personnel<br>Mandatory trainings |
| 13.4. Do you have national/regional/local training programmes for the personnel of tissue establishments? | No |
| 13.4.2. If no, in which country(ies) is your personnel trained? | EU countries<br>Non-EU countries |
| 13.4.2.1. Please specify EU-countries. | Spain, Italy, Germany, UK, Austria |
| 13.4.2.2. Please specify non EU-countries. | USA |
| 13.5. Any additional comments on quality management, responsible person, personnel? | No |
| **14. Reception, processing, storage, labelling and packaging (Art 19-22 Directive 2004/23/EC)** | |
| 14.1. How do you ensure that tissue establishments in your country fulfill the requirments of the Art. 19 (Tissue and cell reception) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | National regulation/policy for reception of tissues/cells<br>Inspections of tissue establishments<br>Internal audits of tissue establishments |
| 14.2. How do you ensure that tissue establishments in your country fulfill the requirements of the Art. 20 (Tissue and cell processing) of Directive 2004/23/EC? (more than 1 answer possible) | SOPs for all processes affecting quality and safety are mandatory for authorisation<br>Inspections of tissue establishments<br>Internal audits of tissue establishments |
| 14.3. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 21 (tissue and cell storage conditions) of Directive 2004/23/EC? (more than 1 answer possible) | SOPs for procedures associated with storage of tissues and cells are mandatory for authorisation<br>Inspections of tissue establishments<br>Internal audits of tissue establishments |
| 14.4. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | SOPs for procedures associated with labelling and packaging are mandatory for authorisation<br>Inspections of tissue establishments<br>Internal audits of tissue establishments |
| 14.5. Any additional comments on reception, processing, storage, labelling and packaging? | No |
| **15. Third party agreements (Art. 24 Directive 2004/23/EC)** | |
| 15.1. Are third party agreements foreseen/allowed in your national legislation? | Yes |
| 15.1.1. If yes, have tissue establishments in your Member State notified third party agreements? | No |
| 15.2. Any additional comments on third party agreements? | No |
| **16. General comments - implementation** | |
| 16.1. Do you have at national level more stringent quality and safety requirements than those requested by the EU legislation in this field (e.g. restrictions concerning the donation/use of certain tissues/cells, mandatory unpaid donation etc.)? | No |
| 16.2. Has your Member State encountered any difficulties in implementing the requirements in the EU Tissues and Cells Directives? Please choose from the options below. | ART provisions<br>Authorisation-accreditation-licensing of TEs<br>Inspections |
| 16.2.1. For all selected options in question 16.2., please provide a short description. | For ART - complains of the ART centers that ther equiremnts of the EU Directives are excessive for this field For accreditation of TEs and inspections - The accreditation issued by National Transplant Agency needs to be approved by the Ministry of Health. For inspections - since 2012, NTA is not allowed anymore to provide inspections but only evaluations of the TEs. |
| 16.3. In your opinion, in which of the following Directives are there shortcomings (if any)? (more than 1 answer possible) | No shortcomings |

## *A.1.26. Survey response Slovakia*

| **1. Public information** | |
|---|---|
| 1.1. Name of National Competent Authority (NCA) 1: | Ministry of Health of the Slovak Republic |
| 1.1.2. Address of NCA 1: | Ministry of Health of the Slovak Republic Limbová 2 837 52 Bratislava Slovak Republic |
| 1.1.3. Telephone (central access point): | +4212 59373111 |
| 1.1.4. E-mail (central access point): | office@health.gov.sk |
| 1.1.5. Website: | www.health.gov.sk |
| 1.1.6. The NCA is responsible for? (more than 1 answer possible) | Non-reproductive tissues and cells<br>Reproductive tissues and cells<br>Blood and blood components |
| 1.1.7. What are the role/tasks of the NCA? (more than 1 answer possible) | Accreditation, authorisation, licensing of TEs |
| 1.2. National Competent Authority 2? | No |
| 1.5. Please give a short description of the legal status and organisation of the National Competent Authority(ies) (e.g. departments, staffing, number of senior and junior inspectors, staff working on EU affairs and legal matters, vigilance officers, budget, independence from government etc.). | Section of Health together with Section of Legislation Department of Health Care Ministry of Health of the Slovak Republic |
| 1.6. In case of MS with federal or decentralised systems, please indicate the roles/tasks of the Regional Competent Authority(ies). (more than 1 answer possible) | Not applicable |
| 1.7. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies) for tissues and cells: | Regional Competent Authorities can only approve so called Common Examination and Therapeutic Establishments (SVaLZ) which might serve as helper in procurement of tissues and cells |
| **2. Procurement (Article 5 Directive 2004/23/EC)** | |
| 2.1. Do you authorise the "conditions of procurement"? | Yes |
| 2.1.1. How do you authorise the "conditions of procurement"? (more than 1 answer possible) | Other |
| Please specify 'other': | by administration approval |
| 2.1.2. How many such authorisations were granted in 2011 (01/01-31/12/2011)? | 3 |
| 2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011). | 1 |
| 2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011). | 1 |
| 2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues were carried out in 2011 (01/01-31/12/2011). | 1 |
| 2.2.4. Please provide the number of procurement centers in which procurement of tissues/cells for ATMP manufacturing were carried out in 2011 (01/01-31/12/2011). | 0 |
| 2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC and its implementing Directive 2006/17/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) ? (more than 1 answer possible) | Analysis of the mandatory documentation |
| 2.4. Are you also responsible for the accreditation, designation, authorisation or licensing of laboratories performing donor testing? | No |
| 2.4.2. Which National Authority is in charge of this activity? | SNAS - Slovak National Acreditation Service |
| 2.5. How do you ensure, as CA for T&C, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art. 5(2))? (more than 1 answer possible) | Analysis of the mandatory documentation requested from the tissue establishment |
| 2.6. Please provide data on qualified laboratories accredited, | 32 |

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| authorised or licensed in your country (e.g. number, year of accreditation/authorisation/license, which donor tests are performed etc.). | |
| 2.7. Do you have any additional comments on procurement? | NO |
| **3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)** | |
| 3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>HBs AG<br>Anti HBc<br>Anti HCV-Ab<br>Treponema Pallidum |
| 3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>HBs AG<br>Anti HBc<br>Anti HCV-Ab<br>Treponema Pallidum |
| 3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to encourage its use? Please specify why or why not (e.g. number of additional cases detected, cost-benefit etc.). | Proposals were given |
| 3.4. Do you have concerns on accuracy of the available tests and test procedures for deceased donors? | No |
| 3.5. Are any other laboratory tests required for donors of non-reproductive tissues and cells in your Member State? | No |
| 3.6. Are any other laboratory tests required for donors of reproductive tissues and cells in your Member State? | No |
| 3.7. Do you request/use international accreditation systems for testing laboratories? | No |
| 3.8. Do you have any additional comments on testing? | NO |
| **4. Accreditation, designation, authorisation or licensing of tissue establishments (Article 6, Directive 2004/23/EC)** | |
| 4.1. Do you have a system of designation, authorisation, accreditation or licensing for all types of tissue establishments under your responsability? | Yes |
| 4.2. Is inspection a prerequisite for the designation, authorisation, accreditation or licensing of tissue establishments? | No |
| 4.3. Are preparation processes authorised? | No |
| 4.4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were suspended in 2011? | 0 |
| 4.5. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011? | 0 |
| 4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)? | No |
| **4bis. Overview of tissue/cells establishments authorised by the NCA** | |
| 4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible): | HSC tissue establishments<br>ART tissue establishments<br>Multi-tissue establishments |
| 4.7.5. How many HSC tissue establishments? | 2 |
| 4.7.7. How many ART tissue establishments? | 1 |
| 4.7.8. How many multi-tissue establishments? | 1 |
| 4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible): | HSC tissue establishments<br>ART tissue establishments<br>Multi-tissue establishments |
| 4.8.5. How many HSC tissue establishments? | 1 |
| 4.8.7. How many ART tissue establishments? | 1 |
| 4.8.8. How many multi-tissue establishments? | 1 |
| 4.9. Tissue establishments first time authorised between 01/01/2011 and 31/12/2011 (more than 1 answer possible): | ART tissue establishments |

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| 4.9.7. How many ART tissue establishments? | 1 |
| 4.10. All tissue establishments authorised by 31/12/2011 (more than 1 answer possible): | HSC tissue establishments<br>ART tissue establishments<br>Multi-tissue establishments |
| 4.10.5.1. How many public HSC tissue establishments? | 1 |
| 4.10.5.2. How many private HSC tissue establishments? | 1 |
| 4.10.7.1. How many public ART tissue establishments? | 0 |
| 4.10.7.2. How many private ART tissue establishments? | 1 |
| 4.10.8.1. How many public multi-tissue establishments? | 1 |
| 4.10.8.2. How many private multi-tissue establishments? | 0 |
| 4.11. How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Art. 6(5) during 2011? Please provide number(s) per type tissues/cells. | 0 |
| **4ter. Sanctions** | |
| 4.16. Have penalties for infringements of the national provisions pursuant to the Directive been defined (Article 27)? | No |
| 4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing? | No |
| **5. Inspections (Article 7, Directive 2004/23/EC)** | |
| 5.1. Is a system in place for organising inspections and control measures of tissue establishments? | No |
| 5.1.3. If no, please specify why not. | In preparation |
| 5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible) | No |
| 5.3. How many routine inspections of tissue establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011)? | 1 |
| 5.3.1. How many inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) following serious adverse events or reactions, or suspicion thereof ? | 0 |
| 5.3.2. How many other type of inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | 0 |
| 5.3.3. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | 1 |
| 5.3.4. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where minor shortcomings were noted? | 0 |
| 5.3.5. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where major shortcomings were noted? | 0 |
| 5.3.6. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by suspension of authorisation? | 0 |
| 5.3.7. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by closure? | 0 |
| 5.3.8. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of other inspections carried out? Please specify. | 0 |

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| 5.4. How many routine inspections were conducted in ART establishments (from 1/1/2011 to 31/12/2011)? | 0 |
| 5.4.1. How many inspections were conducted in ART establishments following serious adverse events or reactions, or suspicion thereof (from 1/1/2011 to 31/12/2011)? | 0 |
| 5.4.2. How many other type of inspections were conducted on ART establishments (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | 0 |
| 5.4.3. Outcome of inspections of ART tissue establishments carried out in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | 0 |
| 5.4.4. What was the number of inspections carried out in ART establishments where minor shortcomings were noted? | 0 |
| 5.4.5. What was the number of inspections carried out in ART establishments where major shortcomings were noted? | 0 |
| 5.4.6. What was the number of inspections carried out in ART establishments followed by suspension of authorisation? | 0 |
| 5.4.7. What was the number of inspections carried out in ART establishments followed by closure of respective establishements? | 0 |
| 5.4.8. What was the number of other inspections of ART establishments? Please specify. | 0 |
| 5.5. Which type of routine inspections do you conduct? (more than 1 answer possible) | General system-oriented inspections |
| 5.6. How do you decide which type of routine inspection to conduct? | According to needs |
| 5.7. Until 2011, did you implement the requirement concerning the time interval between two inspections (Art. 7.3.)? | Yes |
| 5.8. How many TEs were inspected at least twice between 2008-2011 (01/01/2008-31/12/2011)? | 0 |
| 5.9. Did you perform/conduct inspections of procurement sites outside tissue establishments? | No |
| 5.9.2. If no, why not? | Because of absence of inspectors |
| 5.10. Did you carry out inspections of third parties? | No |
| 5.10.2. If no, why not? | There was no need |
| 5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)? | Yes |
| 5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)? | Yes |
| 5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)? | 5 |
| 5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))? | No |
| 5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))? | No |
| 5.15. Did you organise any inspections of procurement centres or tissue establishments in third countries from which tissues and/or cells were imported in your country (as recorded by 31/12/2011)? | No |
| 5.16. Have you asked another MS, or have you been requested by any other MS, on the results and control measures of your inspections, as part of an enquiry/investigation? | No |
| 5.17. Would you be interested in developing joint inspections? Joint inspections should be understood as inspections of tissue establishments conducted jointly by two or more Member States' Competent Authorities on their territory or in third countries. | Yes |
| 5.18. Do you have any additional comments on inspections? | No |

| **6. Import/export (Article 9 Directive 2004/23/EC)** | |
|---|---|
| 6.1. Do you have a register of authorised tissue establishments that are explicitly authorised to perform import/export of tissues and celles from/to third countries? | No |
| 6.2. Please specify the number of tissue establishments authorised to import tissues and cells from third countries (recorded by 31/12/2011). | 0 |
| 6.3. Please specify the number of tissue establishments authorised to export tissues and cells from third countries (recorded by 31/12/2011). | 1 |
| 6.4. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of skin from third countries. | no import from third countries |
| 6.5. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of musculo-skeletal (bone, tendons, fascia etc.) tissues from third countries. | no import from third countries |
| 6.6. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of ophtalmic (cornea, sclera, etc) tissues from third countries. | no import from third countries |
| 6.7. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cardio vascular tissues from third countries. | no import from third countries |
| 6.8. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) (other than cord blood) from third countries. | no import from third countries |
| 6.9. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cord blood from third countries. | no import from third countries |
| 6.10. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of reproductive cells (sperm, egg cells) from third countries. | no import from third countries |
| 6.11. Did you import tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | No |
| 6.12. Did you export tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | No |
| 6.13. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on imports/exports of tissues/cells between your country and other third countries? | No |
| 6.14. What is the relation between import/export of tissues and cells and self-sufficiency? (more than 1 answer possible) | A. Export of tissues/cells is authorised only after checking that local/national needs are fulfilled. |
| 6.14.1. If A or D were selected, please explain how you quantify local/national needs. | checking of hospital requests |
| 6.15. Did you authorise direct imports of tissues/cells to hospitals/clinics in your country? | No |
| 6.16. Do you have any additional comments on import/export? | no |
| **7. Distribution/intra community exchanges (Article 23 Directive 2004/23/EC)** | |
| 7.1. Do you have intra-community exchanges of tissues and cells? | No |
| 7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify. | checking of TE records |
| 7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible). | Yes, but only via an authorised TE in my MS |
| 7.4. Have you authorised direct distribution to the recipient of specific tissues and cells (Art. 6, Directive 2006/17/EC)? | Yes |
| 7.4.1. If yes, how many authorisations were given in 2011 (01/01/2011 to 31/12/2011)? | 0 |
| 7.4.2. If yes, for which tissues/cells? | according to requests |

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| 7.5. Do you collect data regarding the cross-border exchange of tissue/cells between your country and other EU MS? | Yes |
| 7.5.1. Please provide us with data (country of destination, type of tissue/cell and number of units distributed) concerning distribution to other MS in 2011 (01/01/2011-31/12/2011). | valid since 12/12 |
| 7.5.2. Please provide us with data (country of origin, type of tissue/cell and number of units distributed) concerning distribution to other MS in 2011 (01/01/2011-31/12/2011) | N/A |
| 7.6. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on cross-border exchanges of tissues/cells between your country and other EU MS? | No |
| 7.7. Do you allow brokerage companies for either distribution in EU and/or import/export of tissues/cells? In this context, a brokerage company means a body that arranges transactions between a supplier (tissue establishment/company selling tissues or cells) and a buyer (a tissue establishment/a hospital or clinic/an individual) without undertaking activities of processing, preservation or storage. | No |
| 7.8. Are brokers actively supplying health professionals/establishments in your country? | No |
| 7.9. Do you have any additional comments on distribution? | no |
| **8. Register of tissue establishments and reporting obligations (Article 10, Directive 2004/23/EC)** | |
| 8.1. Do you have an annual report model/template on the activities of tissue establishments in your Member State? (Article 10(1)). If yes, please upload the template. | Yes |
| 8.2. How many tissue establishments submitted annual reports of their activities during 2011. Please provide an estimation. (1 answer possible) | 60-99% |
| 8.3. Are these reports publicly available? (Article 10(1)) | No |
| 8.4. Do you publish a national annual report of the consolidated activities of all tissue establishments in your country? | No |
| 8.4.2. If no, why not? | they are kept in paper form |
| 8.5. Is there a publicly accessible register of authorised tissue establishements in place? (Article 10(2)) | No |
| 8.5.2. If no, why not? | in preparation |
| 8.6. Do you provide data regarding tissues and cells activities to the EUROCET registry (non-mandatory reporting)? | Yes |
| 8.6.1. If yes, what data are provided to EUROCET? Please specify. | according to their data forms |
| 8.7. Do you have any additional comments on reporting? | no |
| **9. Traceability (Article 8, Directive 2004/23/EC; and Directive 2006/86/EC)** | |
| 9.1. Was the donor identification system (Art. 8(2)) implemented in your country? | Yes |
| 9.2. Who assigns the unique code for each donation? (only 1 answer possible) | National Competent Authority |
| 9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible) | Both paper records and electronic forms |
| 9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify. | TEs are working no longer than 17 years |
| 9.5. Do you have any additional comments on traceability? | no |
| **10. Notification of serious adverse events and reactions (Article 11 Directive 2004/23, Article 6 Directive 2006/76)** | |
| 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))? | No |
| 10.1.3. If no, why not? | every TE has to have vigilance system (national system is not finalized yet) |
| 10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use the SAR/E (to the CA (2006/76 art 6.4)) templates developed to the Annual reporting ot the EC also at national level? | Yes |
| 10.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level? | Yes |
| 10.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all TEs? | No |

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| 10.4.1. Why not? | System is not finalized yet |
| 10.5. How many tissue establishments provided in 2011 the SAR/SAE data as requested (please provide the % from the total number of TEs authorised in your country). | 70-99% |
| 10.6. Do you have a mandatory procedure for the transplantation centres when reporting SAR/SAE to the TEs which distributed the tissues/cells (Art 11.2)? | No |
| 10.6.2. If no, how do you ensure that SAR/SAE are reported to the TEs? | It is mandaty according to the Government Regulation nr.622/2007 sec4 |
| 10.7. Do you give feedback to the TEs regarding SAR/SAE recorded at national level? | Yes |
| 10.7.1. Please specify. | via letter of CA |
| 10.8. Do you give feedback to the TEs regarding SAR/SAE recorded at EU level? | Yes |
| 10.8.1. Please specify. | via letter of CA |
| 10.9. Do you require your TEs to have a recall procedure? | Yes |
| 10.10. How many recalls related to safety and quality of tissues/cells were issued in your country in 2011? Please specify the number and which tissues were recalled and why (e.g. missing consent, quality defects etc). | 0 |
| 10.11. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites in case of a national rapid alert? | Yes |
| 10.11.1. If yes, please give a short description of the system/procedure. | via phone and e-mail to RP and TE |
| 10.12. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites when a rapid alert is issued via the EU RATC platform? | Yes |
| 10.12.1. If yes, please give a short description of the system/procedure. | via phone and e-mail to RP and TE |
| 10.13. Do you provide data regarding SAR/SAE to the EUROCET registry (non-mandatory reporting)? | Yes |
| 10.13.1. If yes, please specify what data. | as required by EUROCET |
| 10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems? | No |
| 10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S? | No |
| 10.15.2. If no, please specify why not. | There were change of people (person who was already applied changed job) |
| 10.16. Do you have any additional comments on SARE reporting? | no |
| **11. Consent and personal data protection (Article 13 and 14, Directive 2004/23/EC)** | |
| 11.1. What consent system for living tissue/cell donation do you have in place within your Member State? | Explicit consent (opt-in) |
| 11.1.1. Please specify your choice of consent system for living tissue/cell donation. | signed informed consent |
| 11.2. What consent system for deceased tissue/cell donation do you have in place within your Member State? | Presumed consent (opt-out) |
| 11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible) | Other |
| Please specify 'other'. | Slovak National Transplantation Organization - Registry of non-donors |
| 11.4. Is the consent system for deceased tissue donation the same as for organs? | Yes |
| 11.5. How is this consent verified during inspections? (more than 1 answer possible) | Analysis of documentation |
| 11.6. What measures are in place to ensure that donors/relatives/authorising persons on behalf of donors are provided with the appropriate information, as requested by Art. | Information for donors are standardised at national/regional level |

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| 13(2)? (more than 1 answer possible) | |
| 11.7. What measures are in place to ensure that both donors and recipients remain unidentifiable when access is given to third parties (Art. 14(1)). Please specify. | Only unique code of the tissue is given to the third party |
| 11.8. Please specify what measures are in place to ensure that the identity of the receipient is not disclosed to the donor and vice versa. | Only unique code of the tissue is given |
| 11.9. Does your national legislation allows disclosure of donor data in case of gametes donation? | No |
| 11.9.1. If no, please specify the circumstances and measures in place. | Only unique code of gametes is given |
| 11.10. Do you have any additional comments on consent and data protection? | no |
| **12. Selection, evaluation and procurement (Article 15 Directive 2004/23; Annexes I-IV Directive 2006/17)** | |
| 12.1. How do you ensure that all requirements related to the evaluation and selection of donors (except donors of reproductive cells) are respected in your country (Art. 15(1), Annex I Directive 2006/17/EC)? (more than 1 answer possible) | Stadardised questionnaires at national levels |
| 12.2. How do you ensure that all requirements related to the evaluation and selection of donors of reproductive cells are respected in your country (Art 15 (1), Annex III of Directive 2006/17/EC)? (more than 1 answer possible) | Standardised questionnaires at national level |
| 12.3. Do you have more stringent criteria for donor selection than those listed in Annex I of the Directive 2006/17/EC? | No |
| 12.4. What sources are required in your MS for the evaluation of a deceased donor of tissues/cells? (more than 1 answer possible) | Medical records of the donor<br>Autopsy report<br>Other |
| Please specify 'other'. | other examination if needed |
| 12.5. Do you have more stringent criteria for selection of donors of reproductive cells than those listed in Annex III of the Directive 2006/17/EC? | No |
| 12.6. Do you have more stringent criteria for autologous donation than those listed in Annex I of the Directive 2006/17/EC? | No |
| 12.7. Do you require more information on the donation of tissues/cells than the mandatory one as laid down in the Annex of Directive 2004/23/EC (Art 15(3)? | No |
| 12.8. How do you ensure that all requirements regarding tissues and cells' procurement, packaging and transport are complied with by tissue establishments in your country (Art 15(1), Annex IV of Directive 2006/17/EC? (more than 1 answer possible)(For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)) | Inspection of tissue establishment |
| 12.9. Do you have any additional comments on selection, evaluation and procurement? | no |
| **13. Quality management, responsible person, personnel (Article 16, 17, 18 Directive 2004/23/EC)** | |
| 13.1. How do you ensure that tissue establishments in your country have in place a quality system respecting the provisions of the Directive 2004/23/EC Art 16.1? (more than 1 answer possible). (For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)). | Inspections |
| 13.2. How do you ensure that tissue establishments have a responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible) | Inspections |

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| 13.3. How do you ensure an appropriate training for the personnel directly involved in the activities of tissue establishments? (more than 1 answer possible) | Inspections |
| 13.4. Do you have national/regional/local training programmes for the personnel of tissue establishments? | Yes |
| 13.4.1. If yes, please specify. | Certified training course at the Slovak Medical University |
| 13.5. Any additional comments on quality management, responsible person, personnel? | no |
| **14. Reception, processing, storage, labelling and packaging (Art 19-22 Directive 2004/23/EC)** | |
| 14.1. How do you ensure that tissue establishments in your country fulfill the requirments of the Art. 19 (Tissue and cell reception) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | National regulation/policy for reception of tissues/cells<br>Inspections of tissue establishments |
| 14.2. How do you ensure that tissue establishments in your country fulfill the requirements of the Art. 20 (Tissue and cell processing) of Directive 2004/23/EC? (more than 1 answer possible) | Inspections of tissue establishments |
| 14.3. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 21 (tissue and cell storage conditions) of Directive 2004/23/EC? (more than 1 answer possible) | Inspections of tissue establishments |
| 14.4. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | Inspections of tissue establishments |
| 14.5. Any additional comments on reception, processing, storage, labelling and packaging? | no |
| **15. Third party agreements (Art. 24 Directive 2004/23/EC)** | |
| 15.1. Are third party agreements foreseen/allowed in your national legislation? | Yes |
| 15.1.1. If yes, have tissue establishments in your Member State notified third party agreements? | No |
| 15.2. Any additional comments on third party agreements? | no |
| **16. General comments - implementation** | |
| 16.1. Do you have at national level more stringent quality and safety requirements than those requested by the EU legislation in this field (e.g. restrictions concerning the donation/use of certain tissues/cells, mandatory unpaid donation etc.)? | No |
| 16.2. Has your Member State encountered any difficulties in implementing the requirements in the EU Tissues and Cells Directives? Please choose from the options below. | Import-export<br>Authorisation-accreditation-licensing of TEs<br>Inspections |
| 16.2.1. For all selected options in question 16.2., please provide a short description. | System of authorisation-acreditation-licensing of TEs and inspections system are not finalized yet |
| 16.3. In your opinion, in which of the following Directives are there shortcomings (if any)? (more than 1 answer possible) | Directive 2004/23/EC |
| 16.3.1. How would you suggest to solve these issues in Directive 2004/23/EC? | Preambule 18: As a matter of principle, tissue and cell application programmes should be founded on the philosophy of voluntary and unpaid donation. Article 12 paragraph 2 .... Member states shall endeavour to ensure that the procurement of tissues and cells as such is carried out on a non-profit basis. These provisions and paragraphs were transponed into Slovak legislation. But still does exist chaos what can be paid and what can not be paid, how to handle with potential brokers etc. We have to put these problems on agenda of our regular meetings with advice of lawyers. |

## *A.1.27. Survey response Slovenia*

| **1. Public information** | |
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| 1.1. Name of National Competent Authority (NCA) 1: | Javna agencija Republike Slovenije za zdravila in medicinske pripomočke / Agency for Medicinal Products and Medical Devices of the Republic of Slovenia |
| 1.1.2. Address of NCA 1: | Ptujska ulica 21 SI-1000 Ljubljana Slovenia |
| 1.1.3. Telephone (central access point): | +386 (0)8 2000 500 |
| 1.1.4. E-mail (central access point): | info@jazmp.si |
| 1.1.5. Website: | www.jazmp.si |
| 1.1.6. The NCA is responsible for? (more than 1 answer possible) | Non-reproductive tissues and cells<br>Reproductive tissues and cells<br>Blood and blood components<br>Pharmaceuticals<br>Medical devices |
| 1.1.7. What are the role/tasks of the NCA? (more than 1 answer possible) | Accreditation, authorisation, licensing of TEs<br>Inspection<br>Vigilance |
| 1.2. National Competent Authority 2? | No |
| 1.5. Please give a short description of the legal status and organisation of the National Competent Authority(ies) (e.g. departments, staffing, number of senior and junior inspectors, staff working on EU affairs and legal matters, vigilance officers, budget, independence from government etc.). | JAZMP is an Independent agency founded 1.1.2007. The Agency was established and operates according to the legislation which explicitly states its competences and tasks ("Medicinal Products Act" (2006, 2008), "Medical Devices Act" (2009), "Blood Supply Act" (2000, 2004, 2006), "Act on Quality, Safety of Human Tissues and Cells" (2007)). JAZMP is organised in 12 sectors. EU issues are as a rule treated with very high priority by JAZMP. |
| 1.6. In case of MS with federal or decentralised systems, please indicate the roles/tasks of the Regional Competent Authority(ies). (more than 1 answer possible) | Not applicable |
| 1.7. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies) for tissues and cells: | NA |
| **2. Procurement (Article 5 Directive 2004/23/EC)** | |
| 2.1. Do you authorise the "conditions of procurement"? | Yes |
| 2.1.1. How do you authorise the "conditions of procurement"? (more than 1 answer possible) | By inspecting all procurement centres |
| 2.1.2. How many such authorisations were granted in 2011 (01/01-31/12/2011)? | 16 |
| 2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011). | 10 |
| 2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011). | 14 |
| 2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues were carried out in 2011 (01/01-31/12/2011). | 3 |
| 2.2.4. Please provide the number of procurement centers in which procurement of tissues/cells for ATMP manufacturing were carried out in 2011 (01/01-31/12/2011). | 1 |
| 2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC and its implementing Directive 2006/17/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) ? (more than 1 answer possible) | Inspections of the site/centre<br>Analysis of the mandatory documentation |
| 2.4. Are you also responsible for the accreditation, designation, authorisation or licensing of laboratories performing donor testing? | No |
| 2.4.2. Which National Authority is in charge of this activity? | Ministry of Health (3 laboratories perform donor testing) |
| 2.5. How do you ensure, as CA for T&C, that tests required for | Analysis of the mandatory documentation requested from the tissue |

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| donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art. 5(2))? (more than 1 answer possible) | establishment |
| 2.6. Please provide data on qualified laboratories accredited, authorised or licensed in your country (e.g. number, year of accreditation/authorisation/license, which donor tests are performed etc.). | NA |
| 2.7. Do you have any additional comments on procurement? | Please see 3.8 |
| **3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)** | |
| 3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>Ag HIV<br>HBs AG<br>Anti HBc<br>Anti HCV-Ab<br>Treponema Pallidum |
| 3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>Ag HIV<br>HBs AG<br>Anti HBc<br>Anti HCV-Ab<br>Treponema Pallidum |
| 3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to encourage its use? Please specify why or why not (e.g. number of additional cases detected, cost-benefit etc.). | This issue was not discused yet. |
| 3.4. Do you have concerns on accuracy of the available tests and test procedures for deceased donors? | Yes |
| 3.4.1. Please specify why: | Cases of false-positive HIV test results in deceased donors. |
| 3.5. Are any other laboratory tests required for donors of non-reproductive tissues and cells in your Member State? | No |
| 3.6. Are any other laboratory tests required for donors of reproductive tissues and cells in your Member State? | No |
| 3.7. Do you request/use international accreditation systems for testing laboratories? | No |
| 3.8. Do you have any additional comments on testing? | - Licences for testing laboratories are in Ministry of Health competences - Laboratories performing tissues and cells donor testings perform also testing for blood donations - The testing laboratories are included in national and international testing scheemes - Testing laboratories must have quality system in place (Legal requirement) |
| **4. Accreditation, designation, authorisation or licensing of tissue establishments (Article 6, Directive 2004/23/EC)** | |
| 4.1. Do you have a system of designation, authorisation, accreditation or licensing for all types of tissue establishments under your responsability? | Yes |
| 4.2. Is inspection a prerequisite for the designation, authorisation, accreditation or licensing of tissue establishments? | Yes |
| 4.2.1. How many inspections were performed in 2011 for authorising/accrediting/licensing/designating TEs? | 5 |
| 4.3. Are preparation processes authorised? | Yes |
| 4.3.1. How are they authorised? (more than 1 answer possible) | During routine inspections<br>During inspections organised for this purpose<br>By review of a submitted application with supporting documentation |
| 4.4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were suspended in 2011? | 0 |
| 4.5. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011? | 0 |

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| 4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)? | No |
| **4bis. Overview of tissue/cells establishments authorised by the NCA** | |
| 4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible): | Other tissue establishments |
| 4.7.9. Please specify the type of tissues/cells and how many. | No pendinng approvals at 01/01/2011. |
| 4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible): | Multi-tissue establishments |
| 4.8.8. How many multi-tissue establishments? | 5 |
| 4.9. Tissue establishments first time authorised between 01/01/2011 and 31/12/2011 (more than 1 answer possible): | Cord blood tissue establishments<br>Multi-tissue establishments |
| 4.9.6. How many cord blood tissue establishments? | 1 |
| 4.9.8. How many multi-tissue establishments? | 5 |
| 4.10. All tissue establishments authorised by 31/12/2011 (more than 1 answer possible): | Musculo-skeletal tissue establishments<br>Cord blood tissue establishments<br>Multi-tissue establishments |
| 4.10.2.1. How many public musculo-skeletal tissue establishments? | 1 |
| 4.10.2.2. How many private musculo-skeletal tissue establishments? | 2 |
| 4.10.6.1. How many public cord blood tissue establishments? | 0 |
| 4.10.6.2. How many private cord blood tissue establishments? | 2 |
| 4.10.8.1. How many public multi-tissue establishments? | 16 |
| 4.10.8.2. How many private multi-tissue establishments? | 2 |
| 4.11. How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Art. 6(5) during 2011? Please provide number(s) per type tissues/cells. | 0 |
| **4ter. Sanctions** | |
| 4.16. Have penalties for infringements of the national provisions pursuant to the Directive been defined (Article 27)? | Yes |
| 4.16.1. Have penalties already been imposed? | No |
| 4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing? | No |
| **5. Inspections (Article 7, Directive 2004/23/EC)** | |
| 5.1. Is a system in place for organising inspections and control measures of tissue establishments? | Yes |
| 5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections. | Inspection |
| 5.1.2. If yes, please specify staffing (how many inspectors). | 4 inspectors |
| 5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible) | Yes |
| 5.2.1. If yes, please specify. (more than 1 answer possible) | Blood |
| 5.3. How many routine inspections of tissue establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011)? | 26 inspections in 5 Tissue Establishments |
| 5.3.1. How many inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) following serious adverse events or reactions, or suspicion thereof ? | 0 |
| 5.3.2. How many other type of inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | 0 |
| 5.3.3. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | 0 |
| 5.3.4. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where minor | 0 |

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| shortcomings were noted? | |
| 5.3.5. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where major shortcomings were noted? | 5 |
| 5.3.6. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by suspension of authorisation? | 0 |
| 5.3.7. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by closure? | 0 |
| 5.3.8. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of other inspections carried out? Please specify. | 0 |
| 5.4. How many routine inspections were conducted in ART establishments (from 1/1/2011 to 31/12/2011)? | 3 |
| 5.4.1. How many inspections were conducted in ART establishments following serious adverse events or reactions, or suspicion thereof (from 1/1/2011 to 31/12/2011)? | 0 |
| 5.4.2. How many other type of inspections were conducted on ART establishments (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | 0 |
| 5.4.3. Outcome of inspections of ART tissue establishments carried out in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | 0 |
| 5.4.4. What was the number of inspections carried out in ART establishments where minor shortcomings were noted? | 0 |
| 5.4.5. What was the number of inspections carried out in ART establishments where major shortcomings were noted? | 3 |
| 5.4.6. What was the number of inspections carried out in ART establishments followed by suspension of authorisation? | 0 |
| 5.4.7. What was the number of inspections carried out in ART establishments followed by closure of respective establishements? | 0 |
| 5.4.8. What was the number of other inspections of ART establishments? Please specify. | 0 |
| 5.5. Which type of routine inspections do you conduct? (more than 1 answer possible) | General system-oriented inspections |
| 5.6. How do you decide which type of routine inspection to conduct? | We consider that during the routine inspection general system-oriented inspection should be performed. |
| 5.7. Until 2011, did you implement the requirement concerning the time interval between two inspections (Art. 7.3.)? | Yes |
| 5.8. How many TEs were inspected at least twice between 2008-2011 (01/01/2008-31/12/2011)? | 23 |
| 5.9. Did you perform/conduct inspections of procurement sites outside tissue establishments? | Yes |
| 5.9.1. If yes, how many? | 10 |
| 5.10. Did you carry out inspections of third parties? | Yes |
| 5.10.1. If yes, how many? | 2 |
| 5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)? | Yes |
| 5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)? | Yes |
| 5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)? | 5 |

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| 5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))? | No |
| 5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))? | No |
| 5.15. Did you organise any inspections of procurement centres or tissue establishments in third countries from which tissues and/or cells were imported in your country (as recorded by 31/12/2011)? | No |
| 5.16. Have you asked another MS, or have you been requested by any other MS, on the results and control measures of your inspections, as part of an enquiry/investigation? | Yes |
| 5.16.1. If yes, please specify. | We asked for outcomes of inspections: UK: outcome of inspection in one TE NL: outcome of inspection in one TE BE: outcome of inspection in one TE DE: outcome of inspection in one TE |
| 5.17. Would you be interested in developing joint inspections? Joint inspections should be understood as inspections of tissue establishments conducted jointly by two or more Member States' Competent Authorities on their territory or in third countries. | Yes |
| 5.18. Do you have any additional comments on inspections? | No. |
| **6. Import/export (Article 9 Directive 2004/23/EC)** | |
| 6.1. Do you have a register of authorised tissue establishments that are explicitly authorised to perform import/export of tissues and celles from/to third countries? | Yes |
| 6.2. Please specify the number of tissue establishments authorised to import tissues and cells from third countries (recorded by 31/12/2011). | 6 |
| 6.3. Please specify the number of tissue establishments authorised to export tissues and cells from third countries (recorded by 31/12/2011). | 6 |
| 6.4. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of skin from third countries. | Authorisation procedure, Inspections |
| 6.5. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of musculo-skeletal (bone, tendons, fascia etc.) tissues from third countries. | Authorisation procedure, Inspections |
| 6.6. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of ophtalmic (cornea, sclera, etc) tissues from third countries. | Authorisation procedure, Inspections |
| 6.7. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cardio vascular tissues from third countries. | Authorisation procedure, Inspections |
| 6.8. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) (other than cord blood) from third countries. | Authorisation procedure, Inspections |
| 6.9. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cord blood from third countries. | Authorisation procedure, Inspections |
| 6.10. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of reproductive cells (sperm, egg cells) from third countries. | Authorisation procedure, Inspections |
| 6.11. Did you import tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | Yes |
| 6.11.1. If yes, please provide the data concerning the number/volume of imported tissues and cells by country of origin. | From USA: 3x Achiles Tendom, 1x Bone Tendom with Qurad Hemi Small Bone, 1x Anterior Tibialis Tendom From Bosnia and Herzegovina: 1x cord blood for autologous storage |
| 6.12. Did you export tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | No |

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| 6.13. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on imports/exports of tissues/cells between your country and other third countries? | No |
| 6.14. What is the relation between import/export of tissues and cells and self-sufficiency? (more than 1 answer possible) | C. Export of tissues/cells is authorised irrespective of national needs |
| 6.15. Did you authorise direct imports of tissues/cells to hospitals/clinics in your country? | Yes |
| 6.15.1. If yes, please specify the number of cases and for which type of tissues/cells. | 1 case, inport from USA, infertility treatment, sperm cells (man's authologous sperm) for a couple. |
| 6.16. Do you have any additional comments on import/export? | No. |
| **7. Distribution/intra community exchanges (Article 23 Directive 2004/23/EC)** | |
| 7.1. Do you have intra-community exchanges of tissues and cells? | Yes |
| 7.1.1. If yes, how do you address the possible more stringent quality and safety measures established by other Member States? Please specify. | It's member state's right to ensure Q&S, if it is needed. |
| 7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States? | No |
| 7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify. | Before cross-border exchange is authorised by Slovene CA, copy of valid authorisation of TE issued by relevant national CA is needed. According to our law, foreigin TE are considered as third parties. |
| 7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible). | Other |
| Please specify 'other'. | We allow direct distribution to hospitals/ clinics, but with special authorisation issued for each case. Tissues and cells are used on physician's responsability. |
| 7.4. Have you authorised direct distribution to the recipient of specific tissues and cells (Art. 6, Directive 2006/17/EC)? | Yes |
| 7.4.1. If yes, how many authorisations were given in 2011 (01/01/2011 to 31/12/2011)? | 0 |
| 7.4.2. If yes, for which tissues/cells? | NA |
| 7.5. Do you collect data regarding the cross-border exchange of tissue/cells between your country and other EU MS? | Yes |
| 7.5.1. Please provide us with data (country of destination, type of tissue/cell and number of units distributed) concerning distribution to other MS in 2011 (01/01/2011-31/12/2011). | To Germany: 77 cord blood units for autologous use (storage) To Belgium: 446 cord blood units for autologous use (storage) |
| 7.5.2. Please provide us with data (country of origin, type of tissue/cell and number of units distributed) concerning distribution to other MS in 2011 (01/01/2011-31/12/2011) | From Slovenia: 523 units of cord blood for authologous use (storage) |
| 7.6. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on cross-border exchanges of tissues/cells between your country and other EU MS? | No |
| 7.7. Do you allow brokerage companies for either distribution in EU and/or import/export of tissues/cells? In this context, a brokerage company means a body that arranges transactions between a supplier (tissue establishment/company selling tissues or cells) and a buyer (a tissue establishment/a hospital or clinic/an individual) without undertaking activities of processing, preservation or storage. | No |
| 7.8. Are brokers actively supplying health professionals/establishments in your country? | No |
| 7.9. Do you have any additional comments on distribution? | Companies described in 7.7. can only be the third parties of Slovene Tissue Establishment, authorised for import, export and cross-border distribution. |
| **8. Register of tissue establishments and reporting obligations (Article 10, Directive 2004/23/EC)** | |
| 8.1. Do you have an annual report model/template on the activities of tissue establishments in your Member State? (Article 10(1)). If yes, please upload the template. | Yes |
| 8.2. How many tissue establishments submitted annual reports of their activities during 2011. Please provide an estimation. (1 answer possible) | 100% (all) |
| 8.3. Are these reports publicly available? (Article 10(1)) | No |

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| 8.4. Do you publish a national annual report of the consolidated activities of all tissue establishments in your country? | Yes |
| 8.4.1. Please insert the link to the published national annual report. | http://www.slovenija-transplant.si/index.php?id=porocila |
| 8.5. Is there a publicly accessible register of authorised tissue establishements in place? (Article 10(2)) | Yes |
| 8.5.1. If yes, please provide us with the link to the register's web site. | http://www.slovenija-transplant.si/index.php?id=presajanje-tkiv |
| 8.6. Do you provide data regarding tissues and cells activities to the EUROCET registry (non-mandatory reporting)? | Yes |
| 8.6.1. If yes, what data are provided to EUROCET? Please specify. | Tissue establishments, tissue banks, their activities and type of tissues and cells |
| 8.7. Do you have any additional comments on reporting? | No. |
| **9. Traceability (Article 8, Directive 2004/23/EC; and Directive 2006/86/EC)** | |
| 9.1. Was the donor identification system (Art. 8(2)) implemented in your country? | Yes |
| 9.2. Who assigns the unique code for each donation? (only 1 answer possible) | Other |
| Please specify 'other'. | Procurement centre or tissue establishments, depends on type of tissue or cells |
| 9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible) | Only paper records |
| 9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify. | There's a legal provision in national legislation. |
| 9.5. Do you have any additional comments on traceability? | We have data stored in paper records up to 2013, from 2013 data are stored in electronic database. Electronic database includes national coding system ( natioanl code is given automaticaly) and is EU compatible. |
| **10. Notification of serious adverse events and reactions (Article 11 Directive 2004/23, Article 6 Directive 2006/76)** | |
| 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))? | Yes |
| 10.1.1. If yes, which CA/institution is responsible? | Agency of Medicinal products and medical Devices of the Republic of Slovenia; some tasks, mostly on national level, are assigned to Slovenija-transplant. |
| 10.1.2. If yes, please provide a short description of its organisation. | Please see 1.5 |
| 10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use the SAR/E (to the CA (2006/76 art 6.4)) templates developed to the Annual reporting ot the EC also at national level? | No |
| 10.2.1. If no, what template do you use? You are welcome to upload the template if you wish. | We use tamplates prepared nationaly , they are templates from Directive 2006/86/EC, Ann III, Part A, B; Annex IV, Part A, B, in slovene language. |
| 10.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level? | Yes |
| 10.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all TEs? | Yes |
| 10.5. How many tissue establishments provided in 2011 the SAR/SAE data as requested (please provide the % from the total number of TEs authorised in your country). | 100% |
| 10.6. Do you have a mandatory procedure for the transplantation centres when reporting SAR/SAE to the TEs which distributed the tissues/cells (Art 11.2)? | Yes |
| 10.6.1. If yes, please provide a brief description. | All SARE should be reported to TE. |
| 10.7. Do you give feedback to the TEs regarding SAR/SAE recorded at national level? | Yes |
| 10.7.1. Please specify. | At annual meeting of responseble persons the feedback is given to the TEs. |
| 10.8. Do you give feedback to the TEs regarding SAR/SAE recorded at EU level? | Yes |
| 10.8.1. Please specify. | At annual meeting of responseble persons the feedback is given to the TEs. |
| 10.9. Do you require your TEs to have a recall procedure? | Yes |
| 10.10. How many recalls related to safety and quality of tissues/cells | 0 |

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| were issued in your country in 2011? Please specify the number and which tissues were recalled and why (e.g. missing consent, quality defects etc). | |
| 10.11. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites in case of a national rapid alert? | Yes |
| 10.11.1. If yes, please give a short description of the system/procedure. | All relevant TEs are informed/ contacted immidiatly by phone, e-mails, personal contacts. |
| 10.12. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites when a rapid alert is issued via the EU RATC platform? | Yes |
| 10.12.1. If yes, please give a short description of the system/procedure. | All relevant TEs are informed/ contacted immidiatly by phone, e-mails, personal contacts. |
| 10.13. Do you provide data regarding SAR/SAE to the EUROCET registry (non-mandatory reporting)? | No |
| 10.13.2. If no, please specify why not. | Not required by national legislation. |
| 10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems? | Yes |
| 10.14.1. If yes, please specify which of the following systems are usually contacted. (more than 1 answer possible) | Haemovigilance<br>Pharmacovilance<br>Medical devices<br>Other |
| Please specify 'other'. | National Institute of Health, in cases of epidemiological alerts. |
| 10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S? | Yes |
| 10.15.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (insufficient) - 2 (sufficient) 3 (good) - 4 (very good) to 5 (essential)? | 5 |
| 10.16. Do you have any additional comments on SARE reporting? | No. |
| **11. Consent and personal data protection (Article 13 and 14, Directive 2004/23/EC)** | |
| 11.1. What consent system for living tissue/cell donation do you have in place within your Member State? | Explicit consent (opt-in) |
| 11.1.1. Please specify your choice of consent system for living tissue/cell donation. | We will have data stored in paper records up to 2013, from 2013 in electronic database. |
| 11.2. What consent system for deceased tissue/cell donation do you have in place within your Member State? | Presumed (opt-out) and explicit (opt-in) consent |
| 11.2.1. If you have chosen both consent systems for deceased tissue/cell dontation, please specify. | National legislation presumes that every citizen agree on donation if he/she disagree. Legislation includes opt-in registry. |
| 11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible) | First degree relatives (including spouse)<br>Other relatives<br>Non-marital partners<br>Friends |
| 11.4. Is the consent system for deceased tissue donation the same as for organs? | Yes |
| 11.5. How is this consent verified during inspections? (more than 1 answer possible) | Analysis of documentation<br>Interviews with personnel |
| 11.6. What measures are in place to ensure that donors/relatives/authorising persons on behalf of donors are provided with the appropriate information, as requested by Art. 13(2)? (more than 1 answer possible) | Only trained personnel is allowed to provide such information |
| 11.7. What measures are in place to ensure that both donors and recipients remain unidentifiable when access is given to third parties (Art. 14(1)). Please specify. | Every donor (donation) and recipient must get a local unique code in order to prevent personal data abuse. |
| 11.8. Please specify what measures are in place to ensure that the identity of the receipient is not disclosed to the donor and vice versa. | Provisions in legislation, every donor and recipient must get a local unique code in order to prevent personal data abuse. |
| 11.9. Does your national legislation allows disclosure of donor data in case of gametes donation? | Yes |
| 11.10. Do you have any additional comments on consent and data protection? | Comment to 11.9: Yes, but for medical purposes to the medical staff only! |

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| **12. Selection, evaluation and procurement (Article 15 Directive 2004/23; Annexes I-IV Directive 2006/17)** | |
| 12.1. How do you ensure that all requirements related to the evaluation and selection of donors (except donors of reproductive cells) are respected in your country (Art. 15(1), Annex I Directive 2006/17/EC)? (more than 1 answer possible) | Stadardised questionnaires at national levels<br>Inspections of TEs and procurement sites<br>Audit of documentation |
| 12.2. How do you ensure that all requirements related to the evaluation and selection of donors of reproductive cells are respected in your country (Art 15 (1), Annex III of Directive 2006/17/EC)? (more than 1 answer possible) | Standardised questionnaires at national level<br>Inspections of ART centres<br>Audit documentation |
| 12.3. Do you have more stringent criteria for donor selection than those listed in Annex I of the Directive 2006/17/EC? | No |
| 12.4. What sources are required in your MS for the evaluation of a deceased donor of tissues/cells? (more than 1 answer possible) | Interview with the donor's family or a person who knew the donor well<br>Medical records of the donor<br>Autopsy report |
| 12.5. Do you have more stringent criteria for selection of donors of reproductive cells than those listed in Annex III of the Directive 2006/17/EC? | No |
| 12.6. Do you have more stringent criteria for autologous donation than those listed in Annex I of the Directive 2006/17/EC? | No |
| 12.7. Do you require more information on the donation of tissues/cells than the mandatory one as laid down in the Annex of Directive 2004/23/EC (Art 15(3)? | No |
| 12.8. How do you ensure that all requirements regarding tissues and cells' procurement, packaging and transport are complied with by tissue establishments in your country (Art 15(1), Annex IV of Directive 2006/17/EC? (more than 1 answer possible)(For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)) | Inspection of tissue establishment<br>Audit of tissue establishment |
| 12.9. Do you have any additional comments on selection, evaluation and procurement? | No. |
| **13. Quality management, responsible person, personnel (Article 16, 17, 18 Directive 2004/23/EC)** | |
| 13.1. How do you ensure that tissue establishments in your country have in place a quality system respecting the provisions of the Directive 2004/23/EC Art 16.1? (more than 1 answer possible). (For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)). | Authorisation requirement<br>Inspections<br>Internal audits<br>External audits |
| 13.2. How do you ensure that tissue establishments have a responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible) | Authorisation requirement<br>Inspections |
| 13.3. How do you ensure an appropriate training for the personnel directly involved in the activities of tissue establishments? (more than 1 answer possible) | Authorisation requirement<br>Inspections |
| 13.4. Do you have national/regional/local training programmes for the personnel of tissue establishments? | Yes |
| 13.4.1. If yes, please specify. | Events with lecturers, strongly recommendeted for responsible person, recomendated for other. |
| 13.5. Any additional comments on quality management, responsible person, personnel? | No. |
| **14. Reception, processing, storage, labelling and packaging (Art 19-22 Directive 2004/23/EC)** | |
| 14.1. How do you ensure that tissue establishments in your country fulfill the requirments of the Art. 19 (Tissue and cell reception) of | Inspections of tissue establishments |

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| Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | |
| 14.2. How do you ensure that tissue establishments in your country fulfill the requirements of the Art. 20 (Tissue and cell processing) of Directive 2004/23/EC? (more than 1 answer possible) | SOPs for all processes affecting quality and safety are mandatory for authorisation<br>Inspections of tissue establishments |
| 14.3. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 21 (tissue and cell storage conditions) of Directive 2004/23/EC? (more than 1 answer possible) | SOPs for procedures associated with storage of tissues and cells are mandatory for authorisation<br>Inspections of tissue establishments |
| 14.4. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | SOPs for procedures associated with labelling and packaging are mandatory for authorisation<br>Inspections of tissue establishments |
| 14.5. Any additional comments on reception, processing, storage, labelling and packaging? | No. |
| **15. Third party agreements (Art. 24 Directive 2004/23/EC)** | |
| 15.1. Are third party agreements foreseen/allowed in your national legislation? | Yes |
| 15.1.1. If yes, have tissue establishments in your Member State notified third party agreements? | Yes |
| 15.1.1.1. Under which circumstances and for which responsibilities? | Third part agreements for: Transport, Procurement, Testing, Processing in cases when TE is not able to perform all tasks. Third part agreement for Back-up procedures is legal requirement for all TEs. |
| 15.1.1.2. How are third party agreements controlled (Art 6.2) by the Competent Auhtority(ies) in your MS? Please specify. | Agreemennts should be submitted to CA before authorisation is granted. CA assesses if the agreements are in line with the legislation. All variations in agreements should be submitted to CA. |
| 15.2. Any additional comments on third party agreements? | No. |
| **16. General comments - implementation** | |
| 16.1. Do you have at national level more stringent quality and safety requirements than those requested by the EU legislation in this field (e.g. restrictions concerning the donation/use of certain tissues/cells, mandatory unpaid donation etc.)? | No |
| 16.2. Has your Member State encountered any difficulties in implementing the requirements in the EU Tissues and Cells Directives? Please choose from the options below. | ART provisions<br>Procurement provisions<br>Testing provisions<br>Traceability |
| 16.2.1. For all selected options in question 16.2., please provide a short description. | ART, procurement and Testing: special law and/or rules in national legislation. Tracebility: no unique EU- code is available. |
| 16.3. In your opinion, in which of the following Directives are there shortcomings (if any)? (more than 1 answer possible) | Directive 2004/23/EC<br>Directive 2006/17/EC<br>Directive 2006/86/EC |
| 16.3.1. How would you suggest to solve these issues in Directive 2004/23/EC? | We support suggestions for changes presented at CA meeting in Dec2012. |
| 16.3.2. How would you suggest to solve these issues in Directive 2006/17/EC? | We support suggestions for changes presented at CA meeting in Dec2012. |
| 16.3.3. How would you suggest to solve these issues in Directive 2006/86/EC? | We support suggestions for changes presented at CA meeting in Dec2012. |

## *A.1.28. Survey response Spain*

| **1. Public information** | |
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| 1.1. Name of National Competent Authority (NCA) 1: | Organización Nacional de Trasplantes |
| 1.1.2. Address of NCA 1: | Sinesio Delgado 4-8, Pabellón 3, 28029-Madrid, Spain |
| 1.1.3. Telephone (central access point): | +34-902300224 |
| 1.1.4. E-mail (central access point): | ont@msssi.es |
| 1.1.5. Website: | www.ont.es |
| 1.1.6. The NCA is responsible for? (more than 1 answer possible) | Non-reproductive tissues and cells<br>Human organs |
| 1.1.7.What are the role/tasks of the NCA? (more than 1 answer possible) | Other |
| Please specify 'other': | The ONT is a coordinating and technical body for the development of functions related to the procurement and clinical use of organs, tissues and cells.<br>Other areas of work: training programs; international cooperation; relation with the media; research projects; transplant registries; quality and safety; regulation and ethics; promotion and education. |
| 1.2. National Competent Authority 2? | Yes |
| 1.2.1. Name of National Competent Authority 2: | National Commission on ARTs. |
| 1.2.2. Address of NCA 2: | Ministry of Health, Social Services & Equity.<br>National Commission on ARTs.<br>Paseo del Prado 18-20<br>28071- Madrid |
| 1.2.3. Telephone (central access point): | +34915964106 |
| 1.2.4. E-mail (central access point): | jrey@msssi.es |
| 1.2.5. Website: | http://www.cnrha.msssi.gob.es/ |
| 1.2.6. The NCA is responsible for? (more than 1 answer possible) | Reproductive tissues and cells |
| 1.2.7. What are the role/tasks of the NCA? (more than 1 answer possible) | Other |
| Please specify 'other': | The Commission is an advisory board to the Ministry of Health on ARTs and also has a role in providing public information on activities related to ARTs developed by Autonomous Communities, which are in charge of authorization and control of these activities by the centers in their respective territories. |
| 1.3. National Competent Authority 3? | No |
| 1.5. Please give a short description of the legal status and organisation of the National Competent Authority(ies) (e.g. departments, staffing, number of senior and junior inspectors, staff working on EU affairs and legal matters, vigilance officers, budget, independence from government etc.). | The National Organisation for Transplantation (ONT) is the technical and coordinating institution that deals with donation and transplantation matters. It belongs to the Ministry of Health, Social Services and Equity (hereinafter MoH).<br>In addition to those areas of work described in question 1.1.7, it should be remarked again the coordinating role of the ONT. In this line, the ONT acts as the interface between the MoH and the regional authorities and also between them and the EC and other MS.<br>Some of the areas of work directly related to tissues and cells are: scientific aid, regulatory provision, inspection support, coordination of the surveillance network and support for professionals training courses, registries of activity, information to public, provision of national policies, etc.<br>Personnel at the ONT: Director; General Secretary; Medical staff; Nursing staff; Technical staff; IT staff and General staff. Total: 43 people. Their duties are carried out by interdisciplinary working teams.<br>The National Commission on ART is an advisory board under the head of the Spanish General Secretary for Health and Consumer Affairs, made up by eighteen members representing different social, professional and administrative organizations. Four of them, representing Autonomous Communities, are appointed by the Spanish Interterritorial Council of the National Health System. The Interterritorial Council is the coordination body of the Regional Health Authorities and the Ministry of Health.<br>The Commission is not endowed with executive competences, except its role to inform the requirements made to the Regional Authorities on some special practices of PGD. |
| 1.6. In case of MS with federal or decentralised systems, please | Authorization |

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| indicate the roles/tasks of the Regional Competent Authority(ies). (more than 1 answer possible) | Inspection<br>Vigilance<br>Other |
| Please specify 'other': | The former selected answers are specific of the Regional CAs, however, they are responsible at a regional level for many other elements of the activity. |
| 1.7. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies) for tissues and cells: | The healthcare provision in Spain and its organization is transferred to the Regional Authorities (hereinafter, RAs). Each regional authority has its independent healthcare system.<br>The Interterritorial Council for the National Health System is the common forum to coordinate the health-care in Spain. Consisting of several committees, there is a specific one dealing with donation and transplantation matters, for the discussion as well as political and technical agreements on the area.<br>As regards the human tissues and cells, all the policies are discussed at the so-called Permanent Commission for Transplantation, the one mentioned above. The RAs are represented in this Committee. It is chaired by the Director of the ONT. As already mentioned, all these representatives discuss and make joint decisions on the affairs included in the agenda of each session.<br>Regarding the coordination role of the ONT, see answers 1.1.7 and 1.5.<br>The healthcare provision in Spain and its organization is transferred to the Regional Authorities (hereinafter, CCAA). Each Regional Authority has its independent healthcare system.<br>The Interterritorial Council for the National Health System is the common forum to coordinate the health-care in Spain. Made up by several committees, some of them (the one related to public health; another one coping with benefits of the Spanish Health Care System) have to do with ARTs and its deployment in reproductive general, public or private centers. |
| **2. Procurement (Article 5 Directive 2004/23/EC)** | |
| 2.1. Do you authorise the "conditions of procurement"? | Yes |
| 2.1.1. How do you authorise the "conditions of procurement"? (more than 1 answer possible) | By inspecting all procurement centres<br>Other |
| Please specify 'other': | A system for the authorization exists at a national level and is regulated in the Royal Decree. Nevertheless, the RAs provide the authorizations, as already mentioned. |
| 2.1.2. How many such authorisations were granted in 2011 (01/01-31/12/2011)? | 86 |
| 2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011). | 211 |
| 2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011). | 272 |
| 2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues were carried out in 2011 (01/01-31/12/2011). | There is no disposable information for 2011. As an answer to the requests of Eurocet made through the Italian National Institute of Health, in January 2013 it was sent to Eurocet a list of Spanish centers practicing different activities included in or related to ARTs. The total number of centers included in the list at that time was 390. In march 20th, 2013 it was received a new request from that Institute, on behalf of Eurocet, asking to adapt the list previously sent, which was a copy of the register of centers appearing at the web page of the Spanish Commision on ARTs, to a new format proposed by Eurocet. This new format means the exclusion of a certain number of centers developing some kind of activities related to ARTs, like the ones only being banks of sperm, oocytes or embryos. After some consultations with Eurocet, the last one being answered in September 2th, a new list will be sent along September. |
| 2.2.4. Please provide the number of procurement centers in which procurement of tissues/cells for ATMP manufacturing were carried out in 2011 (01/01-31/12/2011). | There is not a specific authorization for procurement centres for ATMP, nevertheless those centres which are authorized for the procurement of "traditional tissues and cells" hold the authorization as the source of cells to produce Advance Therapies. |
| 2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC | Inspections of the site/centre<br>Analysis of the mandatory documentation |

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| and its implementing Directive 2006/17/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) ? (more than 1 answer possible) | |
| 2.4. Are you also responsible for the accreditation, designation, authorisation or licensing of laboratories performing donor testing? | No |
| 2.4.1. Please provide the number of the laboratories performing donor testing. | There are not available data. |
| 2.4.2. Which National Authority is in charge of this activity? | The authorization of control of this activity relies on the RAs.<br>The National authority lays down national requisites and regulation and coordinates the transmission of results and the dissemination of other information when it is necessary. |
| 2.5. How do you ensure, as CA for T&C, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art. 5(2))? (more than 1 answer possible) | Inspections of the laboratories<br>Analysis of the mandatory documentation requested from the tissue establishment |
| 2.6. Please provide data on qualified laboratories accredited, authorised or licensed in your country (e.g. number, year of accreditation/authorisation/license, which donor tests are performed etc.). | The ONT does not have that kind of information at that level of detail, nevertheless it is estimated that the number of qualified labs is similar to the one for Tissue Establishments. |
| 2.7. Do you have any additional comments on procurement? | No |
| **3. Testing (Art 4; Annexes I, II and III of Directive 2006/17/EC)** | |
| 3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>HBs AG<br>Anti HBc<br>Anti HCV-Ab |
| 3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>Ag HIV<br>HBs AG<br>Anti HBc<br>Anti HCV-Ab<br>Treponema Pallidum |
| 3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to encourage its use? Please specify why or why not (e.g. number of additional cases detected, cost-benefit etc.). | NAT is broadly used.<br>For ART it has not foreseen as for now. Activities are widely developed at private centers and controls have not produced any problems with less expensive and more traditional methods. |
| 3.4. Do you have concerns on accuracy of the available tests and test procedures for deceased donors? | No |
| 3.5. Are any other laboratory tests required for donors of non-reproductive tissues and cells in your Member State? | Yes |
| 3.5.1. Please specify. | Anti-HTLV II<br>For HSC it is also required PCR in addition to Anti HCV Ab. |
| 3.6. Are any other laboratory tests required for donors of reproductive tissues and cells in your Member State? | No |
| 3.6.1. Please specify. | Clinical studies are applied to exclude clinical phases of toxoplamosis, rubella, herpes, cytomegalovirus, neisseria or Chlamydia, but laboratory test for these diseases are not mandatory in the absence of clinical symptoms. |
| 3.7. Do you request/use international accreditation systems for testing laboratories? | Yes<br>(No for ART) |
| 3.8. Do you have any additional comments on testing? | Some testing laboratories in Spain usually search for international accreditation (ISO, etc) besides the CA authorisation. |
| **4. Accreditation, designation, authorisation or licensing of tissue establishments (Article 6, Directive 2004/23/EC)** | |
| 4.1. Do you have a system of designation, authorisation, accreditation or licensing for all types of tissue establishments under your responsability? | No |
| 4.1.1. Please specify. | A system for the authorization exists at national level and is regulated in the Royal Decree. Nevertheless, the RAs provide the authorizations, as already mentioned. |
| 4.2. Is inspection a prerequisite for the designation, | Yes |

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| authorisation, accreditation or licensing of tissue establishments? | (No for ART) |
| 4.2.1. How many inspections were performed in 2011 for authorising/accrediting/licensing/designating TEs? | Data not available at national level.<br>The inspections are responsibility of the RAs. In general, the procedure for authorization and register of health establishments by the Regional Authorities requires the submission of documentation as well as to carry out inspections and audits. |
| 4.3. Are preparation processes authorised? | Yes<br>(No for ART) |
| 4.3.1. How are they authorised? (more than 1 answer possible) | During routine inspections<br>During inspections organized for this purpose |
| 4.4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were suspended in 2011? | Data not available at national level. Inspections are responsibility of the RAs. In general, the procedure for authorization and register of health establishments by the Regional Authorities requires the submission of documentation as well as to carry out inspections and audits. |
| 4.5. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011? | None<br>(For ART data are not available at national level) |
| 4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)? | No |
| 4.6.1. What is the relation between the independent certification(s) (e.g. ISO, JACIE, FACT) and the CA authorisation of the tissue establishments? (more than 1 answer possible) | Other |
| 4.6.2. Please specify | The certification/accreditation is optional.<br>TEs may obtain the accreditation by JACIE, ISO, etc. if they apply for it. |
| **4bis. Overview of tissue/cells establishments authorised by the NCA** | |
| 4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible): | ART tissue establishments<br>(The RAs provide the authorizations, as already mentioned. Following the Spanish regulation, the ONT receives the final information including the authorized centers, nevertheless the data pertaining to the 'authorizations pending for approval' remains at the regional level.) |
| 4.7.1. How many ocular tissue establishments? | Please see 4.7 |
| 4.7.5. How many HSC tissue establishments? | Please see 4.7 |
| 4.7.7. How many ART tissue establishments? | Data not available at national level |
| 4.7.8. How many multi-tissue establishments? | Please see 4.7 |
| 4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible): | ART tissue establishments |
| 4.8.8. How many multi-tissue establishments? | Please see 4.7 |
| 4.9. Tissue establishments first time authorised between 01/01/2011 and 31/12/2011 (more than 1 answer possible): | ART tissue establishments |
| 4.10. All tissue establishments authorised by 31/12/2011 (more than 1 answer possible): | ART tissue establishments |
| 4.10.2.1. How many authorised centres (2012 data) | 502 |
| 4.10.2.2. How many Skin tissue establishments? | 42 |
| 4.10.3.1. How many Musculo-skeletal tissue establishments? | 149 |
| 4.10.3.2. How many Ocular tissue establishments | 245 |
| 4.10.5.1. How many Cardiovascular tissue establishments? | 62 valves centres, 83 segments centres |
| 4.10.5.2. How many HSC tissue establishments? | 90 |
| 4.10.6.1. How many Cord blood tissue establishments? | 272 |
| 4.10.6.2. How many Multi-tissue establishments? | 321 |
| 4.10.7.1. Other tissue establishments | 194 |
| 4.11. How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Art. 6(5) during 2011? Please provide number(s) per type tissues/cells. | Data not available |
| **4ter. Sanctions** | |
| 4.16. Have penalties for infringements of the national provisions pursuant to the Directive been defined (Article 27)? | Yes |
| 4.16.1. Have penalties already been imposed? | No<br>For ART data not available, as penalties would have been imposed at |

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| | regional level |
| 4.16.1.1. How many penalties have been imposed in 2011 (from 01/01/2011-31/12/2011)? | None<br>For ART data not available |
| 4.16.1.2. What were the reasons for imposing the penalties? Please describe. | NA |
| 4.16.1.3. What kind of penalties were imposed? Please describe (e.g. suspension of authorisation, criminal penalty etc.) | NA |
| 4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing? | Currently, there are several disciplinary proceedings ongoing. |
| 5. Inspections (Article 7, Directive 2004/23/EC) | |
| 5.1. Is a system in place for organising inspections and control measures of tissue establishments? | Yes |
| 5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections. | Regional competent authorities (RAs). |
| 5.1.2. If yes, please specify staffing (how many inspectors). | Data not available at national level. |
| 5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible) | Yes |
| 5.2.1. If yes, please specify. (more than 1 answer possible) | Blood<br>Organs<br>Pharmaceuticals<br>Advanced therapies<br>Medical devices<br>Hospitals<br>Accreditation organisations (e.g. JACIE) |
| 5.3. How many routine inspections of tissue establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011)? | Data not available at national level since the competencies for the inspections rely on the RAs. |
| 5.3.1. How many inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) following serious adverse events or reactions, or suspicion thereof ? | Please see 5.3 |
| 5.3.2. How many other type of inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | Please see 5.3 |
| 5.3.3. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | Please see 5.3 |
| 5.3.4. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where minor shortcomings were noted? | Please see 5.3 |
| 5.3.5. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where major shortcomings were noted? | Please see 5.3 |
| 5.3.6. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by suspension of authorisation? | 0 |
| 5.3.7. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by closure? | 0 |
| 5.3.8. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of other inspections carried out? Please | Please see 5.3 |

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| specify. | |
| 5.4. How many routine inspections were conducted in ART establishments (from 1/1/2011 to 31/12/2011)? | Data not available |
| 5.4.1. How many inspections were conducted Fin ART establishments following serious adverse events or reactions, or suspicion thereof (from 1/1/2011 to 31/12/2011)? | NA |
| 5.4.2. How many other type of inspections were conducted on ART establishments (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | Data not available |
| 5.4.3. Outcome of inspections of ART tissue establishments carried out in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | Data not available at national level |
| 5.4.4. What was the number of inspections carried out in ART establishments where minor shortcomings were noted? | Data not available at national level |
| 5.4.5. What was the number of inspections carried out in ART establishments where major shortcomings were noted? | Data not available at national level |
| 5.4.6. What was the number of inspections carried out in ART establishments followed by suspension of authorisation? | Data not available at national level |
| 5.4.7. What was the number of inspections carried out in ART establishments followed by closure of respective establishements? | Data not available at national level |
| 5.4.8. What was the number of other inspections of ART establishments? Please specify. | Data not available at national level |
| 5.5. Which type of routine inspections do you conduct? (more than 1 answer possible) | General system-oriented inspections<br>Desk based reviews |
| 5.6. How do you decide which type of routine inspection to conduct? | The regional authority plans ahead the type of inspection. |
| 5.7. Until 2011, did you implement the requirement concerning the time interval between two inspections (Art. 7.3.)? | Yes<br>(For ART data not available at national level) |
| 5.7.1. Why not? | Regional Authorities are in charge of inspections. |
| 5.7.2. How do you prioritize tissue establishments to be inspected? | The regional authority prioritizes the Tissue Establishement to be inspected. |
| 5.8. How many TEs were inspected at least twice between 2008-2011 (01/01/2008-31/12/2011)? | Data not available at national level. |
| 5.9. Did you perform/conduct inspections of procurement sites outside tissue establishments? | Yes |
| 5.9.1. If yes, how many? | Data not available at national level. |
| 5.10. Did you carry out inspections of third parties? | No |
| 5.10.1. If yes, how many? | Data not available |
| 5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)? | Yes<br>For ART No since the Ministry of Health has no capacity to carry direct inspections of centres in the Authonomous Regions |
| 5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)? | Yes<br>For ART No |
| 5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)? | 4 |
| 5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))? | No |
| 5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))? | Yes<br>For ART No |
| 5.14.1. Could you please explain why? | The inspectors of the HTA (UK) inspected the Transplant Services Foundation (TSF), Spain, to allow the export of skin.<br>For ART Inspections of centres at the request of another country have to be deployed by Regional Authorities. In some cases concerned regional |

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| | authorities have been asked to inspect some centers at the request of NCAs of other countries. |
| 5.15. Did you organise any inspections of procurement centres or tissue establishments in third countries from which tissues and/or cells were imported in your country (as recorded by 31/12/2011)? | No |
| 5.16. Have you asked another MS, or have you been requested by any other MS, on the results and control measures of your inspections, as part of an enquiry/investigation? | No |
| 5.17. Would you be interested in developing joint inspections? Joint inspections should be understood as inspections of tissue establishments conducted jointly by two or more Member States' Competent Authorities on their territory or in third countries. | Yes<br>For ART No |
| 5.18. Do you have any additional comments on inspections? | No |
| 6. Import/export (Article 9 Directive 2004/23/EC) | |
| 6.1. Do you have a register of authorised tissue establishments that are explicitly authorised to perform import/export of tissues and celles from/to third countries? | No |
| 6.2. Please specify the number of tissue establishments authorised to import tissues and cells from third countries (recorded by 31/12/2011). | The authorizations in Spain are given for all the activities at a time, i.e. procurement, processing, storing, distribution, import and export, so that all the TEs are authorized to import and export.<br>For ART, exchanges of sperm, oocytes or embryos with other countries belonging to the EU, which are the more frequent in ARTs cannot be considered import nor export, and cannot be subject of any kind of special controls. |
| 6.3. Please specify the number of tissue establishments authorised to export tissues and cells from third countries (recorded by 31/12/2011). | Please see 6.2 |
| 6.4. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of skin from third countries. | The requests to import tissues and cells are received at the ONT from the concerned TE.<br>The ONT prepares the favorable report which is sent to the Ministry of Health (Public Health General Directorate). Imports are specifically authorized by this DG.<br>The TE presents the requested documents at the ONT. Since several requirements have to be met, the responsible at the ONT verifies that the standards of quality and safety are equivalents to the Spanish ones. |
| 6.5. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of musculo-skeletal (bone, tendons, fascia etc.) tissues from third countries. | Please see 6.4 |
| 6.6. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of ophtalmic (cornea, sclera, etc) tissues from third countries. | Please see 6.4 |
| 6.7. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cardio vascular tissues from third countries. | Please see 6.4 |
| 6.8. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) (other than cord blood) from third countries. | Please see 6.4 |
| 6.9. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cord blood from third countries. | Please see 6.4 |
| 6.10. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of reproductive cells (sperm, egg cells) from third countries. | Importation of sperm, oocytes or embryos from third countries not belonging to the UE is very uncommon, reduced to a little number of individual requests. When these cases take place, they are directed to some fixed customs, following the procedure described in 6.4. |
| 6.11. Did you import tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | Yes<br>For ART not applicable |

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| 6.11.1. If yes, please provide the data concerning the number/volume of imported tissues and cells by country of origin. | CBU 60, PBSC 49, BM 18, musculoskeletal 700 |
| 6.12. Did you export tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | Yes<br>For ART not applicable |
| 6.12.1. If yes, please provide the data concerning the number/volume of exported tissues and cells by country of destination.* | CBU 96, PBSC 3, blood vessel 2, musculoskeletal 25 |
| 6.13. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on imports/exports of tissues/cells between your country and other third countries? | No |
| 6.14. What is the relation between import/export of tissues and cells and self-sufficiency? (more than 1 answer possible) | A. Export of tissues/cells is authorised only after checking that local/national needs are fulfilled.<br>D. Import of tissues/cells is authorised only after checking that local/national needs are not fulfilled |
| 6.14.1. If A or D were selected, please explain how you quantify local/national needs. | Each regional authority checks the local needs and the availability of tissues. Then, the ONT does the same at the national level before preparing the report which is sent to the Ministry of Health (Public Health General Directorate). Please see also 6.4.<br>The HSC are regulated by a different system, based on the Bone Marrow Donors Worldwide (BMDW) Standards. |
| 6.15. Did you authorise direct imports of tissues/cells to hospitals/clinics in your country? | No |
| 6.16. Do you have any additional comments on import/export? | |
| 7. Distribution/intra community exchanges (Article 23 Directive 2004/23/EC) | |
| 7.1. Do you have intra-community exchanges of tissues and cells? | Yes |
| 7.1.1 Please specify | The free circulation of tissues and cells among the EU Member States is assumed in Spain.<br>For ART is the same. |
| 7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States? | No |
| 7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify. | By the inspections |
| 7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible). | Other |
| 7.3.1 Please specify | All the tissues and cells are distributed through a Spanish TE except for the distribution of products derived of human tissues such as DBM and lyophilized products which may have a direct distribution to hospital/clinics.<br>For ART it is only via an authorised TE in my MS |
| 7.4. Have you authorised direct distribution to the recipient of specific tissues and cells (Art. 6, Directive 2006/17/EC)? | No |
| 7.5. Do you collect data regarding the cross-border exchange of tissue/cells between your country and other EU MS? | Yes<br>For ART No |
| 7.5.1. Please provide us with data (country of destination, type of tissue/cell and number of units distributed) concerning distribution to other MS in 2011 (01/01/2011-31/12/2011). | Germany: CBU 7, PBSC 4, cardiac tissue 49, blood vessel 7, musculoskeletal 54;<br>Austria: CBU 6, PBSC 1, cardiac tissue 6, blood vessel 3;<br>Belgium: CBU 5, PBSC 1;<br>Czech Republic: CBU 1;<br>Croatia: CBU 1;<br>Denmark: CBU 4;<br>France: CBU 48, PBSC 6, BM 2, blood vessel 2, musculoskeletal 30;<br>Greece: CBU 5, cardiac tissue 1, musculoskeletal 202;<br>Netherlands: CBU 20, cardiac tissue 8, blood vessel 7, musculoskeletal 42;<br>Hungary: CBU 6;<br>UK: CBU 23, PBSC 2, skin 72, cardiac tissue 2,<br>Italy: CBU 10, cornea ;<br>Poland: PBSC 1; |

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| | Portugal: CBU 1, skin 4, musculoskeletal 115 |
| 7.5.2. Please provide us with data (country of origin, type of tissue/cell and number of units distributed) concerning distribution to other MS in 2011 (01/01/2011-31/12/2011) | Germany: CBU 8, PBSC 134, BM 58;<br>UK: CBU 3, PBSC 12, BM 8;<br>Portugal: PBSC 13, BM 1;<br>France: CBU 6, PBSC 7, BM 6;<br>Italy: CBU 2, PBSC 2, BM 2, cornea 1;<br>Poland: PBSC 2;<br>Belgium: CBU 1;<br>Netherlands: musculoskeletal 1243 |
| 7.6. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on cross-border exchanges of tissues/cells between your country and other EU MS? | No |
| 7.7. Do you allow brokerage companies for either distribution in EU and/or import/export of tissues/cells? In this context, a brokerage company means a body that arranges transactions between a supplier (tissue establishment/company selling tissues or cells) and a buyer (a tissue establishment/a hospital or clinic/an individual) without undertaking activities of processing, preservation or storage. | Yes<br>For ART No |
| 7.7.1. Please describe the legal requirements and your role (if any) as a Competent Authority, in their authorization /monitoring or inspection | A system for the authorization exists and is regulated in the Royal Decree.<br>Nevertheless, the RAs provide the authorizations, as already mentioned. |
| 7.8. Are brokers actively supplying health professionals/establishments in your country? | Yes<br>For ART No |
| 7.8.1. Where are the brokers located? | Your country<br>Another country |
| 7.8.2. If the broker is located in another country, how easy/difficult is it to ensure that safety and quality requirements are met? | If the tissues are coming into Spain from a non- EU country, there is a thorough document revision. |
| 7.9. Do you have any additional comments on distribution? | No. |
| **8. Register of tissue establishments and reporting obligations (Article 10, Directive 2004/23/EC)** | |
| 8.1. Do you have an annual report model/template on the activities of tissue establishments in your Member State? (Article 10(1)). If yes, please upload the template. | Yes<br>For ART the report, based on a noncompulsory register on activities in ARTs, is made by the Spanish Society of Fertility (SEF), according to an annual contract signed by the Society and the Ministry of Health. The results are used to send data required to different European registers (Eurocet; ESHRE) |
| 8.2. How many tissue establishments submitted annual reports of their activities during 2011. Please provide an estimation. (1 answer possible) | 100% (all)<br>For ART 50-69% |
| 8.3. Are these reports publicly available? (Article 10(1)) | Yes |
| 8.3.1. If yes, please insert the link(s) to the report(s). | The data are included in the national annual report.<br>http://www.ont.es/infesp/Paginas/DatosdeDonacionyTrasplante.aspx<br>For ART Data informing on activity and outcomes of each center, to be known by interested users, may be accessed at: http://www.cnrha.msssi.gob.es/registros/actividades.htm |
| 8.4. Do you publish a national annual report of the consolidated activities of all tissue establishments in your country? | Yes<br>For ART Ministry of Health receives this annual report according to the terms of the contract signed with SEF. The report is not published by the Ministry of Health, but SEF makes public the data in its own bulletin. |
| 8.4.1. Please insert the link to the published national annual report | http://www.ont.es/infesp/Paginas/DatosdeDonacionyTrasplante.aspx |
| 8.5. Is there a publicly accessible register of authorised tissue establishements in place? (Article 10(2)) | Yes |
| 8.5.1. If yes, please provide us with the link to the register's web site. | https://reports.ont.es/Autorizaciones.aspx<br>For ART http://www.cnrha.msssi.gob.es/registros/centros/home.htm |
| 8.6. Do you provide data regarding tissues and cells activities to the EUROCET registry (non-mandatory reporting)? | Yes |
| 8.6.1. If yes, what data are provided to EUROCET? Please specify. | All data requested by EUROCET for tissues and cells.<br>For ART, data requested by EUROCET in the format provided for |

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| | ARTs. |
| 8.7. Do you have any additional comments on reporting? | No. |
| **9. Traceability (Article 8, Directive 2004/23/EC; and Directive 2006/86/EC)** | |
| 9.1. Was the donor identification system (Art. 8(2)) implemented in your country? | No |
| 9.1.1. If no, why not? | It has been partially implemented, awaiting the final guidance from the Commission.<br>For ART, a compulsory general register of donors is not yet implemented. Data of donors are conserved at the centers. |
| 9.2. Who assigns the unique code for each donation? (only 1 answer possible) | Other |
| Please specify | It has been partially implemented, awaiting the final guidance from the Commission. |
| 9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible) | Both paper records and electronic forms |
| 9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify. | There is an obligation as stated in the regulation.<br>For ART not yet regulated. |
| 9.5. Do you have any additional comments on traceability? | No. |
| **10. Notification of serious adverse events and reactions (Article 11 Directive 2004/23, Article 6 Directive 2006/86)** | |
| 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))? | Yes<br>For ART No |
| 10.1.1. If yes, which CA/institution is responsible? | The ONT as the National Competent Authority, the regional competent authorities and the National Group of Biovigilance.<br>For ART, Regional Authorities are responsible of control of ARTs centers in its own territories |
| 10.1.2. If yes, please provide a short description of its organisation. | The Vigilance Network is constituted by three levels:<br>1) hospital/centres- all authorized centres (for procurement, processing and transplantation).<br>2) regional level- regional competent authorities<br>3) national level- the ONT<br><br>The National Group of Biovigilance is responsible for the coordination of vigilance tasks and also gives the approval to the annual national report. |
| 10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use the SAR/E (to the CA (2006/86 art 6.4)) templates developed to the Annual reporting ot the EC also at national level? | Yes |
| 10.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level? | Yes<br>For ART No |
| 10.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all TEs? | Yes<br>For ART No |
| 10.4.1. Why not? | Not applicable to ART |
| 10.5. How many tissue establishments provided in 2011 the SAR/SAE data as requested (please provide the % from the total number of TEs authorised in your country). | 100% |
| 10.6. Do you have a mandatory procedure for the transplantation centres when reporting SAR/SAE to the TEs which distributed the tissues/cells (Art 11.2)? | Yes<br>For ART No |
| 10.6.1. If yes, please provide a brief description. | There is a procedure approved* in 2009 by the Interterritorial Council for the reporting and management of SAR/SAE occurred in procurement centres, tissue establishments and transplantation centres. Please note that the procedure takes into account possible SAR/SAES in living donors at procurement centres.<br>The system establishes principles and rules for notification and management and respects the internal organisation of the National Health System and the Spanish administration.<br>* National Vigilance Protocol, accessible at http://www.ont.es/infesp/TejidosPHCelulas/Sistema_de_Biovigilancia.p |

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| 10.7. Do you give feedback to the TEs regarding SAR/SAE recorded at national level? | Yes<br>For ART No |
| 10.7.1. Please specify | An annual report is provided in a specific meeting to the network, then presented to the Transplantation Committee of the Interterritorial council, and finally sent, in written format, to the network. |
| 10.8. Do you give feedback to the TEs regarding SAR/SAE recorded at EU level? | Yes<br>For ART No |
| 10.8.1. Please specify | Alerts are transmitted to the TE through the Vigilance Network |
| 10.9. Do you require your TEs to have a recall procedure? | Yes<br>For ART No |
| 10.10. How many recalls related to safety and quality of tissues/cells were issued in your country in 2011? Please specify the number and which tissues were recalled and why (e.g. missing consent, quality defects etc). | None in 2011 |
| 10.11. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites in case of a national rapid alert? | Yes<br>For ART No |
| 10.11.1. If yes, please give a short description of the system/procedure. | An alert can be quickly transmitted to the vigilance network by an established dissemination procedure, using mail and the 24 hours coordination office at the ONT. |
| 10.12. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites when a rapid alert is issued via the EU RATC platform? | Yes<br>For ART No |
| 10.12.1. If yes, please give a short description of the system/procedure | The same system is used for EU alerts transmitted via RATC platform. |
| 10.13. Do you provide data regarding SAR/SAE to the EUROCET registry (non-mandatory reporting)? | No |
| 10.13.2. If no, please specify why not | Because those data are sent to the European Commission. |
| 10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems? | Yes<br>For ART No |
| 10.14.1. If yes, please specify which of the following systems are usually contacted. (more than 1 answer possible) | Haemovigilance<br>Pharmacovilance<br>Medical devices |
| 10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S? | Yes<br>For ART No |
| 10.15.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1(insufficient) - 2 (sufficient) 3 (good) - 4 (very good) to 5 (essential)? | 4 very good |
| 10.16. Do you have any additional comments on SARE reporting? | No. |
| **11. Consent and personal data protection (Article 13 and 14, Directive 2004/23/EC)** | |
| 11.1. What consent system for living tissue/cell donation do you have in place within your Member State? | Explicit consent (opt-in) |
| 11.1.1. Please specify your choice of consent system for living tissue/cell donation. | Written consent is a mandatory requisite for living donation. It cannot be carried out without it, likewise i.e. being of age, or good health status. |
| 11.2. What consent system for deceased tissue/cell donation do you have in place within your Member State? | Presumed (opt-out) and explicit (opt-in) consent |
| 11.2.1. If you have chosen both consent systems for deceased tissue/cell donation, please specify | Although in Spain there is presumed consent by law (i.e. Ley 30/1979 art.5), in practice the families are always approached and they have the last decision, which is respected (a form is always signed). |
| 11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible) | First degree relatives (including spouse)<br>Other relatives<br>Other |
| Please specify 'other'. | 'Other relatives' are asked (i.e. siblings) for the donation whenever there are no first degree relatives (spouse, parent, or sons/daughters). |

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| | For ART no further authorization is needed |
| 11.4. Is the consent system for deceased tissue donation the same as for organs? | No |
| 11.4.1. If no, please describe the difference. | Sometimes the consent is given for organs and tissues together, and sometimes it is specific for tissues. |
| 11.5. How is this consent verified during inspections? (more than 1 answer possible) | Analysis of documentation<br>Other |
| Please specify 'other'. | The consent form remains in the corresponding record for each donor. |
| 11.6. What measures are in place to ensure that donors/relatives/authorising persons on behalf of donors are provided with the appropriate information, as requested by Art. 13(2)? (more than 1 answer possible) | Only trained personnel is allowed to provide such information<br>Information for donors are standardised at national/regional level<br>For ART information for donors are controlled at regional level |
| 11.7. What measures are in place to ensure that both donors and recipients remain unidentifiable when access is given to third parties (Art. 14(1)). Please specify. | - Restricted Access to personal information.<br>- Confidentiality regulated by Law, and sanctionable in cases it is not fulfilled.<br>- Dissociation mechanisms in place.<br>- Contracts with third parties establishing such obligation.<br>- Data protection supervision at hospital, regional and national level etc. |
| 11.8. Please specify what measures are in place to ensure that the identity of the receipient is not disclosed to the donor and vice versa. | - All those mentioned above plus a specific ban to disclose any information which may allow identification between donor and recipient or to their relatives. |
| 11.9. Does your national legislation allows disclosure of donor data in case of gametes donation? | No |
| 11.9.1. If no, please specify the circumstances and measures in place. | Disclosure of donor data can only be done in case of congenital diseases appeared. |
| 11.10. Do you have any additional comments on consent and data protection? | No |
| **12. Selection, evaluation and procurement (Article 15 Directive 2004/23; Annexes I-IV Directive 2006/17)** | |
| 12.1. How do you ensure that all requirements related to the evaluation and selection of donors (except donors of reproductive cells) are respected in your country (Art. 15(1), Annex I Directive 2006/17/EC)? (more than 1 answer possible) | Inspections of TEs and procurement sites<br>Audit of documentation |
| 12.2. How do you ensure that all requirements related to the evaluation and selection of donors of reproductive cells are respected in your country (Art 15 (1), Annex III of Directive 2006/17/EC)? (more than 1 answer possible) | Inspections of ART centres |
| 12.3. Do you have more stringent criteria for donor selection than those listed in Annex I of the Directive 2006/17/EC? | No |
| 12.4. What sources are required in your MS for the evaluation of a deceased donor of tissues/cells? (more than 1 answer possible) | Interview with the donor's family or a person who knew the donor well<br>Medical records of the donor<br>Interview with the treating physician<br>Interview with the general practitioner<br>Autopsy report |
| 12.5. Do you have more stringent criteria for selection of donors of reproductive cells than those listed in Annex III of the Directive 2006/17/EC? | No |
| 12.6. Do you have more stringent criteria for autologous donation than those listed in Annex I of the Directive 2006/17/EC? | No |
| 12.7. Do you require more information on the donation of tissues/cells than the mandatory one as laid down in the Annex of Directive 2004/23/EC (Art 15(3)? | No |
| 12.8. How do you ensure that all requirements regarding tissues and cells' procurement, packaging and transport are complied with by tissue establishments in your country (Art 15(1), Annex IV of Directive 2006/17/EC? (more than 1 answer possible)(For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written | Inspection of tissue establishment<br>Audit of tissue establishment<br>Inspection of the centre of human application (e.g. transplantation centre, ART centre)<br>Audit of the centre of human application |

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| SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)) | |
| 12.9. Do you have any additional comments on selection, evaluation and procurement? | No. |
| **13. Quality management, responsible person, personnel (Article 16, 17, 18 Directive 2004/23/EC)** | |
| 13.1. How do you ensure that tissue establishments in your country have in place a quality system respecting the provisions of the Directive 2004/23/EC Art 16.1? (more than 1 answer possible). (For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)). | Authorisation requirement<br>Inspections |
| 13.2. How do you ensure that tissue establishments have a responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible) | Authorisation requirement<br>Inspections |
| 13.3. How do you ensure an appropriate training for the personnel directly involved in the activities of tissue establishments? (more than 1 answer possible) | Authorisation requirement<br>Inspections<br>Regular evaluation of personnel<br>Mandatory trainings |
| 13.4. Do you have national/regional/local training programmes for the personnel of tissue establishments? | Yes.<br>For ART No |
| 13.4.1. If yes, please specify. | There are training programmes dedicated to T&C donation and transplantation and all aspects related, as well as specific programmes dedicated to particular areas (i.e. inspections). |
| 13.5. Any additional comments on quality management, responsible person, personnel? | |
| **14. Reception, processing, storage, labelling and packaging (Art 19-22 Directive 2004/23/EC)** | |
| 14.1. How do you ensure that tissue establishments in your country fulfill the requirments of the Art. 19 (Tissue and cell reception) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | National regulation/policy for reception of tissues/cells<br>Inspections of tissue establishments |
| 14.2. How do you ensure that tissue establishments in your country fulfill the requirements of the Art. 20 (Tissue and cell processing) of Directive 2004/23/EC? (more than 1 answer possible) | SOPs for all processes affecting quality and safety are mandatory for authorisation<br>Inspections of tissue establishments |
| 14.3. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 21 (tissue and cell storage conditions) of Directive 2004/23/EC? (more than 1 answer possible) | SOPs for procedures associated with storage of tissues and cells are mandatory for authorisation<br>Inspections of tissue establishments |
| 14.4. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | SOPs for procedures associated with labelling and packaging are mandatory for authorisation<br>Inspections of tissue establishments |
| 14.5. Any additional comments on reception, processing, storage, labelling and packaging? | No |
| **15. Third party agreements (Art. 24 Directive 2004/23/EC)** | |
| 15.1. Are third party agreements foreseen/allowed in your national legislation? | Yes<br>For ART No |
| 15.1.1. If yes, have tissue establishments in your Member State notified third party agreements? | Yes |
| 15.1.1.1. Under which circumstances and for which responsibilities? | Those allowed in the regulation, i.e, supply of materials, storage, etc. |
| 15.1.1.2. How are third party agreements controlled (Art 6.2) by the Competent Auhtority(ies) in your MS? Please specify. | Regulation establishes the conditions under which contracts with third parties can be signed: ie. Those contracts have to be communicated to the corresponding CA, or can be subject to inspection, etc. |

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| 15.2. Any additional comments on third party agreements? | No |
| **16. General comments - implementation** | |
| 16.1. Do you have at national level more stringent quality and safety requirements than those requested by the EU legislation in this field (e.g. restrictions concerning the donation/use of certain tissues/cells, mandatory unpaid donation etc.)? | No |
| 16.2. Has your Member State encountered any difficulties in implementing the requirements in the EU Tissues and Cells Directives? Please choose from the options below. | ART provisions<br>Import-export<br>Traceability |
| 16.2.1. For all selected options in question 16.2., please provide a short description. | Import-export: it is necessary the publication of the Directive with homogeneous criteria of import/export.<br>Traceability: clarifications on the coding are needed in order to have more functional and traceable systems.<br>For ART: a high percent of ART centers are private. ART policies are not a priority for many regional authorities, being on the contrary a high priority for a short number of them. National policies are more difficult in this context. |
| 16.3. In your opinion, in which of the following Directives are there shortcomings (if any)? (more than 1 answer possible) | No shortcomings |

## *A.1.29. Survey response Sweden*

| **1. Public information** | |
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| 1.1. Name of National Competent Authority (NCA) 1: | Health and Social Care Inspectorate / Inspektionen för vård och Omsorg (IVO) |
| 1.1.2. Address of NCA 1: | IVO Box 45184 104 30 Stockholm Sweden |
| 1.1.3. Telephone (central access point): | +46 10 788 50 00 |
| 1.1.4. E-mail (central access point): | registrator@ivo.se |
| 1.1.5. Website: | www.ivo.se |
| 1.1.6. The NCA is responsible for? (more than 1 answer possible) | Non-reproductive tissues and cells<br>Reproductive tissues and cells<br>Blood and blood components<br>Human organs |
| 1.1.7. What are the role/tasks of the NCA? (more than 1 answer possible) | Accreditation, authorisation, licensing of TEs<br>Inspection<br>Vigilance |
| 1.2. National Competent Authority 2? | Yes |
| 1.2.1. Name of National Competent Authority 2: | Medical Products Agency |
| 1.2.2. Address of NCA 2: | Läkemedelsverket Box 26 751 03 Uppsala Sweden |
| 1.2.3. Telephone (central access point): | +46 18 1746 00 |
| 1.2.4. E-mail (central access point): | registrator@mpa.se |
| 1.2.5. Website: | www.lakemedelsverket.se |
| 1.2.6. The NCA is responsible for? (more than 1 answer possible) | Pharmaceuticals<br>Medical devices<br>Other |
| Please specify 'other': | Tissues and cells for manufacturing of Advanced therpuetic medicinal products (ATMP) |
| 1.2.7. What are the role/tasks of the NCA? (more than 1 answer possible) | Accreditation, authorisation, licensing of TEs<br>Inspection<br>Vigilance |
| 1.3. National Competent Authority 3? | Yes |
| 1.3.1. Name of National Competent Authority 3: | The National Board of Health and Welfare |
| 1.3.2. Address of NCA 3: | Socialstyrelsen 106 30 Stockholm Sweden |
| 1.3.3. Telephone (central access point): | +46 75 247 30 00 |
| 1.3.4. E-mail (central access point): | socialstyrelsen@socialstyrelsen.se |
| 1.3.5. Website: | www.socialstyrelsen.se |
| 1.3.6. The NCA is responsible for? (more than 1 answer possible) | Non-reproductive tissues and cells<br>Reproductive tissues and cells<br>Blood and blood components<br>Human organs |
| 1.3.7. What are the role/tasks of the NCA? (more than 1 answer possible) | Other |
| Please specify 'other': | Regulatory, Disease precautions, National registries and statistics |
| 1.4. National Competent Authority 4? | No |
| 1.5. Please give a short description of the legal status and organisation of the National Competent Authority(ies) (e.g. departments, staffing, number of senior and junior inspectors, staff working on EU affairs and legal matters, vigilance officers, budget, independence from government etc.). | Health and Social Care Inspectorate: Independent CA with assignment from the governement to supervise and authorize health care and social care in Sweden. Total no of staff approx 500 localized as six regional offices and one central office. The staff consists of expertise in the areas for supervision, accordingly most personnel holds a degree in medicine- or social sciences alternativly are legal advisors. Supervision according to EU directives is centralized to one regional department in Stockholm and those inspectors (3) are contact points for EU affairs dealing with Blood, tissues and cells and organs. Medical Products Agency: Independent CA responsible for regulation and surveillance of the development, manufacturing and sale of drugs and other medicinal products. Its operations are largely financed through fees. Approximately 750 people work at the agency; most are pharmacists and doctors. The agency is divided into four departements; Development, Licencing, Supervision and Usage. The agency are actively involved in EU matters in the field of pharmaceuticals and medicinal poducts. The National Board of health and Welfare: Independent CA with |

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| | assignment from the governement to perform follow up, national guidelines, issue bylaws and keep national registries in the areas of Health care and Social care. Total no of staff is approx 400 divided into three departments ; Regulation, Statistics and Knowledge based Policy and Guidance. EU matters in these areas are coordinated from the staff of the Director Gerneral . |
| 1.6. In case of MS with federal or decentralised systems, please indicate the roles/tasks of the Regional Competent Authority(ies). (more than 1 answer possible) | Not applicable |
| 1.7. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies) for tissues and cells: | Not applicable; |
| **2. Procurement (Article 5 Directive 2004/23/EC)** | |
| 2.1. Do you authorise the "conditions of procurement"? | Yes |
| 2.1.1. How do you authorise the "conditions of procurement"? (more than 1 answer possible) | By inspecting some procurement centres<br>By inspecting the documentation associated with procurement that is available in the tissue establishment working with procurement centres |
| 2.1.2. How many such authorisations were granted in 2011 (01/01-31/12/2011)? | The TE holds the authorization , only procurement is not authorized. |
| 2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011). | 34 |
| 2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011). | 7 |
| 2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues were carried out in 2011 (01/01-31/12/2011). | 17 |
| 2.2.4. Please provide the number of procurement centers in which procurement of tissues/cells for ATMP manufacturing were carried out in 2011 (01/01-31/12/2011). | 3 |
| 2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC and its implementing Directive 2006/17/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) ? (more than 1 answer possible) | Inspections of the site/centre<br>Analysis of the mandatory documentation<br>Other |
| Please specify 'other': | Most of the TE ´s (i.e 45 out of 52) also procure the tissues & cells and for the other TE´s it is the responsibility of the TE to perform audits at the procurement center, and the result of these audits are examined during the inspection of the TE |
| 2.4. Are you also responsible for the accreditation, designation, authorisation or licensing of laboratories performing donor testing? | No |
| 2.4.2. Which National Authority is in charge of this activity? | The Swedish Board for Accreditation and Conformity Assessment (SWEDAC) www.swedac.se |
| 2.5. How do you ensure, as CA for T&C, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art. 5(2))? (more than 1 answer possible) | Analysis of the mandatory documentation requested from the tissue establishment<br>Other |
| Please specify 'other': | The TE are requested to show which laboratory they use for donor testing (and have a written agreement if applicable ) The accrediatation by SWEDAC is publicly available and the laboratory holds an accrediatation licence. |
| 2.6. Please provide data on qualified laboratories accredited, authorised or licensed in your country (e.g. number, year of accreditation/authorisation/license, which donor tests are | 32 laboratories (Clinical microbiology are accredited by SWEDAC ) http://search.swedac.se/sv/ackrediteringar?ackomrade=1%3AKlinisk%20mikrobiologi. |

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| performed etc.). | |
| 2.7. Do you have any additional comments on procurement? | |
| **3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)** | |
| 3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>Ag HIV<br>HBs AG<br>Anti HBc<br>Anti HCV-Ab<br>Treponema Pallidum |
| 3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>Ag HIV<br>HBs AG<br>Anti HBc<br>Anti HCV-Ab<br>HTLV-2<br>Treponema Pallidum |
| 3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to encourage its use? Please specify why or why not (e.g. number of additional cases detected, cost-benefit etc.). | Epidemiological data in Sweden does not motivate a legal obligation to perform NAT testing. The National Board of Helath and Welfare and the Swedish Institute for Communicable Disease Control have the responisibility to follow and perform risk assessments of these diseases and for the moment we have no indications that NAT testing will be mandatory. |
| 3.4. Do you have concerns on accuracy of the available tests and test procedures for deceased donors? | No |
| 3.5. Are any other laboratory tests required for donors of non-reproductive tissues and cells in your Member State? | No |
| 3.6. Are any other laboratory tests required for donors of reproductive tissues and cells in your Member State? | No |
| 3.7. Do you request/use international accreditation systems for testing laboratories? | Yes |
| 3.7.1. Please specify. | The Accreditation by SWEDAC is based on SS-EN ISO 15189:2007 alternatively SS-EN ISO 17025: 2005 |
| 3.8. Do you have any additional comments on testing? | All tissue establishments are legally obliged to use an Accredited laboratory for donor testing, and some may also have additional tests performed depending on their own wishes i.e EBV, CMV for HPC donors or Chlamydia for oozyte donors. |
| **4. Accreditation, designation, authorisation or licensing of tissue establishments (Article 6, Directive 2004/23/EC)** | |
| 4.1. Do you have a system of designation, authorisation, accreditation or licensing for all types of tissue establishments under your responsability? | Yes |
| 4.2. Is inspection a prerequisite for the designation, authorisation, accreditation or licensing of tissue establishments? | No |
| 4.3. Are preparation processes authorised? | Yes |
| 4.3.1. How are they authorised? (more than 1 answer possible) | By review of a submitted application with supporting documentation |
| 4.4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were suspended in 2011? | 0 |
| 4.5. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011? | 0 |
| 4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)? | No |
| **4bis. Overview of tissue/cells establishments authorised by the NCA** | |
| 4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible): | Skin tissue establishments<br>Musculo-skeletal tissue establishments<br>Ocular tissue establishments |

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| | Cardiovascular tissue establishments<br>HSC tissue establishments<br>Cord blood tissue establishments<br>ART tissue establishments<br>Multi-tissue establishments<br>Other tissue establishments |
| 4.7.1. How many skin tissue establishments? | 0 |
| 4.7.2. How many musculo-skeletal tissue establishments? | 0 |
| 4.7.3. How many ocular tissue establishments? | 0 |
| 4.7.4. How many cardiovascular tissue establishments? | 0 |
| 4.7.5. How many HSC tissue establishments? | 0 |
| 4.7.6. How many cord blood tissue establishments? | 0 |
| 4.7.7. How many ART tissue establishments? | 0 |
| 4.7.8. How many multi-tissue establishments? | 0 |
| 4.7.9. Please specify the type of tissues/cells and how many. | TE´s processing Cells for ATMP = 0 pending |
| 4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible): | Skin tissue establishments<br>Musculo-skeletal tissue establishments<br>Ocular tissue establishments<br>Cardiovascular tissue establishments<br>HSC tissue establishments<br>Cord blood tissue establishments<br>ART tissue establishments<br>Multi-tissue establishments<br>Other tissue establishments |
| 4.8.1. How many skin tissue establishments? | 0 |
| 4.8.2. How many musculo-skeletal tissue establishments? | 0 |
| 4.8.3. How many ocular tissue establishments? | 0 |
| 4.8.4. How many cardiovascular tissue establishments? | 0 |
| 4.8.5. How many HSC tissue establishments? | 0 |
| 4.8.6. How many cord blood tissue establishments? | 0 |
| 4.8.7. How many ART tissue establishments? | 1 |
| 4.8.8. How many multi-tissue establishments? | 0 |
| 4.8.9. Please specify the type of tissues/cells and how many. | TE´s processing cells for ATMP = 0 pending |
| 4.9. Tissue establishments first time authorised between 01/01/2011 and 31/12/2011 (more than 1 answer possible): | Skin tissue establishments<br>Musculo-skeletal tissue establishments<br>Ocular tissue establishments<br>Cardiovascular tissue establishments<br>HSC tissue establishments<br>Cord blood tissue establishments<br>ART tissue establishments<br>Multi-tissue establishments<br>Other tissue establishments |
| 4.9.1. How many skin tissue establishments? | 0 |
| 4.9.2. How many musculo-skeletal tissue establishments? | 0 |
| 4.9.3. How many ocular tissue establishments? | 0 |
| 4.9.4. How many cardiovascular tissue establishments? | 0 |
| 4.9.5. How many HSC tissue establishments? | 0 |
| 4.9.6. How many cord blood tissue establishments? | 0 |
| 4.9.7. How many ART tissue establishments? | 0 |
| 4.9.8. How many multi-tissue establishments? | 0 |
| 4.9.9. Please specify the type of tissues/cells and how many. | TE´s processing cells for ATMP = 0 |
| 4.10. All tissue establishments authorised by 31/12/2011 (more than 1 answer possible): | Skin tissue establishments<br>Musculo-skeletal tissue establishments<br>Ocular tissue establishments<br>Cardiovascular tissue establishments<br>HSC tissue establishments<br>Cord blood tissue establishments<br>ART tissue establishments<br>Multi-tissue establishments<br>Other tissue establishments |

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| 4.10.1.1. How many public skin tissue establishments? | 3 |
| 4.10.1.2. How many private skin tissue establishments? | 0 |
| 4.10.2.1. How many public musculo-skeletal tissue establishments? | 15 |
| 4.10.2.2. How many private musculo-skeletal tissue establishments? | 0 |
| 4.10.3.1. How many public ocular tissue establishments? | 2 |
| 4.10.3.2. How many private ocular tissue establishments? | 0 |
| 4.10.4.1. How many public cardiovascular tissue establishments? | 1 |
| 4.10.4.2. How many private cardiovascular tissue establishments? | 0 |
| 4.10.5.1. How many public HSC tissue establishments? | 5 |
| 4.10.5.2. How many private HSC tissue establishments? | 0 |
| 4.10.6.1. How many public cord blood tissue establishments? | 1 |
| 4.10.6.2. How many private cord blood tissue establishments? | 0 |
| 4.10.7.1. How many public ART tissue establishments? | 6 |
| 4.10.7.2. How many private ART tissue establishments? | 10 |
| 4.10.8.1. How many public multi-tissue establishments? | 5 |
| 4.10.8.2. How many private multi-tissue establishments? | 0 |
| 4.10.9.1. Please specify the type of 'other' public tissues/cells establishements and how many. | Public TE processing cells for ATMP = 1 |
| 4.10.9.2. Please specify the type of 'other' private tissues/cells establishements and how many. | Private TE processing cells for ATMP = 1 |
| 4.11. How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Art. 6(5) during 2011? Please provide number(s) per type tissues/cells. | 0 |
| **4ter. Sanctions** | |
| 4.16. Have penalties for infringements of the national provisions pursuant to the Directive been defined (Article 27)? | Yes |
| 4.16.1. Have penalties already been imposed? | No |
| 4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing? | |
| **5. Inspections (Article 7, Directive 2004/23/EC)** | |
| 5.1. Is a system in place for organising inspections and control measures of tissue establishments? | Yes |
| 5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections. | The Health and Social Care Inspectorate (previously the dept of Supervision at National Board of Health and Welfare ) have centralized coordination of the inspections and supervision to one department located in Stockholm. The coordinators plan the inspections which are then performed together with a regional inspector . |
| 5.1.2. If yes, please specify staffing (how many inspectors). | The coordinators are 3 and regional inspectors are 1-2 in each of the six regions. |
| 5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible) | Yes |
| 5.2.1. If yes, please specify. (more than 1 answer possible) | Blood<br>Advanced therapies<br>Hospitals |
| 5.3. How many routine inspections of tissue establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011)? | 32 |
| 5.3.1. How many inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 | 0 |

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| (from 1/1/2011 to 31/12/2011) following serious adverse events or reactions, or suspicion thereof ? | |
| 5.3.2. How many other type of inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | 0 |
| 5.3.3. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | 4 |
| 5.3.4. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where minor shortcomings were noted? | 18 |
| 5.3.5. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where major shortcomings were noted? | 2 |
| 5.3.6. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by suspension of authorisation? | 0 |
| 5.3.7. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by closure? | 0 |
| 5.3.8. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of other inspections carried out? Please specify. | 0 |
| 5.4. How many routine inspections were conducted in ART establishments (from 1/1/2011 to 31/12/2011)? | 16 |
| 5.4.1. How many inspections were conducted in ART establishments following serious adverse events or reactions, or suspicion thereof (from 1/1/2011 to 31/12/2011)? | 0 |
| 5.4.2. How many other type of inspections were conducted on ART establishments (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | 0 |
| 5.4.3. Outcome of inspections of ART tissue establishments carried out in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | 3 |
| 5.4.4. What was the number of inspections carried out in ART establishments where minor shortcomings were noted? | 13 |
| 5.4.5. What was the number of inspections carried out in ART establishments where major shortcomings were noted? | 0 |
| 5.4.6. What was the number of inspections carried out in ART establishments followed by suspension of authorisation? | 0 |
| 5.4.7. What was the number of inspections carried out in ART establishments followed by closure of respective establishements? | 0 |
| 5.4.8. What was the number of other inspections of ART establishments? Please specify. | 0 |
| 5.5. Which type of routine inspections do you conduct? (more than 1 answer possible) | General system-oriented inspections<br>Thematic inspections<br>Desk based reviews |
| 5.6. How do you decide which type of routine inspection to conduct? | The general system oriented inspection is always one part, then a theme/focus for the routine inspection is decided by the coordinators, depending on occurances during the year (reported SAR/SARE, risk assessment or any paricular questions / unclear matters that have been |

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| | discussed since last inspection round) . Each inspection is preceeded by a demand to send certain documentation to the inspector (Respond to a Questionaire and attach relevand documents) and these are reviewed prior to the inspection. |
| 5.7. Until 2011, did you implement the requirement concerning the time interval between two inspections (Art. 7.3.)? | No |
| 5.7.1. Why not? | All TE´s were authorized 2010, and accordingly inspected for the first time 2010 and 2011. Thereafter the time interval between inspections has not exceeded 2 years. |
| 5.7.2. How do you prioritise tissue establishments to be inspected? | Our first two inspections (2010) were chosen in order to test and evaluate our inspection protocol; we chose one TE that we suspected had everything "in place" and one TE that we suspected to have some problems. Thereafter we evaluated our inspection protocol, and inspected a multi-TE in order to get an overview of the various procedures for different tissues and cells. After this, inspctions have been carried out according to their location and the most suited coordinator and according to the time scheme. |
| 5.8. How many TEs were inspected at least twice between 2008-2011 (01/01/2008-31/12/2011)? | 1 (one of the first pilot TE´s that did not have all mandatory routines / documents in place was inspected 2010 and 2011 based on the result of the pilot-inspection) |
| 5.9. Did you perform/conduct inspections of procurement sites outside tissue establishments? | No |
| 5.9.2. If no, why not? | Most TE´s also procure the tissues and cells and if not, we require (and review) a written agreement between the procurement center and the TE. |
| 5.10. Did you carry out inspections of third parties? | No |
| 5.10.2. If no, why not? | Written agreements are required (and reviewed) if any third part is involved in the chain between procurement and clinical use of the T&C . The most pertinent "third part" , the laboratory performing donor testing, is Accredited by another CA and we do not intervene or overlap with other CA´s inspections. In addition it is the resonisbility of the TE to perform audits/ review any third part that they have agreement with. |
| 5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)? | No |
| 5.11.1. If no, which guidelines/regulations are used for inspections at national level? | In principle we follow the Guidelines for inspections, but adapted to the organisation of TE´s in Sweden. The regulations "Socialstyrelsens föreskrifter" SOSFS 2009:30, SOSFS 2009:31 and 2009:32 covers Donation - Tissue establishments - and Usage of Tissues and Cells respectively and our inspections are based on these regulations. |
| 5.11.2. If no, please provide a hyperlink to these guidelines/inspections. | http://www.socialstyrelsen.se/sosfs/2009-30; http://www.socialstyrelsen.se/sosfs/2009-31; http://www.socialstyrelsen.se/sosfs/2009-32 |
| 5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)? | No |
| 5.12.2. Why not? | Lack of time |
| 5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))? | No |
| 5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))? | No |
| 5.15. Did you organise any inspections of procurement centres or tissue establishments in third countries from which tissues and/or cells were imported in your country (as recorded by 31/12/2011)? | No |
| 5.16. Have you asked another MS, or have you been requested by any other MS, on the results and control measures of your inspections, as part of an enquiry/investigation? | No |

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| 5.17. Would you be interested in developing joint inspections? Joint inspections should be understood as inspections of tissue establishments conducted jointly by two or more Member States' Competent Authorities on their territory or in third countries. | Yes |
| 5.18. Do you have any additional comments on inspections? | 1.Joint inspections would be valuable in particular in the situation where a TE has procurement activities in an other MS . 2. The number of inspections (non-reproductive tissues and cells) exceeds the total number of "minor"- "major"- and "no shortcomings" due to that some TE´s have more than one site and inspections were carried out on more than one site, wheras only one inspection report to the TE was written. |
| **6. Import/export (Article 9 Directive 2004/23/EC)** | |
| 6.1. Do you have a register of authorised tissue establishments that are explicitly authorised to perform import/export of tissues and celles from/to third countries? | Yes |
| 6.2. Please specify the number of tissue establishments authorised to import tissues and cells from third countries (recorded by 31/12/2011). | 6 |
| 6.3. Please specify the number of tissue establishments authorised to export tissues and cells from third countries (recorded by 31/12/2011). | 6 |
| 6.4. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of skin from third countries. | it is the responibility of the importing TE to ensure that quality and safety of the tissues and cells to be imported corresponds to the same standard as the T&C Directive (no import licences for skin is currently authorized) |
| 6.5. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of musculo-skeletal (bone, tendons, fascia etc.) tissues from third countries. | it is the responibility of the importing TE to ensure that quality and safety of the tissues and cells to be imported corresponds to the same standard as the T&C Directive (one import licence for tendons is currently authorized and the exporting TE is authorized by FDA) |
| 6.6. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of ophtalmic (cornea, sclera, etc) tissues from third countries. | it is the responibility of the importing TE to ensure that quality and safety of the tissues and cells to be imported corresponds to the same standard as the T&C Directive ( one import licence for ophtalmic tissue is currently authorized and the exporting TE is authorized by FDA) |
| 6.7. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cardio vascular tissues from third countries. | it is the responibility of the importing TE to ensure that quality and safety of the tissues and cells to be imported corresponds to the same standard as the T&C Directive (no import licences for cardio vascular tissue is currently authorized) |
| 6.8. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) (other than cord blood) from third countries. | it is the responibility of the importing TE to ensure that quality and safety of the tissues and cells to be imported corresponds to the same standard as the T&C Directive and they use the following criteria 1. Does the exporting TE hold an other accreditation , FACTS, JACIE, WMDA ? 2. if not, a Questionaire with focus on quality and safety and traceability will be sent out and depending on the answers the importing TE will accept the HPC . Since import of HPC is intended for a given patient in need of a transplantation, a risk assessment will be performed by the medically responisble person wherafter the dicision will be documented. |
| 6.9. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cord blood from third countries. | see answer to 6.8 |
| 6.10. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of reproductive cells (sperm, egg cells) from third countries. | It is not legally possible to import frozen reproductive cells from third countries (Swedish law: Lag 2006:351 om genetisk integritet mm ) http://www.notisum.se/rnp/sls/lag/20060351.htm |
| 6.11. Did you import tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | Yes |
| 6.11.1. If yes, please provide the data concerning the number/volume of imported tissues and cells by country of origin. | The import was HPC but number of HPC-units as well as the country of origin is not collected by the CA (only the tot number of tissues / cells recieved from another TE is collected and that "other TE " may be National, within another MS or from third country) |
| 6.12. Did you export tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | Yes |
| 6.12.1. If yes, please provide the data concerning the | 12 HPC units were exported TO 3rd countries during 2011 . The country of |

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| number/volume of exported tissues and cells by country of destination. | destination is not reported to the CA . |
| 6.13. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on imports/exports of tissues/cells between your country and other third countries? | No |
| 6.14. What is the relation between import/export of tissues and cells and self-sufficiency? (more than 1 answer possible) | C. Export of tissues/cells is authorised irrespective of national needs<br>E. Import of tissues/cells is authorised based on estimations showing that there is chronic deficiency of those tissues/cells<br>F. Other |
| Please specify 'other': | Import and Export of HPC are performed on a patient based need , and the TE´s authorized for import/export of HPC decide without additional permit from the CA . |
| 6.15. Did you authorise direct imports of tissues/cells to hospitals/clinics in your country? | No |
| 6.16. Do you have any additional comments on import/export? | |
| **7. Distribution/intra community exchanges (Article 23 Directive 2004/23/EC)** | |
| 7.1. Do you have intra-community exchanges of tissues and cells? | Yes |
| 7.1.1. If yes, how do you address the possible more stringent quality and safety measures established by other Member States? Please specify. | We use the interpretation that it is the responisbility of the recieving MS to make sure that the delivering MS fulfill the national quality and safety measures. If necessary, the recieving MS may ask the Swedish TE to add some assay in the donor testing (i.e NAT assays) or any other additional requirement that can be fulfilled. |
| 7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States? | Yes |
| 7.1.2.1. How do you address this difference for tissues and cells coming from a MS with minimum quality requirements? Please specify. | For reproductive cells (sperms) the Swedish law require that the donor identity must be avalable to the child at adult age, which prohibits the use of frozen sperms from other MS where anonomous donations are allowed. Since it is the responisbility of the recieving MS (i.e the Swedish TE) to make sure that Swedish regulations on quality and Safety are fulfilled the Swedish TE can not use such tissues and cells without violating the national laws and regulations. For other tissues and cells (including ATMP) Sweden do not have more stringent quality and safety measures than other MS and we rely on the authorization given in each MS to be in accordance with the Directive and thecnical directives. |
| 7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify. | It is included in our inspections, to ensure that TE´s have validated their methods for distribution. |
| 7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible). | Yes, but only via an authorised TE in my MS |
| 7.4. Have you authorised direct distribution to the recipient of specific tissues and cells (Art. 6, Directive 2006/17/EC)? | No |
| 7.5. Do you collect data regarding the cross-border exchange of tissue/cells between your country and other EU MS? | Yes |
| 7.5.1. Please provide us with data (country of destination, type of tissue/cell and number of units distributed) concerning distribution to other MS in 2011 (01/01/2011-31/12/2011). | Only the number of (unis) tissues and cells distributed to other EU MS are reported, not the country of destination. During 2011; 33 HPC units and 20 blood vessels were distributed to other EU MS / EES. |
| 7.5.2. Please provide us with data (country of origin, type of tissue/cell and number of units distributed) concerning distribution to other MS in 2011 (01/01/2011-31/12/2011) | = 7.5.1 ?? |
| 7.6. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on cross-border exchanges of tissues/cells between your country and other EU MS? | No |
| 7.7. Do you allow brokerage companies for either distribution in EU and/or import/export of tissues/cells? In this context, a brokerage company means a body that arranges transactions between a supplier (tissue establishment/company selling tissues or cells) and a buyer | No |

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| (a tissue establishment/a hospital or clinic/an individual) without undertaking activities of processing, preservation or storage. | |
| 7.8. Are brokers actively supplying health professionals/establishments in your country? | No |
| 7.9. Do you have any additional comments on distribution? | |
| **8. Register of tissue establishments and reporting obligations (Article 10, Directive 2004/23/EC)** | |
| 8.1. Do you have an annual report model/template on the activities of tissue establishments in your Member State? (Article 10(1)). If yes, please upload the template. | Yes |
| 8.2. How many tissue establishments submitted annual reports of their activities during 2011. Please provide an estimation. (1 answer possible) | 100% (all) |
| 8.3. Are these reports publicly available? (Article 10(1)) | Yes |
| 8.3.1. If yes, please insert the link(s) to the report(s). | They are as all material within a governemental authority in Sweden publicly available upon request. |
| 8.4. Do you publish a national annual report of the consolidated activities of all tissue establishments in your country? | Yes |
| 8.4.1. Please insert the link to the published national annual report. | http://www.ivo.se/publiceratmaterial/rapporter/Documents/lagesrapport-for-vavnadsinrattningar-2011-2012.pdf |
| 8.5. Is there a publicly accessible register of authorised tissue establishements in place? (Article 10(2)) | Yes |
| 8.5.1. If yes, please provide us with the link to the register's web site. | http://www.ivo.se/Tillstand-och-register/register/vavnadsinrattningar/Sidor/default.aspx |
| 8.6. Do you provide data regarding tissues and cells activities to the EUROCET registry (non-mandatory reporting)? | Yes |
| 8.6.1. If yes, what data are provided to EUROCET? Please specify. | All available data, but Eurocet do ask for much more data than specified in the Directive and all of these data are not collected by the CA. In particular concerning ART (different IVF methods, no.of births ect) and HPC (diagnoses , number of searches in different registries etc ) |
| 8.7. Do you have any additional comments on reporting? | |
| **9. Traceability (Article 8, Directive 2004/23/EC; and Directive 2006/86/EC)** | |
| 9.1. Was the donor identification system (Art. 8(2)) implemented in your country? | No |
| 9.1.1. If no, why not? | All TE´s have a donor identification system, but it is not (yet) a common coding system for all TE´s . Most tissues and cells are procured, storaged and used within the same TE or hospital and therefore we have accepted local coding systems . For HPC that are distributed between TE´s - hospitals and cross- borders the ISBT128 coding system is used. |
| 9.2. Who assigns the unique code for each donation? (only 1 answer possible) | Tissue establishment |
| 9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible) | Both paper records and electronic forms |
| 9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify. | This is included in our inspections, and for those that have only paper the storage is in fire-resistant cupboards, for the electronic form we make sure that the TE have required from their information system support that electronic storage is accessible also after new versions of software etc. |
| 9.5. Do you have any additional comments on traceability? | |
| **10. Notification of serious adverse events and reactions (Article 11 Directive 2004/23, Article 6 Directive 2006/76)** | |
| 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))? | Yes |
| 10.1.1. If yes, which CA/institution is responsible? | The Health and Social Care Inspectorate (tissues and cells) and the Medical Products Agency (ATMP) |
| 10.1.2. If yes, please provide a short description of its organisation. | SAR and SAE are reported directly to the coordinators at the CA close to the event/reaction and in addition an annual report of all SAR and SAE should follow the annual report for the activity of the TE. The coordinators collect |

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| | the reports, evaluate the suggested/ performed actions and classify the reports according to clasification that should be reported later to the EC. If needed the coordinators may ask for additional actions, that have to be completed before the report is closed. |
| 10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use the SAR/E (to the CA (2006/76 art 6.4)) templates developed to the Annual reporting ot the EC also at national level? | Yes |
| 10.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level? | Yes |
| 10.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all TEs? | No |
| 10.4.1. Why not? | This is the same staff that perform inspections (i.e the coordinators) |
| 10.5. How many tissue establishments provided in 2011 the SAR/SAE data as requested (please provide the % from the total number of TEs authorised in your country). | <50% |
| 10.6. Do you have a mandatory procedure for the transplantation centres when reporting SAR/SAE to the TEs which distributed the tissues/cells (Art 11.2)? | Yes |
| 10.6.1. If yes, please provide a brief description. | The user of tissues and cells should report back to the TE both the actual usage (i.e recipient identification-that may be coded or if discarded) and if any serious adverese events or reactions occured according to the national regulation SOSFS 2009:32 on "Usage of Tissues and Cells within health care and clinical reseach" |
| 10.7. Do you give feedback to the TEs regarding SAR/SAE recorded at national level? | Yes |
| 10.7.1. Please specify. | Every second year we invite 2 staff members from each TE to a meeting where feedback from the recorded SAR/E as well as from inspections is provided. In addition we also discuss interpretation questions and other relevant issues. A summary of the recorded SAR/E is also provided in the written report which is publically available (see Q .8.4.1) |
| 10.8. Do you give feedback to the TEs regarding SAR/SAE recorded at EU level? | Yes |
| 10.8.1. Please specify. | At the meeting mentioned above, with the TE but also at other meetings where coordinators are invited to speak about issues relevant to the TE´s . |
| 10.9. Do you require your TEs to have a recall procedure? | Yes |
| 10.10. How many recalls related to safety and quality of tissues/cells were issued in your country in 2011? Please specify the number and which tissues were recalled and why (e.g. missing consent, quality defects etc). | 0 |
| 10.11. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites in case of a national rapid alert? | Yes |
| 10.11.1. If yes, please give a short description of the system/procedure. | The coordinators have a contact list covering all TE ´s and an e-mail is sent out togther with an alert on our public webpage. |
| 10.12. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites when a rapid alert is issued via the EU RATC platform? | Yes |
| 10.12.1. If yes, please give a short description of the system/procedure. | see 10.11.1 and the contact list is divided according to the specific tissues and cells handled by the TE so only the relevant TE´s are notified. |
| 10.13. Do you provide data regarding SAR/SAE to the EUROCET registry (non-mandatory reporting)? | No |
| 10.13.2. If no, please specify why not. | We provide data to the EC, and upon request we could provide corresponding data also to Eurocet. |
| 10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems? | Yes |
| 10.14.1. If yes, please specify which of the following systems are usually contacted. (more than 1 answer possible) | Medical devices<br>Other |
| Please specify 'other'. | If applicable we will notify the MPA (i.e tissues and cells for production of |

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| | ATMP) If a medical devise is involved in an event regarding T&C the TE is obliged to report this event also to the MPA according to SOSFS 2009:31 kap 11 4§. |
| 10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S? | No |
| 10.15.2. If no, please specify why not. | Lack of time |
| 10.16. Do you have any additional comments on SARE reporting? | |
| **11. Consent and personal data protection (Article 13 and 14, Directive 2004/23/EC)** | |
| 11.1. What consent system for living tissue/cell donation do you have in place within your Member State? | Explicit consent (opt-in) |
| 11.1.1. Please specify your choice of consent system for living tissue/cell donation. | Written and signed consent is required and in case of minors written consent from parents and an additional permit after application to the National Board of Health and Welfare is needed. |
| 11.2. What consent system for deceased tissue/cell donation do you have in place within your Member State? | Presumed (opt-out) and explicit (opt-in) consent |
| 11.2.1. If you have chosen both consent systems for deceased tissue/cell dontation, please specify. | If the deseased possible donor has not registered his/her will in the national donor registry a person who knew the diseased well need to give their consent. |
| 11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible) | First degree relatives (including spouse)<br>Other relatives<br>Non-marital partners<br>Friends |
| 11.4. Is the consent system for deceased tissue donation the same as for organs? | Yes |
| 11.5. How is this consent verified during inspections? (more than 1 answer possible) | Analysis of documentation<br>Interviews with personnel |
| 11.6. What measures are in place to ensure that donors/relatives/authorising persons on behalf of donors are provided with the appropriate information, as requested by Art. 13(2)? (more than 1 answer possible) | Only trained personnel is allowed to provide such information<br>Information for donors are standardised at national/regional level |
| 11.7. What measures are in place to ensure that both donors and recipients remain unidentifiable when access is given to third parties (Art. 14(1)). Please specify. | Donor code and recipient code is used |
| 11.8. Please specify what measures are in place to ensure that the identity of the receipient is not disclosed to the donor and vice versa. | The Donor code is used in the recipient documentation and the recipient code is used in the donor documentation. |
| 11.9. Does your national legislation allows disclosure of donor data in case of gametes donation? | Yes |
| 11.10. Do you have any additional comments on consent and data protection? | Disclosure of donor ID is only possible for the born child at adult age and not for the parents. |
| **12. Selection, evaluation and procurement (Article 15 Directive 2004/23; Annexes I-IV Directive 2006/17)** | |
| 12.1. How do you ensure that all requirements related to the evaluation and selection of donors (except donors of reproductive cells) are respected in your country (Art. 15(1), Annex I Directive 2006/17/EC)? (more than 1 answer possible) | Stadardised questionnaires at national levels<br>Inspections of TEs and procurement sites |
| 12.2. How do you ensure that all requirements related to the evaluation and selection of donors of reproductive cells are respected in your country (Art 15 (1), Annex III of Directive 2006/17/EC)? (more than 1 answer possible) | Standardised questionnaires at national level<br>Inspections of ART centres |
| 12.3. Do you have more stringent criteria for donor selection than those listed in Annex I of the Directive 2006/17/EC? | No |
| 12.4. What sources are required in your MS for the evaluation of a deceased donor of tissues/cells? (more than 1 answer possible) | Interview with the donor's family or a person who knew the donor well<br>Medical records of the donor<br>Interview with the treating physician |
| 12.5. Do you have more stringent criteria for selection of donors of reproductive cells than those listed in Annex III of the Directive 2006/17/EC? | No |

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| 12.6. Do you have more stringent criteria for autologous donation than those listed in Annex I of the Directive 2006/17/EC? | No |
| 12.7. Do you require more information on the donation of tissues/cells than the mandatory one as laid down in the Annex of Directive 2004/23/EC (Art 15(3)? | No |
| 12.8. How do you ensure that all requirements regarding tissues and cells' procurement, packaging and transport are complied with by tissue establishments in your country (Art 15(1), Annex IV of Directive 2006/17/EC? (more than 1 answer possible)(For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)) | Inspection of tissue establishment<br>Inspection of the centre of human application (e.g. transplantation centre, ART centre) |
| 12.9. Do you have any additional comments on selection, evaluation and procurement? | In combination with inspections document reviews are performed and all TE for reproductive tissue are also ART centers, so also the centers for "human application" have been inspected. |
| **13. Quality management, responsible person, personnel (Article 16, 17, 18 Directive 2004/23/EC)** | |
| 13.1. How do you ensure that tissue establishments in your country have in place a quality system respecting the provisions of the Directive 2004/23/EC Art 16.1? (more than 1 answer possible). (For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)). | Authorisation requirement<br>Inspections<br>Internal audits<br>External audits |
| 13.2. How do you ensure that tissue establishments have a responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible) | Authorisation requirement<br>Inspections<br>Other |
| Please specify 'other'. | In case of a change of responsible person, an application together with CV of the new responsible person must be approved by the CA. |
| 13.3. How do you ensure an appropriate training for the personnel directly involved in the activities of tissue establishments? (more than 1 answer possible) | Authorisation requirement<br>Inspections<br>Regular evaluation of personnel<br>Other |
| Please specify 'other'. | During inspection we also interview the personell and their possibity to get extended training is one of the questions. |
| 13.4. Do you have national/regional/local training programmes for the personnel of tissue establishments? | Yes |
| 13.4.1. If yes, please specify. | Personnel working in the laboratory of a TE must be licenced as Biomedical Analysts, other personnel are are licenced nurses, MD´s or have a degree in biomedicine depending on their assignement in the TE. Additional training specific for the TE is provided locally as well as by regional and national courses arranged by the National Tissue Council. (Vävnadsrådet; www.vavnad.se) |
| 13.5. Any additional comments on quality management, responsible person, personnel? | |
| **14. Reception, processing, storage, labelling and packaging (Art 19-22 Directive 2004/23/EC)** | |
| 14.1. How do you ensure that tissue establishments in your country fulfill the requirments of the Art. 19 (Tissue and cell reception) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | National regulation/policy for reception of tissues/cells<br>Inspections of tissue establishments<br>Internal audits of tissue establishments<br>External audits of tissue establishments (e.g. ISO) |
| 14.2. How do you ensure that tissue establishments in your country fulfill the requirements of the Art. 20 (Tissue and cell processing) of Directive 2004/23/EC? (more than 1 answer possible) | SOPs for all processes affecting quality and safety are mandatory for authorisation<br>Inspections of tissue establishments<br>Internal audits of tissue establishments |

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| | External audits of tissue establishments (e.g. ISO) |
| 14.3. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 21 (tissue and cell storage conditions) of Directive 2004/23/EC? (more than 1 answer possible) | SOPs for procedures associated with storage of tissues and cells are mandatory for authorisation<br>Inspections of tissue establishments<br>Internal audits of tissue establishments<br>External audits of tissue establishments (e.g. ISO) |
| 14.4. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | SOPs for procedures associated with labelling and packaging are mandatory for authorisation<br>Inspections of tissue establishments<br>Internal audits of tissue establishments<br>External audits of tissue establishments(e.g. ISO) |
| 14.5. Any additional comments on reception, processing, storage, labelling and packaging? | |
| **15. Third party agreements (Art. 24 Directive 2004/23/EC)** | |
| 15.1. Are third party agreements foreseen/allowed in your national legislation? | Yes |
| 15.1.1. If yes, have tissue establishments in your Member State notified third party agreements? | Yes |
| 15.1.1.1. Under which circumstances and for which responsibilities? | Donor testing: only laboratories that are accredited by SWEDAC are accepted and the agreement covers reponsibility issues relating to testing, electronic transfer of test results (if applicable), obligation to notify the TE if testresults are unreliable/ failures in the compulsary assay comparisons etc. Procurement from diseased donors (ocular tissue, skin, heart valves) where the agreement covers responibility to perform procurement according to the SOP´s from the TE and the permission to allow the TE to perform audits . Data storage: the TE´s processing and distributing allogeneic HPC have agreements with the National Registry of Bone Marrow donors (Tobias registret) covering the responisbility of the registry to keep and maintain records of the donor-identity when the TE only get a donor code as identity. |
| 15.1.1.2. How are third party agreements controlled (Art 6.2) by the Competent Auhtority(ies) in your MS? Please specify. | Before the authorization and during routine inspections. |
| 15.2. Any additional comments on third party agreements? | In case of new third party agreements; it is considered as a major change in the TE , that has to be approved by the CA ( by document review) |
| **16. General comments - implementation** | |
| 16.1. Do you have at national level more stringent quality and safety requirements than those requested by the EU legislation in this field (e.g. restrictions concerning the donation/use of certain tissues/cells, mandatory unpaid donation etc.)? | No |
| 16.2. Has your Member State encountered any difficulties in implementing the requirements in the EU Tissues and Cells Directives? Please choose from the options below. | Testing provisions |
| 16.2.1. For all selected options in question 16.2., please provide a short description. | The 24 hr time limit to perform donor testing in case of diseased donor have a negative effect on donor availability for procurement as it may take longer for the concent to be given. |
| 16.3. In your opinion, in which of the following Directives are there shortcomings (if any)? (more than 1 answer possible) | Directive 2006/17/EC |
| 16.3.2. How would you suggest to solve these issues in Directive 2006/17/EC? | Annex II 2.4 Change the time limit from 24 hr to 48 hrs since no scientific evidence was the basis for the 24 hrs time limit. Annex II 2.5 (b) add for clarification: "under these circumstances tissues and cells are in quarantine until results from the second test are available and evaluated " |

## *A.1.30. Survey response United Kingdom*

| UK - HFEA | |
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| **1. Public information** | |
| 1.1. Name of National Competent Authority (NCA) 1: | Human Fertilisation and Embryology Authority |
| 1.1.2. Address of NCA 2: | Finsbury Tower 103-105 Bunhill Row London EC1Y 8HF United Kingdom |
| 1.1.3. Telephone (central access point): | 0207 291 8200 |
| 1.1.4. E-mail (central access point): | admin@hfea.gov.uk |
| 1.1.5. Website: | www.hfea.gov.uk |
| 1.1.6. The NCA is responsible for? (more than 1 answer possible) | Reproductive tissues and cells |
| 1.1.7. What are the role/tasks of the NCA? (more than 1 answer possible) | Accreditation, authorisation, licensing of TEs<br>Inspection<br>Vigilance<br>Other |
| Please specify 'other': | The HFEA is the UK's national regulator for ensuring ART clinics adhere to the requirements of the Human Fertilisation and Embryology Act 1990 (as amended) [the HF&E Act 1990 (as amended)]. The HFEA also licenses and monitors establishments undertaking human or human admixed embryo research. We also maintain a Register of Information. The HFEA Register is a data set on regulated fertility treatments, including the handling and storage of embryos, eggs and sperm. |
| 1.2. National Competent Authority 2? | No |
| 1.5. Please give a short description of the legal status and organisation of the National Competent Authority(ies) (e.g. departments, staffing, number of senior and junior inspectors, staff working on EU affairs and legal matters, vigilance officers, budget, independence from government etc.). | The HFEA is an independent regulator, operating as a UK arms-length body, sponsored by the Department of Health. It employs approximately 69 staff, divided into three directorates: Compliance and Information; Strategy; Finance, Facilities and Information Technogy. Each of these directorates are led by a Director, reporting to the CEO. The Compliance team has 2 senior inspectors and 10 inspectors (who comprise the inspection and vigilance team), reporting to either the Head of Inspection or the Head of Research Regulation and Clinical Governance. The HFEA also has a board. There are also 12 members of the Authority (the board) who determine HFEA policies and review treatment and research licence applications. Members have a broad range of expertise, from medicine to law and religion to philosophy. To ensure that the HFEA has an objective and independent view, the HFE Act requires the Chair, Deputy Chair and at least half of the HFEA Members are not doctors or scientists involved in human embryo research or fertility treatment. |
| 1.6. In case of MS with federal or decentralised systems, please indicate the roles/tasks of the Regional Competent Authority(ies). (more than 1 answer possible) | Not applicable |
| 1.7. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies) for tissues and cells: | Not applicable |
| **2. Procurement (Article 5 Directive 2004/23/EC)** | |
| 2.1. Do you authorise the "conditions of procurement"? | Yes |
| 2.1.1. How do you authorise the "conditions of procurement"? (more than 1 answer possible) | By inspecting some procurement centres<br>By inspecting the documentation associated with procurement that is available in the tissue establishment working with procurement centres<br>Other |
| Please specify 'other': | We license and inspect establishments that carry out procurement activities where they also process and use gametes and / or embryos. We also issue a Code of Practice in which we provide advice on the requirements related to conditions of procurement. We may not inspect all procurement centres as some procurement centres operate |

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| | through a third party agreement with a licensed establishment. The Person Responsible (i.e 'responsible persons') at these licensed establishments must ensure that the practices, staff and premises are suitable at any third party establishment. They will do this in a variety of ways, including conducting audits of the third party. The HFEA reviews third party arrangements during a routine inspection of the licensed establishment. |
| 2.1.2. How many such authorisations were granted in 2011 (01/01-31/12/2011)? | 35 HFEA licences were renewed in in 2011. In addition one new licences was granted in 2011. |
| 2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011). | Procurement of traditional tissue and cells is authorised by the Human Tissue Authority (HTA) |
| 2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011). | Procurement of haematopoietic stem cells is authoroised by the HTA. |
| 2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues were carried out in 2011 (01/01-31/12/2011). | 115 of which 111 are licensed by the HFEA. Four centres procure gametes under third party agreements with a licensed HFEA centre. |
| 2.2.4. Please provide the number of procurement centers in which procurement of tissues/cells for ATMP manufacturing were carried out in 2011 (01/01-31/12/2011). | Procurement of tissue / cells for ATMP manufactoring falls is authorised by the HTA. |
| 2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC and its implementing Directive 2006/17/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) ? (more than 1 answer possible) | Inspections of the site/centre<br>Analysis of the mandatory documentation<br>Other |
| Please specify 'other': | The HFEA, by law, produces a Code of Practice. The HFEA Code of Practice is intended to help and encourage licensed centres to understand and comply with their legal requirements. It also gives guidance on how centres are expected to go about meeting those requirements. In addition which provide guidance through a regular news letter. |
| 2.4. Are you also responsible for the accreditation, designation, authorisation or licensing of laboratories performing donor testing? | Yes |
| 2.4.1. Please provide the number of the laboratories performing donor testing. | The HFEA does not licence laboratories performing donor testing. The HFEA has made it a condition of all treatment and storage licences issued to tissue establishment that donor testing must be carried out by a qualified laboratory, which has suitably accreditated (for example by the Clinical Pathology Accreditation [CPA (UK) Ltd] or another body accrediting to an equivalent standard). The CPA (UK) Ltd , a private organisation, provides a voluntary national accreditation service. Over 95% of UK labs are CPA accredited. |
| 2.5. How do you ensure, as CA for T&C, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art. 5(2))? (more than 1 answer possible) | Analysis of the mandatory documentation requested from the tissue establishment<br>Other |
| Please specify 'other': | During inspections visits to tissue establishments HFEA inspectors will audit the medical records for a number of patients. As part of this audit we look for evidence that the donor testing has been carried out by a qualified laboratory. |
| 2.6. Please provide data on qualified laboratories accredited, authorised or licensed in your country (e.g. number, year of accreditation/authorisation/license, which donor tests are performed etc.). | The HFEA does not accredit, authorise or license laboratories which carry out donor testing. Over 95% of laboratories carrying donor testing are accrediated by the Clinical Pathology Accrediatation [CPA (UK) Ltd). |
| 2.7. Do you have any additional comments on procurement? | The following requirementss are conditions of all licences issued by the HFEA: - Where the sperm is procured at home, the centre must record this in the gamete provider’s records. - No money or other benefit must be given or received in respect to any supply of gametes, embryos or human admixed embryos unless authorised by |

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| | Directions. - There must be a documented system in place that ensures the identification of all gametes and embryos from procurement to use or disposal. |
| **3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)** | |
| 3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>Anti HBc<br>Anti HCV-Ab<br>Treponema Pallidum<br>HTLV-2 |
| 3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>HBs AG<br>Anti HBc<br>Anti HCV-Ab<br>NAT Chlamydia<br>Treponema Pallidum |
| 3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to encourage its use? Please specify why or why not (e.g. number of additional cases detected, cost-benefit etc.). | NAT testing is not currently mandatory in the UK, with the exception of the testing for Chlamydia. The Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) advises UK ministers and health departments on the most appropriate ways to ensure the safety of blood, cells, tissues and organs for transfusion/transplantation. SaBTO has recommended NAT, in particular product testing rather than donor serum testing. |
| 3.4. Do you have concerns on accuracy of the available tests and test procedures for deceased donors? | No |
| 3.5. Are any other laboratory tests required for donors of non-reproductive tissues and cells in your Member State? | No |
| 3.6. Are any other laboratory tests required for donors of reproductive tissues and cells in your Member State? | No |
| 3.7. Do you request/use international accreditation systems for testing laboratories? | No |
| 3.8. Do you have any additional comments on testing? | The testing of donors of non-reproductives cells comes under the authority of the Human Tissue Authority in the UK. Additional testing for donors of reproductive tissue and cells is carried in accordance with the rquirements set out in Annex 111 of Directive 2006/17/EC. |
| **4. Accreditation, designation, authorisation or licensing of tissue establishments (Article 6, Directive 2004/23/EC)** | |
| 4.1. Do you have a system of designation, authorisation, accreditation or licensing for all types of tissue establishments under your responsability? | Yes |
| 4.2. Is inspection a prerequisite for the designation, authorisation, accreditation or licensing of tissue establishments? | Yes |
| 4.2.1. How many inspections were performed in 2011 for authorising/accrediting/licensing/designating TEs? | 37 inspections were performed in 2011 for the purpose of renewing or granting a HFEA licence to tissue establishments. |
| 4.3. Are preparation processes authorised? | Yes |
| 4.3.1. How are they authorised? (more than 1 answer possible) | During routine inspections<br>By review of a submitted application with supporting documentation |
| 4.4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were suspended in 2011? | None |
| 4.5. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011? | 3 licences were revoked |
| 4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)? | No |
| **4bis. Overview of tissue/cells establishments authorised by the NCA** | |
| 4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible): | ART tissue establishments |
| 4.7.7. How many ART tissue establishments? | 4 |

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| 4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible): | ART tissue establishments |
| 4.8.7. How many ART tissue establishments? | 13 |
| 4.9. Tissue establishments first time authorised between 01/01/2011 and 31/12/2011 (more than 1 answer possible): | ART tissue establishments |
| 4.9.7. How many ART tissue establishments? | One |
| 4.10. All tissue establishments authorised by 31/12/2011 (more than 1 answer possible): | ART tissue establishments |
| 4.10.7.1. How many public ART tissue establishments? | 66 (42 of these also treat private patients) |
| 4.10.7.2. How many private ART tissue establishments? | 45 (27 of these also treat publicly funded patients) |
| 4.11. How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Art. 6(5) during 2011? Please provide number(s) per type tissues/cells. | 0 - None |
| **4ter. Sanctions** | |
| 4.16. Have penalties for infringements of the national provisions pursuant to the Directive been defined (Article 27)? | Yes |
| 4.16.1. Have penalties already been imposed? | Yes |
| 4.16.1.1. How many penalties have been imposed in 2011 (from 01/01/2011-31/12/2011)? | One licence had a condition placed on it to restrict the number of ART treatment cycles which could be carried per month. |
| 4.16.1.2. What were the reasons for imposing the penalties? Please describe. | The Person Responsible had failed to ensure that suitable practices (required under section 17(1)(d) of the HF&E Act) were being used in the course of the activities being caried out at the ART centre. |
| 4.16.1.3. What kind of penalties were imposed? Please describe (e.g. suspension of authorisation, criminal penalty etc.) | One licence had a condition placed on it to restrict the number of ART treatment cycles which could be carried per month. |
| 4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing? | In relation to 4.5 three licences were revoked but these were at the request of the Person responsible (i.e. the reponsible person), so we class these as voluntary revocations. In relation to 4.7.7: four tissue establishment were inspected in 2010 but the decision on whether or not the HFEA licence should be renewed was not taken until early 2011. In relation to 4.8.7: 12 tissue eatablishments were inspected in 2011 but the decision on whether or not the HFEA licnece should be renewed was not taken until early 2012. In adition one of the new tissue eatablishments inspected in 2011 was not granted a licnece until 2012. In relation to 4.10.7.1: In the UK there are 66 ART centres located in NHS [National Health Service(public)] hospitals; of these 42 also treat privately funded patients. In relation to 4.10.7.2: In the UK there are 45 private ART centres; of these 27 also treat NHS funded patients. |
| **5. Inspections (Article 7, Directive 2004/23/EC)** | |
| 5.1. Is a system in place for organising inspections and control measures of tissue establishments? | Yes |
| 5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections. | Directorate of Compliance and Information |
| 5.1.2. If yes, please specify staffing (how many inspectors). | The HFEA has two senior inspectors and 10 inspectors. There are also two Heads of Department and a Director. The HFEA also has a panel of external advisors who occassionaly form part of the HFEA's inspection teams. These external advisors are clinicians, nurses, embryologists or counsellor who work in licensed ART centres. A list of the HFEA's external advisors mcan be found in our annual report (http://www.hfea.gov.uk/annual-report.html) |
| 5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible) | Yes |
| 5.2.1. If yes, please specify. (more than 1 answer possible) | Others |
| Please specify other. | As well as being the Competent Authority for tissues and cells for human application, the HFEA is also responsible for ensuring tissue establishments are compliant with the Human Fertilisation and Embryology Act 1990 (as amended) and we are also responsibe for licensing and inspecting laboratories which use human or human |

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| | admixed embryos in research. |
| 5.3. How many routine inspections of tissue establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011)? | N/A |
| 5.3.1. How many inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) following serious adverse events or reactions, or suspicion thereof ? | N/A |
| 5.3.2. How many other type of inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | N/A |
| 5.3.3. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | N/A |
| 5.3.4. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where minor shortcomings were noted? | N/A |
| 5.3.5. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where major shortcomings were noted? | N/A |
| 5.3.6. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by suspension of authorisation? | N/A |
| 5.3.7. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by closure? | N/A |
| 5.3.8. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of other inspections carried out? Please specify. | N/A |
| 5.4. How many routine inspections were conducted in ART establishments (from 1/1/2011 to 31/12/2011)? | 60 |
| 5.4.1. How many inspections were conducted in ART establishments following serious adverse events or reactions, or suspicion thereof (from 1/1/2011 to 31/12/2011)? | 2 |
| 5.4.2. How many other type of inspections were conducted on ART establishments (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | One |
| 5.4.3. Outcome of inspections of ART tissue establishments carried out in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | 3 |
| 5.4.4. What was the number of inspections carried out in ART establishments where minor shortcomings were noted? | 54 |
| 5.4.5. What was the number of inspections carried out in ART establishments where major shortcomings were noted? | 50 |
| 5.4.6. What was the number of inspections carried out in ART establishments followed by suspension of authorisation? | 0 - None |
| 5.4.7. What was the number of inspections carried out in ART establishments followed by closure of respective establishements? | 0 - None |
| 5.4.8. What was the number of other inspections of ART establishments? Please specify. | 3: two to investigate an SARE and one following a complaint/ whistleblower |
| 5.5. Which type of routine inspections do you conduct? (more than 1 answer possible) | General system-oriented inspections<br>Thematic inspections<br>Desk based reviews |
| 5.6. How do you decide which type of routine inspection to conduct? | The HFEA's continuous monitoring cycle of licensed UK fertility centres involves a four year inspection cycle during which the |

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| | majority of centres will receive a four year licence and be inspected once every two years. More frequent inspections may be made when we have concerns about a centre's compliance - particularly if we consider the safety of patients, embryos and gametes are at risk. The purpose of an inspection is to: - assess the extent to which centres comply with the Human Fertilisation and Embryology Act; licence conditions; directions and the provisions of the Code of Practice - provide an independent and professional perspective on the running of the centre - promote good practice so that centres can improve the quality of service they provide to patients and donors Compliance with all of the requirements of the HF&E Act 1990 (as amended), which incorprates the requirements of the EUTCD, are inspected prior to a licence being granted or renewed. An interim inspection takes place mid way through the four year inspection cycle. During the interim inspection the inspection team evaluates: - the action(s) taken by the centre in relation to areas of non-compliance identified either at the last inspection visit or through the continuous monitoring cycle - compliance against the inspection themes (the Authority has decided that a number of areas of practice should be looked at all inspections. These are referred to as 'themes'. The themes are changed every two years.) The HFEA also conducts thematic reviews where we look at compliance against a particular requirement e.g. consent to donation and these may involve additional inspection visits to tissue establishments. The variation of licences is sometimes carried out by desk based reviews. For example if a tissue establishment applied to have an additional licensed activity added to thier licence we would ask them to submit documentation and this would be reviewed without an inspection visit being carried out. |
| 5.7. Until 2011, did you implement the requirement concerning the time interval between two inspections (Art. 7.3.)? | Yes |
| 5.8. How many TEs were inspected at least twice between 2008-2011 (01/01/2008-31/12/2011)? | All TEs licensed by the HFEA between 01/01/2008 -31/12/2011 were inspected at least twice between 2008 -2011. The HFEA continues to carry out a site based inspection of all licensed tissue establishments every two years. |
| 5.9. Did you perform/conduct inspections of procurement sites outside tissue establishments? | No |
| 5.9.2. If no, why not? | The Person Responsible (the Responsible Person) at HFEA licensed tissue establishments are required to have a third party agreement with procurement sites. These third party agreements are reviewed as part of the inspection process. There are only 4 procurements sites that are not licensed by the HFEA. |
| 5.10. Did you carry out inspections of third parties? | No |
| 5.10.2. If no, why not? | No issues were raised during inspections of the licensed tissue establishments and no series adverse events or reactions were reported in relation to third parties. |
| 5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)? | No |
| 5.11.1. If no, which guidelines/regulations are used for inspections at national level? | We do not use the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections, however our inspection guidelines are based on this document. We provide licensed tissue establishments with numerous guidance on our website, to assist them with inspection preparation and guidance on what licensed tissue establishments need to do to comply with the HFEA's Code of Practice. We use internal standard operating procedures to provide guidance for inspectors on how to conduct an inspection. We also hold at least on training day for HFEA inspectors and the HFEA's external advisors per year. These days are used to ensure consistency |

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| | between inspectors. |
| 5.11.2. If no, please provide a hyperlink to these guidelines/inspections. | The information on how the HFEA monitors licensed tisues establishment can be found at http://www.hfea.gov.uk/6670.html. The information on the inspection process can be found at http://www.hfea.gov.uk/6672.html and the information on what licensed tissue establishments need to do to ensure they comply with the HF&E Act 1990 (as amended) and the Code of Practice can be found at http://www.hfea.gov.uk/6676.html. |
| 5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)? | Yes |
| 5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)? | 5 |
| 5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))? | No |
| 5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))? | No |
| 5.15. Did you organise any inspections of procurement centres or tissue establishments in third countries from which tissues and/or cells were imported in your country (as recorded by 31/12/2011)? | No |
| 5.16. Have you asked another MS, or have you been requested by any other MS, on the results and control measures of your inspections, as part of an enquiry/investigation? | No |
| 5.17. Would you be interested in developing joint inspections? Joint inspections should be understood as inspections of tissue establishments conducted jointly by two or more Member States' Competent Authorities on their territory or in third countries. | Yes |
| 5.18. Do you have any additional comments on inspections? | The HFEA continually monitor licensed centres to ensure their compliance with the HF&E Act (as amended), standard licence conditions, additional licence conditions, directions and the Code of Practice. To aid this process the HFEA has developed a tool, known as the Risk Based Assessment Tool, which helps us assess the information provided to us by centres. The Risk Tool analyses information provided to the HFEA through Register submissions and to the HFEA finance directorate to assess quality of service in terms of: - outcomes (in the form of real time analysis of clinical pregnancy rates) - multiple clinical pregnancy rates - submission of critical donor information - incident reporting. Where the analysis shows that a centre's outputs are outside the sector norms we will share this information with the centre and support them in identifying whether there is an opportunity for improvement. The same will apply where clinical multiple birth rates indicate that a centre is not likely to meet HFEA targets; where critical Register submissions are not submitted. A more detailed explanation of the HFEA Risk Tool can be found at http://www.hfea.gov.uk/6674.html. |
| **6. Import/export (Article 9 Directive 2004/23/EC)** | |
| 6.1. Do you have a register of authorised tissue establishments that are explicitly authorised to perform import/export of tissues and celles from/to third countries? | Yes |
| 6.2. Please specify the number of tissue establishments authorised to import tissues and cells from third countries (recorded by 31/12/2011). | 85 |
| 6.3. Please specify the number of tissue establishments authorised to export tissues and cells from third countries (recorded by 31/12/2011). | 85 |
| 6.4. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of skin from third countries. | N/A |

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| 6.5. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of musculo-skeletal (bone, tendons, fascia etc.) tissues from third countries. | N/A |
| 6.6. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of ophtalmic (cornea, sclera, etc) tissues from third countries. | N/A |
| 6.7. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cardio vascular tissues from third countries. | N/A |
| 6.8. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) (other than cord blood) from third countries. | N/A |
| 6.9. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cord blood from third countries. | N/A |
| 6.10. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of reproductive cells (sperm, egg cells) from third countries. | The HFEA requires the tissue establishment in the third country to be accredited, designated, authorised or licensed under the laws or other measures of the country in which it is situated in relation to quality and safety. |
| 6.11. Did you import tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | Yes |
| 6.11.1. If yes, please provide the data concerning the number/volume of imported tissues and cells by country of origin. | In 2011, the UK imported 1104 vials/ampoules/straws of sperm from the following third countries: Australia, USA and Uruguay. The UK also imported 297 eggs from the following third countries: Australia, Russia and the USA. Embryos were also imported from another third country. The HF&E Act 1990 (as amended) prohibits the HFEA from disclosing information which could potentially lead to a patient being identified, for this reason we are unable to provide the quantities imported from third countries and in the case of the imported embryos we are also unable to disclose the name of the country of origin. |
| 6.12. Did you export tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | Yes |
| 6.12.1. If yes, please provide the data concerning the number/volume of exported tissues and cells by country of destination. | In 2011, the UK exported 47 vials/ampoules/straws of sperm to the following third countries: Australia, USA and Uzbekistan. The UK also exported 96 embryos to the following third countries: American Samoa, Australia, Canada, India, Israel, Japan, New Zealand, Singapore, South Africa and the USA. The HF&E Act 1990 (as amended) prohibits the HFEA from disclosing information which could potentially lead to a patient being identified, for this reason we are unable to provide the quantities exported to individual third countries. |
| 6.13. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on imports/exports of tissues/cells between your country and other third countries? | No |
| 6.14. What is the relation between import/export of tissues and cells and self-sufficiency? (more than 1 answer possible) | F. Other |
| Please specify 'other': | THe HFEA does not hold information about local/ national needs. |
| 6.15. Did you authorise direct imports of tissues/cells to hospitals/clinics in your country? | No |
| 6.16. Do you have any additional comments on import/export? | The HFEA has issued General Directions to all tissue establishments, licensed to carry out treatment and storage; theses Directions set out the requirements which must be met in order to permit gametes and / or embryos to be imported or exported. A copy of these Directions can be found at: http://www.hfea.gov.uk/docs/2009-09-09_General_directions_0006_-_Import_and_export_of_gametes_and_embryos_-_version_2.pdf. Where a centre wants to export or import gametes or embryos to or |

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| | from a country outside the EEA or Gibraltar, the person responsible must obtain and retain (for three years) written evidence that: i) the receiving or sending centre is accredited, designated, authorised or licensed under the laws or other measures of the country in which it is situated in relation to quality and safety ii) the centre has appropriate quality management and traceability systems, and iii) the gametes or embryos have been procured and processed in appropriate facilities, and following procedures that minimise bacterial or other contamination. In each case, a copy of the information retained must be provided to the Authority on request. In all cases, all the requirements in the relevant HFEA Directions on import and export of gametes and embryos relating to identification, consent, parenthood, payment of the donor, use of the gametes and embryos, and screening must be met. |
| **7. Distribution/intra community exchanges (Article 23 Directive 2004/23/EC)** | |
| 7.1. Do you have intra-community exchanges of tissues and cells? | Yes |
| 7.1.1. If yes, how do you address the possible more stringent quality and safety measures established by other Member States? Please specify. | It is the responsibility of the Person Responsible to ensure the requirements of other Member States have been met prior to distributing gametes or embryos to tussue establishments in the relevant MS. |
| 7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States? | No |
| 7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify. | Tissue establishments are required to put into place service level agreements with couier compancies which define the obligations for complying with requirements in relation to ensure the quality and saferty of the gametes and embryos are maintained. |
| 7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible). | No |
| 7.4. Have you authorised direct distribution to the recipient of specific tissues and cells (Art. 6, Directive 2006/17/EC)? | No |
| 7.5. Do you collect data regarding the cross-border exchange of tissue/cells between your country and other EU MS? | Yes |
| 7.5.1. Please provide us with data (country of destination, type of tissue/cell and number of units distributed) concerning distribution to other MS in 2011 (01/01/2011-31/12/2011). | In 2011, the UK distributed 42 vials/ampoules/straws of sperm to the following member states: Cyprus, Denmark, Germany, Greece, Ireland and Spain. The UK also sent 32 embryos to the flowing Member states: Germany, Ireland and Spain. The HF&E Act 1990 (as amended) prohibits the HFEA from disclosing information which could potentially lead to a patient being identified, for this reason we are unable to provide the quantities sent to individual MS. |
| 7.5.2. Please provide us with data (country of origin, type of tissue/cell and number of units distributed) concerning distribution to other MS in 2011 (01/01/2011-31/12/2011) | In 2011, the UK received 1003 vials/ampoules/straws of sperm from the following member states: Cyprus, Denmark, Germany, Norway and Spain. The UK also received embryos from a country within the EEA. The HF&E Act 1990 (as amended) prohibits the HFEA from disclosing information which could potentially lead to a patient being identified, for this reason we are unable to provide the quantities received from individual MS and in the case of embryos received we can not disclose the MS from which the embryos were received from. |
| 7.6. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on cross-border exchanges of tissues/cells between your country and other EU MS? | No |
| 7.7. Do you allow brokerage companies for either distribution in EU and/or import/export of tissues/cells? In this context, a brokerage company means a body that arranges transactions between a supplier (tissue establishment/company selling tissues or cells) and a buyer (a tissue establishment/a hospital or clinic/an individual) without undertaking activities of processing, preservation or storage. | No |
| 7.8. Are brokers actively supplying health professionals/establishments in your country? | No |
| 7.9. Do you have any additional comments on distribution? | The wording of questions 7.5.1 and 7.5.2 are virtual identical. Therefore, in relation to question 7.5.1 we have provided data in |

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| | relation to the quanitity of gametes and embryos which were distributed from the UK to other MS and in relation to question 7.5.2 we have provided data in relation to the receipt of gametes and embryos from other MS into the UK. |
| **8. Register of tissue establishments and reporting obligations (Article 10, Directive 2004/23/EC)** | |
| 8.1. Do you have an annual report model/template on the activities of tissue establishments in your Member State? (Article 10(1)). If yes, please upload the template. | Yes |
| 8.2. How many tissue establishments submitted annual reports of their activities during 2011. Please provide an estimation. (1 answer possible) | 60-99% |
| 8.3. Are these reports publicly available? (Article 10(1)) | Yes |
| 8.3.1. If yes, please insert the link(s) to the report(s). | http://www.hfea.gov.uk/1270.html |
| 8.4. Do you publish a national annual report of the consolidated activities of all tissue establishments in your country? | Yes |
| 8.4.1. Please insert the link to the published national annual report. | http://www.hfea.gov.uk/docs/HFEA_Fertility_Trends_and_Figures_2011_-_Annual_Register_Report.pdf and http://www.hfea.gov.uk/1270.html. The HFEA also publishes data in relation to each licensed fertility centre (tissue establishment) this can be found on our website in the 'Choose a Fertility Clinic' section: http://guide.hfea.gov.uk/guide/ |
| 8.5. Is there a publicly accessible register of authorised tissue establishements in place? (Article 10(2)) | Yes |
| 8.5.1. If yes, please provide us with the link to the register's web site. | http://guide.hfea.gov.uk/guide/AllClinics.aspx?x=A |
| 8.6. Do you provide data regarding tissues and cells activities to the EUROCET registry (non-mandatory reporting)? | Yes |
| 8.6.1. If yes, what data are provided to EUROCET? Please specify. | We supply annual activity data to the EC and we assume this information then goes to the EUROCET registry. We complete all mandatory reporting. |
| 8.7. Do you have any additional comments on reporting? | The HFEA collects data and statistics about over 60,000 fertility treatments performed each year in the UK. We are committed to making as much of this information available as possible to aid and inform patients, researchers and clinicians. Our 'Fertility treatment in 2011 – facts and figures' report presents information about patients, treatments and results from 2010 and 2011. It also highlights some short term and longer term changes over time. An new annual report is published each Autumn. The annual return upload only relates to information about treatment cycles involving the insemination using partner sperm. Data on all other ART treatments e.g. IVF using either partner donation or non-partner donation; insemination using non-partner sperm or ICSI using either partner or non-partner donation are submitted to the HFEA register on a regular basis in accordance with HFEA General Directions (http://www.hfea.gov.uk/docs/0005_Collecting_and_recording_information_for_the_HFEA_-_approved.pdf). This information is published in the annual report as well as being available on our website in the 'Choose a fertility' section. |
| **9. Traceability (Article 8, Directive 2004/23/EC; and Directive 2006/86/EC)** | |
| 9.1. Was the donor identification system (Art. 8(2)) implemented in your country? | Yes |
| 9.2. Who assigns the unique code for each donation? (only 1 answer possible) | Other |
| Please specify 'other'. | Tissue establishments or procurement centres |
| 9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible) | Both paper records and electronic forms |
| 9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify. | We require a records retention policy to be in place. We check this is in place both at the initial licence application stage and during inspections. |
| 9.5. Do you have any additional comments on traceability? | All tissue establisments licensed by the HFEA must adhere to a number of licence conditions, the following licnece conditions |

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| | relating to traceability apply to all licensed ART centres: Traceability and coding T99. The centre must establish, implement and comply with documented procedures to ensure that: a. all gametes and embryos, and b. all relevant data relating to anything coming into contact with those gametes or embryos are traceable from procurement of gametes to patient treatment or disposal and vice versa. T100. The documented procedures referred to in licence condition T99 include the following information: a. the unique and accurate identification of each patient/donor b. the unique and accurate identification of each set of gametes and embryos c. date of procurement d. place of procurement e. type of treatment f. description and origin of any and all products associated with the procurement, processing, use and storage of gametes and embryos, and g. description of all processing steps applied to the procurement, use and storage of gametes and embryos. T101. The centre must ensure that all containers (dishes, vials, ampoules, tubes etc) used in the course of procurement, possessing, use and storage of gametes and embryos are labelled with the patient's/donor's full name and a further identifier. If at some stages (eg, labelling patient/donor sperm) it is not possible to label the dishes or tubes with the patient/donor name then it must be ensured that the patient/donor code used is uniquely identifying. T102. The centre must record such information as is necessary to facilitate the traceability of gametes and embryos and any information relating to the quality or safety of gametes and embryos. This information must be provided to the Authority upon request. T103. The centre must keep data necessary to ensure traceability for a minimum of thirty years (and for such longer period as may be specified in Directions) in an appropriate readable storage medium. T104. Records not covered by licence condition T103 and test results that impact on the safety and quality of the embryos and gametes, must be kept so as to ensure access to the data for at least 10 years after the expiry date, clinical use or disposal. |
| **10. Notification of serious adverse events and reactions (Article 11 Directive 2004/23, Article 6 Directive 2006/86)** | |
| 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))? | Yes |
| 10.1.1. If yes, which CA/institution is responsible? | HFEA |
| 10.1.2. If yes, please provide a short description of its organisation. | The HFEA is a non-department goverment body responsible for implemeting the HF&E Act 1990 (as amended) and is one of the two UK Competent Authorties for implemeting the EUTCD. |
| 10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use the SAR/E (to the CA (2006/86 art 6.4)) templates developed to the Annual reporting ot the EC also at national level? | No |
| 10.2.1. If no, what template do you use? You are welcome to upload the template if you wish. | We use the HFEA incident reporting form. The HF&E Act 1990 (as amended) set out the requirments which must be meet by ART centres these rquirments include those set out in the EUTCD but also includes additional requirments in relatio to consent, welfare of the child, legal parnethood. The HFEA also licenses the use of gametes and embryos in treatment. Therefore the incident reporting form reflects our extended powers. |
| 10.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level? | No |
| 10.3.1. If no, please specify what guidelines you use. | The HFEA issues guidance on SAERs in the HFEA Code of Practice, see http://www.hfea.gov.uk/3476.html Licensed establishments are required to report SAREs to the HFEA within 24 hours of them being discovered. |
| 10.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all TEs? | Yes |
| 10.5. How many tissue establishments provided in 2011 the SAR/SAE data as requested (please provide the % from the total number of TEs authorised in your country). | 100% |

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| 10.6. Do you have a mandatory procedure for the transplantation centres when reporting SAR/SAE to the TEs which distributed the tissues/cells (Art 11.2)? | Yes |
| 10.6.1. If yes, please provide a brief description. | The use of gametes and / or embryos in treatment must take place in a licensed centre. These centres must report all SAERs to the HFEA in accordance with General Directions http://www.hfea.gov.uk/docs/2011-10-01_General_directions_0011_-_Version_2.pdf |
| 10.7. Do you give feedback to the TEs regarding SAR/SAE recorded at national level? | Yes |
| 10.7.1. Please specify. | Report / inspection process / HFEA newsletter / workshops |
| 10.8. Do you give feedback to the TEs regarding SAR/SAE recorded at EU level? | Yes |
| 10.8.1. Please specify. | The HFEA notifies establishments about any SARE implications in a regular e-newsletter. |
| 10.9. Do you require your TEs to have a recall procedure? | Yes |
| 10.10. How many recalls related to safety and quality of tissues/cells were issued in your country in 2011? Please specify the number and which tissues were recalled and why (e.g. missing consent, quality defects etc). | No recalls were issued in 2011. |
| 10.11. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites in case of a national rapid alert? | Yes |
| 10.11.1. If yes, please give a short description of the system/procedure. | Alerts are uploaded on to the HFEA clinic portal and TEs are notified via email. |
| 10.12. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites when a rapid alert is issued via the EU RATC platform? | Yes |
| 10.12.1. If yes, please give a short description of the system/procedure. | Alerts are uploaded on to the HFEA clinic portal and TEs are notified via email. |
| 10.13. Do you provide data regarding SAR/SAE to the EUROCET registry (non-mandatory reporting)? | Yes |
| 10.13.1. If yes, please specify what data. | The HFEA provides all the requested information to the EUROCET registry. |
| 10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems? | Yes |
| 10.14.1. If yes, please specify which of the following systems are usually contacted. (more than 1 answer possible) | Medical devices<br>Other |
| Please specify 'other'. | We communicate alerts to the Medicines and Healthcare products Regulatory Agency and the Human Tissue Authority. We also share details of SAREs reported to us if we believe they could have an impact on medicines and healthcare products and/or non-reproductive tissues and cells. |
| 10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S? | Yes |
| 10.15.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (insufficient) - 2 (sufficient) 3 (good) - 4 (very good) to 5 (essential)? | 5 |
| 10.16. Do you have any additional comments on SARE reporting? | 10.5 above is actually not applicable for the HFEA: Establishments report SAREs within 24 hours of their discovery, and not via an annual report. As a result, we may not receive data from every establishment every year, as serious reactions or events may not take place at every establishment. We received a total of 611 incident reports in 2011. We found the training excellent. We follow the EC RATC Platform standard operating procedures when reporting an incident on the RATC platform. |
| **11. Consent and personal data protection (Article 13 and 14, Directive 2004/23/EC)** | |
| 11.1. What consent system for living tissue/cell donation do you have in place within your Member State? | Explicit consent (opt-in) |

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| 11.1.1. Please specify your choice of consent system for living tissue/cell donation. | The use of gametes in treatment may only take place if consent has been provided by the gamete provider. In the case of the use of embryos in treatment consent must have been by both gamete providers. The storage of gametes may only take place in consent has been obtained from the gamete provider. The exception to this is that a parent or guardian may consent to the storage of gametes of a child but these gametes may not be used in treatment without consent of the gamete provider i.e. the child when they become capable of providing the necessary consent. The storage of embryos may only take place provided consent has been obtained from both of the partners (or donors) whose gametes were used to create the embryos. |
| 11.2. What consent system for deceased tissue/cell donation do you have in place within your Member State? | Explicit consent (opt-in) |
| 11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible) | Other |
| Please specify 'other'. | Only the gamete providers may give consent to the use of their gametes or embryos, created using thier gametes, after their death. |
| 11.4. Is the consent system for deceased tissue donation the same as for organs? | No |
| 11.4.1. If no, please describe the difference. | The legislation regarding the consent system for organs is under the regulation of the HTA. |
| 11.5. How is this consent verified during inspections? (more than 1 answer possible) | Analysis of documentation<br>Interviews with personnel<br>Interviews with living donors<br>Other |
| Please specify 'other'. | We also conduct traceability audits to verify the consent documentation in randomly selected cases (including matching stored tissue samples to consent files). |
| 11.6. What measures are in place to ensure that donors/relatives/authorising persons on behalf of donors are provided with the appropriate information, as requested by Art. 13(2)? (more than 1 answer possible) | Only trained personnel is allowed to provide such information<br>Other |
| Please specify 'other'. | Ensure correct procedures are in place at the initial application assessment stage. Follow up during inspections. |
| 11.7. What measures are in place to ensure that both donors and recipients remain unidentifiable when access is given to third parties (Art. 14(1)). Please specify. | The HF&E Act 1990 (as amended)sets out the legal requirements in realtion to the disclosure of information. In summary: A centre may hold information that could lead to the identification of: a) an individual donor or recipient of gametes or embryos b) an individual or couple seeking or receiving treatment services (other than basic partner services), or c) an individual who may have been born as a result of such services or as a result of donated sperm. The centre may disclose this information only in the specific circumstances set out in the HF&E Act 1990 (as amended). The information may, for example, be disclosed: a) to anyone, provided that it is disclosed in such a way that no individual can be identified from it b) to the Authority c) to another licensed centre to enable that centre to carry out its functions under its licence d) to the person to whom the information relates, and to their partner (if they are being treated together, or their partner has served notice of consent to be treated as the legal parent of any resulting child) e) with the consent of each person who could be identified from the information (although disclosure in this case is limited to information other than that from which a donor of gametes could be identified) f) in connection with specific proceedings, including, for example, in relation to the formal complaints procedure, or g) in an emergency, if disclosure is necessary to avert imminent danger to the health of the person to whom the information relates, and it is not reasonably practicable to obtain their consent to disclosure. |
| 11.8. Please specify what measures are in place to ensure that the | Donor details are not stored in recipient notes and vice versa. This |

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| identity of the receipient is not disclosed to the donor and vice versa. | may not be the case if the donation is directed and the donor is known to the recipient (e.g. sibling to sibling, parent to child etc.). |
| 11.9. Does your national legislation allows disclosure of donor data in case of gametes donation? | Yes |
| 11.10. Do you have any additional comments on consent and data protection? | |
| **12. Selection, evaluation and procurement (Article 15 Directive 2004/23; Annexes I-IV Directive 2006/17)** | |
| 12.1. How do you ensure that all requirements related to the evaluation and selection of donors (except donors of reproductive cells) are respected in your country (Art. 15(1), Annex I Directive 2006/17/EC)? (more than 1 answer possible) | Other |
| Please specify 'other'. | Not applicable - this is regulated by the HTA |
| 12.2. How do you ensure that all requirements related to the evaluation and selection of donors of reproductive cells are respected in your country (Art 15 (1), Annex III of Directive 2006/17/EC)? (more than 1 answer possible) | Inspections of ART centres<br>Audit documentation<br>Other |
| Please specify 'other'. | Audit of medical files during inspections. |
| 12.3. Do you have more stringent criteria for donor selection than those listed in Annex I of the Directive 2006/17/EC? | No |
| 12.4. What sources are required in your MS for the evaluation of a deceased donor of tissues/cells? (more than 1 answer possible) | Other |
| Please specify 'other'. | The posthumous use of gametes or embryos created using gametes from a patient / donor who has since deceased may only be used in the gamete provider has been screened in accordance with the requirements set out in the EUTCD. |
| 12.5. Do you have more stringent criteria for selection of donors of reproductive cells than those listed in Annex III of the Directive 2006/17/EC? | Yes |
| 12.5.1. Please specify. | Age of donors |
| 12.6. Do you have more stringent criteria for autologous donation than those listed in Annex I of the Directive 2006/17/EC? | No |
| 12.7. Do you require more information on the donation of tissues/cells than the mandatory one as laid down in the Annex of Directive 2004/23/EC (Art 15(3)? | No |
| 12.8. How do you ensure that all requirements regarding tissues and cells' procurement, packaging and transport are complied with by tissue establishments in your country (Art 15(1), Annex IV of Directive 2006/17/EC? (more than 1 answer possible)(For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)) | Inspection of tissue establishment<br>Audit of tissue establishment<br>Inspection of the centre of human application (e.g. transplantation centre, ART centre)<br>Audit of the centre of human application<br>Other |
| 12.8.1. Please specify. | Ensure correct procedures are in place at the initial application assessment stage. Follow up during inspections. |
| 12.9. Do you have any additional comments on selection, evaluation and procurement? | |
| **13. Quality management, responsible person, personnel (Article 16, 17, 18 Directive 2004/23/EC)** | |
| 13.1. How do you ensure that tissue establishments in your country have in place a quality system respecting the provisions of the Directive 2004/23/EC Art 16.1? (more than 1 answer possible). (For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)). | Authorisation requirement<br>Inspections<br>Internal audits<br>External audits |
| 13.2. How do you ensure that tissue establishments have a responsible person fulfilling the requirements of Art. 17(1)? (more | Authorisation requirement<br>Inspections |

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| than 1 answer possible) | Regular evaluation of personnel<br>Other |
| Please specify 'other'. | An individual can be appointed as the Person Responsible (reponsible person) only with the approval of the HFEA. That person must complete this Persons Responsible Entry Programme (PREP) assessment before the HFEA can consider whether or not to approve them. |
| 13.3. How do you ensure an appropriate training for the personnel directly involved in the activities of tissue establishments? (more than 1 answer possible) | Inspections<br>Regular evaluation of personnel |
| 13.4. Do you have national/regional/local training programmes for the personnel of tissue establishments? | Yes |
| 13.4.1. If yes, please specify. | All Persons Responsible are required to complete a PR entry programme. Other personnel working within the tissue establishment may also complete this training. |
| 13.5. Any additional comments on quality management, responsible person, personnel? | |
| **14. Reception, processing, storage, labelling and packaging (Art 19-22 Directive 2004/23/EC)** | |
| 14.1. How do you ensure that tissue establishments in your country fulfill the requirments of the Art. 19 (Tissue and cell reception) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | National regulation/policy for reception of tissues/cells<br>Inspections of tissue establishments<br>Internal audits of tissue establishments |
| 14.2. How do you ensure that tissue establishments in your country fulfill the requirements of the Art. 20 (Tissue and cell processing) of Directive 2004/23/EC? (more than 1 answer possible) | SOPs for all processes affecting quality and safety are mandatory for authorisation<br>Inspections of tissue establishments<br>Internal audits of tissue establishments |
| 14.3. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 21 (tissue and cell storage conditions) of Directive 2004/23/EC? (more than 1 answer possible) | SOPs for procedures associated with storage of tissues and cells are mandatory for authorisation<br>Inspections of tissue establishments<br>Internal audits of tissue establishments |
| 14.4. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | SOPs for procedures associated with labelling and packaging are mandatory for authorisation<br>Inspections of tissue establishments<br>Internal audits of tissue establishments |
| 14.5. Any additional comments on reception, processing, storage, labelling and packaging? | |
| **15. Third party agreements (Art. 24 Directive 2004/23/EC)** | |
| 15.1. Are third party agreements foreseen/allowed in your national legislation? | Yes |
| 15.1.1. If yes, have tissue establishments in your Member State notified third party agreements? | Yes |
| 15.1.1.1. Under which circumstances and for which responsibilities? | The HF&E Act 1990 (as amended) requires licensed centres to establish written agreements with third parties every time an external activity will be carried out that influences the quality and safety of gametes procured, tested or processed. |
| 15.1.1.2. How are third party agreements controlled (Art 6.2) by the Competent Auhtority(ies) in your MS? Please specify. | Third party agrement are reviewed during the inspection process. |
| 15.2. Any additional comments on third party agreements? | |
| **16. General comments - implementation** | |
| 16.1. Do you have at national level more stringent quality and safety requirements than those requested by the EU legislation in this field (e.g. restrictions concerning the donation/use of certain tissues/cells, mandatory unpaid donation etc.)? | Yes |
| 16.1.1. Please specify. | The HF&E Act 1990 (as amended) provides that only permitted gametes or embryos may be used in treatment. |
| 16.2. Has your Member State encountered any difficulties in implementing the requirements in the EU Tissues and Cells Directives? Please choose from the options below. | No difficulties |
| 16.2.1. For all selected options in question 16.2., please provide a short description. | No specific difficulties to report. |

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| 16.3. In your opinion, in which of the following Directives are there shortcomings (if any)? (more than 1 answer possible) | Directive 2006/17/EC |
| 16.3.2. How would you suggest to solve these issues in Directive 2006/17/EC? | We would like to see a revision of this Directive and in particular Annex III. We consider that the technical nature of this Directive requires that is reviewed on a regular basis to ensure that it continues to reflect scientific development. In particular, we would welcome of a review of the requirment to screen and test non-partner donors each time gametes are procured and a review of the requirement for HTLV testing for all gamete donors |

| **UK - HTA** | |
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| **1. Public information** | |
| 1.1. Name of National Competent Authority (NCA) 1: | Human Tissue Authority (HTA) |
| 1.1.2. Address of NCA 1: | 151 Buckingham Palace Road London SW1W 9SZ United Kingdom |
| 1.1.3. Telephone (central access point): | +4420 7269 1900 |
| 1.1.4. E-mail (central access point): | enquiries@hta.gov.uk |
| 1.1.5. Website: | www.hta.gov.uk |
| 1.1.6. The NCA is responsible for? (more than 1 answer possible) | Non-reproductive tissues and cells<br>Blood and blood components<br>Human organs<br>Other |
| Please specify 'other': | The HTA licenses organisations in England, Wales and Northern Ireland that remove, store and use human tissue for purposes outside of direct patient treatment, under the authority of the Human Tissue Act 2004. These other purposes include anatomy, research, post-mortem examination, teaching, and public display. In Scotland, the Human Tissue (Scotland) Act 2006 applies. |
| 1.1.7. What are the role/tasks of the NCA? (more than 1 answer possible) | Accreditation, authorisation, licensing of TEs<br>Inspection<br>Vigilance<br>Other |
| Please specify 'other': | The HTA also gives approval for organ and bone marrow donations from living people and is involved in policy development and implementation. |
| 1.2. National Competent Authority 2? | No |
| 1.5. Please give a short description of the legal status and organisation of the National Competent Authority(ies) (e.g. departments, staffing, number of senior and junior inspectors, staff working on EU affairs and legal matters, vigilance officers, budget, independence from government etc.). | The HTA is an independent government watchdog, operating as a UK arms-length body, sponsored by the Department of Health. It employs approximately 40 staff, divided into four directorates: Regulation, Communications and Public Affairs, Resources and Strategy and Quality. Each of these directorates are led by a Director, reporting to the CEO. The Regulation team has approximately 17 Regulation Managers (RMs) (who comprise the inspection and vigilance team), reporting to three Heads of Regulation. The Regulation directorate also comprises the licensing and scheduling team and Regulation Officers to support RMs and Heads. RMs and members of the Strategy and Quality Directorate are involved in policy work, including EU affairs. The Resources team include legal, finance and governance and business technology Heads. Decisions about the general strategic direction of the HTA and complex living organ donation matters are made by a board (12 members and a Chair). The board delegates responsibility for some strategic decision making to the senior management team. |
| 1.6. In case of MS with federal or decentralised systems, please indicate the roles/tasks of the Regional Competent Authority(ies). (more than 1 answer possible) | Not applicable |
| 1.7. Could you please describe the competence/mandate of the Regional Competent Authority(ies) and their relation with the National Competent Authority(ies) for tissues and cells: | Not applicable |
| **2. Procurement (Article 5 Directive 2004/23/EC)** | |

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| 2.1. Do you authorise the "conditions of procurement"? | Yes |
| 2.1.1. How do you authorise the "conditions of procurement"? (more than 1 answer possible) | By inspecting some procurement centres<br>By inspecting the documentation associated with procurement that is available in the tissue establishment working with procurement centres<br>Other |
| Please specify 'other': | We license and inspect establishments that carry out procurement activities and provide advice on standards related to conditions of procurement. We may not inspect all procurement centres as some procurement centres operate through a third party agreement with a licensed establishment. Designated Individuals (i.e 'responsible persons') must ensure that suitable practices, staff and premises take place at third party establishments, they will do this in a variety of ways, including conducting audits of the third party. The HTA reviews third party arrangements during a routine inspection of the licensed establishment. |
| 2.1.2. How many such authorisations were granted in 2011 (01/01-31/12/2011)? | Nine new licences were granted in 2011 for procurement activity. We conducted 68 inspections of establishments that were licensed for Procurement in that period. |
| 2.2.1 Please provide the number of procurement centres in which procurement of "traditional tissues and cells" (skeletal tissues, cardiovascular tissues, skin, ocular tissues, amniotic membrane, pancreatic islet, hepatocytes, adipose tissue etc.) were carried out in 2011 (01/01-31/12/2011). | 58 |
| 2.2.2 Please provide the number of procurement centers in which procurement of haematopoietic stem cells (bone marrow, PBSC, cord blood etc.) were carried out in 2011 (01/01-31/12/2011). | 21 |
| 2.2.3 Please provide the number of procurement centers in which procurement of gametes, embryos and other reproductive tissues were carried out in 2011 (01/01-31/12/2011). | Two. This is only applicable for ovarian or testicular tissue. Procurement of gametes, embryos and other reproductive cells are within the remit of the HFEA. |
| 2.2.4. Please provide the number of procurement centers in which procurement of tissues/cells for ATMP manufacturing were carried out in 2011 (01/01-31/12/2011). | 13 |
| 2.3. How do you ensure that procurement centres comply with the requirements laid down in Art. 5 of Directive 2004/23/EC and its implementing Directive 2006/17/EC (e.g. trained personnel, conditions accredited, designated, authorised, licensed) ? (more than 1 answer possible) | Inspections of the site/centre<br>Analysis of the mandatory documentation<br>Other |
| Please specify 'other': | We also require submission of annual activity data by licensed establishments. We investigate allegations made about non-compliance with procurement standards. To ensure continued compliance, we send out correspondence to the sector, for example through the regular HTA newsletter. We run regular workshops for the sector to ensure that they stay up to date with regulatory requirements. Designated Individuals are also required to undergo an online training programme. |
| 2.4. Are you also responsible for the accreditation, designation, authorisation or licensing of laboratories performing donor testing? | Yes |
| 2.4.1. Please provide the number of the laboratories performing donor testing. | There are 98 establishments that are licensed to oversee donor testing. Laboratories are not directly licensed by the HTA. Clinical Pathology Accreditation (CPA), a private organisation, provides a voluntary national accreditation service. over 95% of UK labs are CPA accredited. |
| 2.5. How do you ensure, as CA for T&C, that tests required for donors are carried out only by qualified laboratories accredited, designated, authorised or licensed Art. 5(2))? (more than 1 answer possible) | Inspections of the laboratories<br>Analysis of the mandatory documentation requested from the tissue establishment<br>Other |
| Please specify 'other': | Any laboratory undertaking testing under the EUTCDs must either be a licensed entity or it must be working under a third party agreement (TPA) with a licensed establishment. We verify that establishments are only using laboratories where there is a TPA in |

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| | place; TPA's must include requirements for reporting serious adverse events and reactions and traceability. Even though we do not always inspect laboratories, we do sometimes include laboratories as part of the inspection, including ascertaining that lab testing is done with CE marked kits. |
| 2.6. Please provide data on qualified laboratories accredited, authorised or licensed in your country (e.g. number, year of accreditation/authorisation/license, which donor tests are performed etc.). | There are 98 establishments that are licensed to oversee donor testing. These establishments may include laboratory premises, however laboratories are not directly licensed by the HTA. Clinical Pathology Accreditation (CPA), a private organisation, provides a voluntary national accreditation service. We can directly license laboratories for testing, however there are no active licences held by TEs that are laboratories only. There was one licence held by a laboratory involved in testing in 2011, however this is now inactive. |
| 2.7. Do you have any additional comments on procurement? | The minimum testing requirements can be found in paragraphs 90 – 94 of our Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment . These tests apply to all relevant material for the purposes of the Human Tissue (Quality and Safety for Human Application) Regulations 2007. The following biological tests must be performed for all donors as a minimum requirement: HIV 1 and 2 - Anti-HIV-1,2 Hepatitis B - HBsAg, Anti HBc Hepatitis C - Anti-HCV-Ab Syphilis - Treponema pallidum HTLV-I antibody testing must be performed for donors living in, or originating from, high-prevalence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas. |
| **3. Testing (Art. 4, Annexes I, II and III of Directive 2006/17/EC)** | |
| 3.1. Please specify laboratory tests required for donors of non-reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>HBs AG<br>Anti HBc<br>Anti HCV-Ab<br>Treponema Pallidum<br>HTLV-2 |
| 3.2. Please specify laboratory tests required for donors of reproductive tissues and cells in your Member State. (more than 1 answer possible) | Anti-HIV 1<br>Anti-HIV 2<br>HBs AG<br>Anti HBc<br>Anti HCV-Ab<br>HTLV-2<br>Treponema Pallidum |
| 3.3. If NAT testing is not mandatory in your country, could you please indicate whether you intend to make it mandatory or to encourage its use? Please specify why or why not (e.g. number of additional cases detected, cost-benefit etc.). | NAT testing is not currently mandatory in the UK. The Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) advises UK ministers and health departments on the most appropriate ways to ensure the safety of blood, cells, tissues and organs for transfusion/transplantation. SaBTO has recommended NAT, in particular product testing rather than donor serum testing. The HTA considers that there is a very strong case for requiring mandatory NAT testing, particularly in instances where you might have a treatment involving donation from multiple donors and where the donations are not stored and therefore cannot be retested at 180 days. |
| 3.4. Do you have concerns on accuracy of the available tests and test procedures for deceased donors? | No |
| 3.5. Are any other laboratory tests required for donors of non-reproductive tissues and cells in your Member State? | No |
| 3.6. Are any other laboratory tests required for donors of reproductive tissues and cells in your Member State? | No |
| 3.7. Do you request/use international accreditation systems for testing laboratories? | No |
| 3.8. Do you have any additional comments on testing? | Please note for 3.2 this is only applicable for ovarian or testicular tissue which may come under the HTA's remit. Gametes and |

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| | embryos come under the authority of the Human Fertilisation and Embryology Authority (HFEA) in the UK. Extra tests must be undertaken, for example HTLV-1, when the conditions in Annex 111, 2.4 apply. We do not specifically request or use international accreditation systems for testing laboratories, however, some UK laboratories have European Federation for Immunogenetics Accreditation (EFI). For organ donation audits we do suggest Clinical Pathology Accreditation (a private UK provider), but do not accredit laboratories ourselves. For tissues and cells we ensure that all testing is done using CE marked kits and the correct tests are completed. |
| **4. Accreditation, designation, authorisation or licensing of tissue establishments (Article 6, Directive 2004/23/EC)** | |
| 4.1. Do you have a system of designation, authorisation, accreditation or licensing for all types of tissue establishments under your responsability? | Yes |
| 4.2. Is inspection a prerequisite for the designation, authorisation, accreditation or licensing of tissue establishments? | No |
| 4.3. Are preparation processes authorised? | Yes |
| 4.3.1. How are they authorised? (more than 1 answer possible) | During routine inspections<br>By review of a submitted application with supporting documentation |
| 4.4. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were suspended in 2011? | Four suspensions took place. These were not suspensions of the whole licence, but rather specific licensable activities. For example, one processing activity was suspended on a licence following an inspection and a regulatory action panel where critical shortfalls were found. |
| 4.5. Following inspections/controls (Art. 6.4, Directive 2004/23/EC), how many authorisations/accreditation/licenses were revoked in 2011? | 1 revocation took place. |
| 4.6. Do you require TEs to be certified by an external entity to a quality system standard (e.g. ISO, JACIE, FACT)? | No |
| **4bis. Overview of tissue/cells establishments authorised by the NCA** | |
| 4.7. Tissue establishments with authorisation pending approval at 01/01/2011 (more than 1 answer possible): | Musculo-skeletal tissue establishments |
| 4.7.2. How many musculo-skeletal tissue establishments? | one establishment storing bone. |
| 4.8. Tissue establishments with authorisations pending approval by 31/12/2011 (more than 1 answer possible): | Multi-tissue establishments<br>Other tissue establishments |
| 4.8.8. How many multi-tissue establishments? | one multi-tissue establishment and one "other" establishment. |
| 4.8.9. Please specify the type of tissues/cells and how many. | There were two TEs with pending authorisations at the end of 2011. Both licences were granted in 2012. The first "other" tissue type procures, stores, tests, processes and distributes fetal tissue. The other multi-tissue establishment stores, exports and imports bone, demineralised bone matrix, acellular bone chips, other skeletal tissue and heart valves. |
| 4.9. Tissue establishments first time authorised between 01/01/2011 and 31/12/2011 (more than 1 answer possible): | Skin tissue establishments<br>Musculo-skeletal tissue establishments<br>HSC tissue establishments<br>Cord blood tissue establishments<br>Multi-tissue establishments |
| 4.9.1. How many skin tissue establishments? | One. This is also a multi-tissue establishment. |
| 4.9.2. How many musculo-skeletal tissue establishments? | Five with skeletal tissue only, plus one other multi-tissue establishment. |
| 4.9.5. How many HSC tissue establishments? | Four with HSC type tissue only. There were an additional two multi-tissue establishments storing HSC type tissue. |
| 4.9.6. How many cord blood tissue establishments? | One. This is also a multi-tissue establishment. |
| 4.9.8. How many multi-tissue establishments? | Three multi-tissue establishments. One of these was storing amniotic membrane. |
| 4.10. All tissue establishments authorised by 31/12/2011 (more than 1 answer possible): | Skin tissue establishments<br>Musculo-skeletal tissue establishments<br>Ocular tissue establishments<br>Cardiovascular tissue establishments |

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| | HSC tissue establishments<br>Cord blood tissue establishments<br>Multi-tissue establishments<br>Other tissue establishments |
| 4.10.1.1. How many public skin tissue establishments? | Three public TEs with only skin - some multi-tissue establishments did work with skin tissue and cells among other tissue types. Skin establishments were classified as those working with whole skin, fibroblast and / or keratinocyte cells. |
| 4.10.1.2. How many private skin tissue establishments? | No private TEs with only skin - some multi-tissue establishments did work with skin tissue and cells among other tissue types. Skin establishments were classified as those working with whole skin and/or fibroblast and / or keratinocyte cells. |
| 4.10.2.1. How many public musculo-skeletal tissue establishments? | 41 public TEs with only musculo-skeletal - some multi-tissue establishments did work with musculo-skeletal tissues and cells among other tissue types. Musculo-skeletal establishments were classifed as those working with any combination of the following bone, tendons/ligaments, cartilage and chondral tissue, demineralised bone, acellular bone chips and other skeletal tissue. |
| 4.10.2.2. How many private musculo-skeletal tissue establishments? | 19 private TEs, with only musculo-skeletal. In addition some multi-tissue establishments did work with musculo-skeletal tissues and cells among other tissue types. Musculo-skeletal establishments were classifed as those working with any combination of the following bone, tendons/ligaments, cartilage and chondral tissue, demineralised bone, acellular bone chips and other skeletal tissue. |
| 4.10.3.1. How many public ocular tissue establishments? | Two public TEs with only ocular tissue - some multi-tissue establishments did work with ocular tissue among other tissue types. Establishments were classified as ocular if they worked with cornea, sclear, limbal stem cells and / or other ocular tissue. There were other ocular establishments classified as multi-establishments if working with ocular tissue and amniotic membrane (other). |
| 4.10.3.2. How many private ocular tissue establishments? | One private TE with only ocular tissue. In addition some multi-tissue establishments did work with ocular tissue among other tissue types. Establishments were classified as ocular if they worked with cornea, sclear, limbal stem cells and / or other ocular tissue. There were other ocular establishments classified as multi-establishments if working with ocular tissue and amniotic membrane (other). |
| 4.10.4.1. How many public cardiovascular tissue establishments? | Three public TEs with only cardiovascular tissue - some multi-tissue establishments did work with cardiovascular tissue among other tissue types. Establishments were classified as cardiovascular if reporting work with heart valves, iliac vessels and other vessels. |
| 4.10.4.2. How many private cardiovascular tissue establishments? | One private TEs with only cardiovascular tissue - some multi-tissue establishments did work with cardiovascular tissue (particularly cardiac and iliac vessels) among other tissue types. Establishments were classified as cardiovascular if reporting work with heart valves, iliac vessels and other vessels. |
| 4.10.5.1. How many public HSC tissue establishments? | 28 public TEs with only HSC type cells - some multi-tissue establishments did work with HSC type cells among other tissue types. The HTA does not have a specific reporting category for HSC. For the purpose of the survey establishments were categorised as HSC establishments if working with any combination of the following tissue types: PBSCs, bone marrow, cells for donor lymphocyte infusions, other blood cells and embryonic stem cells. |
| 4.10.5.2. How many private HSC tissue establishments? | Three private TEs with only HSC. In addition, some multi-tissue establishments did work with HSCs among other tissue types. The HTA does not have a specific reporting category for HSC. For the purpose of the survey establishments were categorised as HSC establishments if working with any combination of the following tissue types: PBSCs, bone marrow, cells for donor lymphocyte infusions, other blood cells and embryonic stem cells. |
| 4.10.6.1. How many public cord blood tissue establishments? | Three public TEs with only cord blood - some multi-tissue establishments did work with cord blood among other tissue types. |

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| | Please note, If an establishment reported cord blood and cord tissue, they were categorised as a multi-tissue establishment. |
| 4.10.6.2. How many private cord blood tissue establishments? | Two private TEs with only cord blood - some multi-tissue establishments did work with cord blood among other tissue types. Please note, If an establishment reported cord blood and cord tissue, they were categorised as a multi-tissue establishment. |
| 4.10.8.1. How many public multi-tissue establishments? | There were 46 public multi-tissue establishments. The combination of tissue types held varies. There was one establishment, King's Cell Isolation Unit that reported two types of "other" cells: pancreatic islets and hepatocytes. This was therefore included in the multi-tissue establishment category. |
| 4.10.8.2. How many private multi-tissue establishments? | There were 16 private multi-tissue establishments. The combination of tissue types held varies. |
| 4.10.9.1. Please specify the type of 'other' public tissues/cells establishements and how many. | There were three public tissue establishments in the other category. There were two that did not report any activity in 2011 and the other was the DRWF Human Islet Isolation Facility - reporting work with pancreatic islet cells. There was one establishment, King's Cell Isolation Unit that reported two types of "other" cells: pancreatic islets and hepatocytes. This was therefore included in the count for the multi-tissue establishment category. Other tissue type categories reported to the HTA are: "other tissues and / or cells", umbilical cord tissue, pancreatic islets, hepatocytes, amniotic membrane, adipose tissue (e.g. adipocytes). |
| 4.10.9.2. Please specify the type of 'other' private tissues/cells establishements and how many. | There were four private tissue establishments in the other category. These were: one that did not report any activity in 2011. The other three reporting "other" types of tissues and cells were MTS Cryostores, BioEden and the London Centre of Aesthetic Surgery. Other tissue type categories reported to the HTA are: "other tissues and / or cells", umbilical cord tissue, pancreatic islets, hepatocytes, amniotic membrane, adipose tissue (e.g. adipocytes). |
| 4.11. How many tissues and cells were distributed under the direct agreement of the Competent Authority according to Art. 6(5) during 2011? Please provide number(s) per type tissues/cells. | 0 |
| **4ter. Sanctions** | |
| 4.16. Have penalties for infringements of the national provisions pursuant to the Directive been defined (Article 27)? | Yes |
| 4.16.1. Have penalties already been imposed? | Yes |
| 4.16.1.1. How many penalties have been imposed in 2011 (from 01/01/2011-31/12/2011)? | There were 11 sanctions on establishments imposed in 2011, of varying degrees of severity. There are a range of sanction options open to the HTA ranging from directions and conditions to criminal penalties. For 2011, there were no criminal sanctions imposed. |
| 4.16.1.2. What were the reasons for imposing the penalties? Please describe. | There were a number of reasons for imposing the various penalties managed through the regulatory decision making process. The majority of penalties were imposed following an inspection where shortfalls against regulatory requirements had been identified. |
| 4.16.1.3. What kind of penalties were imposed? Please describe (e.g. suspension of authorisation, criminal penalty etc.) | Penalties imposed included conditions or directions on seven licences, suspensions of specific licensable activities on three licences and one revocation. There were no criminal penalties imposed. |
| 4.17. Do you have any additional comments on accreditation, authorisation, designation and licensing? | The HTA licenses procurement establishments and establishments that store viable cellular tissue for end use for more than 48 hours. From 4.2, while inspection is not a prerequisite for authorisation, we performed 89 routine HA site-based inspections (96 including non-routine inspections). Inspections are a not a prerequisite for licensing, however inspections form part of the ongoing licensing and authorisation process. Initial licence application assessments are desk-based. From 4.10.8.1 and 4.10.8.2: There is no specific HTA reporting category for a multi-tissue establishment. Establishments report on the full range of cell types, rather than identifying specifically as “a multi-tissue establishment”, so this was assessed by manually analysing the annual activity data. An establishment |

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| | was categorised as multi-tissue if it had more than one tissue in any of the EC categories, this included umbilical cord blood + umbilical cord tissue = multi-tissue, and also cord blood + HSCs = multi-tissue. Some of the eye banks also keep amniotic membrane (other) as well as ocular tissue, so these have been classified as multi-tissue establishments. Where an establishment had multiple "other" types of tissues and cells, this was also categorised as a multi-tissue establishment. |
| **5. Inspections (Article 7, Directive 2004/23/EC)** | |
| 5.1. Is a system in place for organising inspections and control measures of tissue establishments? | Yes |
| 5.1.1. If yes, please specify the CA/Department of the CA in charge of inspections. | The Regulation directorate at the HTA is in charge of inspections. |
| 5.1.2. If yes, please specify staffing (how many inspectors). | There are 17 (full time equivalent) Regulation Managers carrying out inspections. Inspections typically require one to two inspectors. |
| 5.2. Does the inspection scheme interact or overlap with the inspection scheme of other activities, for example blood, pharmaceuticals, etc. (e.g. same inspector team, common training, common documentation, etc.)? (more than 1 answer possible) | Yes |
| 5.2.1. If yes, please specify. (more than 1 answer possible) | Blood<br>Organs<br>Advanced therapies<br>Hospitals<br>Accreditation organisations (e.g. JACIE)<br>Others |
| Please specify other. | As well as being the European competent authority for tissues and cells for human application and organs, the HTA inspects a range of establishments across several sectors in the UK, being: post mortem; anatomy, research and public display. |
| 5.3. How many routine inspections of tissue establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011)? | 89 |
| 5.3.1. How many inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) following serious adverse events or reactions, or suspicion thereof ? | There were no non-routine inspections conducted as a result of an SAE or SAR. There were seven non-routine inspections conducted of TEs in 2011, but these were for other reasons such as new premises, changes to licensable activities, follow-up from a previous inspection and follow-up for progress made against conditions on the licence. |
| 5.3.2. How many other type of inspections of tissues establishments for non-reproductive tissues/cells were conducted in 2011 (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | There were seven non routine inspections in 2011 for the following reasons: 1. A move to new premises. 2. A move to new premises. 3. Checking the suitability of proposed in-house testing facilities for donor serology and NAT testing, and also to verify other recent changes to the licence. 4. A more focussed inspection required. 5. To follow up issues found on previous inspection and designated individual suitability. 6. Checking that shortfalls found during previous inspection had been rectified. 7. To assess progress against conditions. |
| 5.3.3. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | 16 |
| 5.3.4. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where minor shortcomings were noted? | 50 |
| 5.3.5. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where major shortcomings were noted? | 24 |
| 5.3.6. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What | One critical shortfall led to regulatory action panel leading to suspension of processing activity (not entire licence) |

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| was the number of inspections carried out that were followed by suspension of authorisation? | |
| 5.3.7. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out that were followed by closure? | 0 |
| 5.3.8. Outcome of inspections of TEs for non-reproductive tissues/cells conducted in 2011 (01/01/2011 to 31/12/2011): What was the number of other inspections carried out? Please specify. | 0 |
| 5.4. How many routine inspections were conducted in ART establishments (from 1/1/2011 to 31/12/2011)? | N/A |
| 5.4.1. How many inspections were conducted in ART establishments following serious adverse events or reactions, or suspicion thereof (from 1/1/2011 to 31/12/2011)? | N/A |
| 5.4.2. How many other type of inspections were conducted on ART establishments (from 1/1/2011 to 31/12/2011) (e.g. due to a whistle-blower)? Please specify. | N/A |
| 5.4.3. Outcome of inspections of ART tissue establishments carried out in 2011 (01/01/2011 to 31/12/2011): What was the number of inspections carried out where no shortcomings were observed? | N/A |
| 5.4.4. What was the number of inspections carried out in ART establishments where minor shortcomings were noted? | N/A |
| 5.4.5. What was the number of inspections carried out in ART establishments where major shortcomings were noted? | N/A |
| 5.4.6. What was the number of inspections carried out in ART establishments followed by suspension of authorisation? | N/A |
| 5.4.7. What was the number of inspections carried out in ART establishments followed by closure of respective establishements? | N/A |
| 5.4.8. What was the number of other inspections of ART establishments? Please specify. | N/A |
| 5.5. Which type of routine inspections do you conduct? (more than 1 answer possible) | General system-oriented inspections<br>Thematic inspections<br>Desk based reviews |
| 5.6. How do you decide which type of routine inspection to conduct? | Desk-based reviews generally take place for the initial application assessment. Inspections are scheduled within the two year time frame using a risk tool to prioritise inspections. The HTA is currently modifying its risk assessment tool. Typical factors include size of establishment and range of activity, experience of designated individual responsible for oversight of the licence and compliance history. The risk tool is also being developed to determine whether inspections should be general or themed. A recent themed inspection pilot used a number of the factors mentioned above, including input from Regulation Managers to identify suitable establishments. |
| 5.7. Until 2011, did you implement the requirement concerning the time interval between two inspections (Art. 7.3.)? | Yes |
| 5.8. How many TEs were inspected at least twice between 2008-2011 (01/01/2008-31/12/2011)? | 112 HA licences were inspected at least twice during this period. |
| 5.9. Did you perform/conduct inspections of procurement sites outside tissue establishments? | No |
| 5.9.2. If no, why not? | The Designated Individual is responsible for oversight of any third parties. Third party agreements (TPAs) are to be reported to the HTA, although this is not authorised by the HTA at the time of submission. TPAs are reviewed during inspection. Annex C - Statutory conditions on licences authorising activities that may involve third parties states: "The Licence Holder, and, where different, the Designated Individual, any person to whom a licence applies, any third party with whom the establishment has a third party agreement, and any personnel of either the licensed establishment or third party, must secure that all necessary arrangements are made to ensure that all information which is collected in pursuance of the licence or a third party agreement in |

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| | relation to the licence: (a) is available for the purpose of tracing donations; (b) is kept up-to-date and corrected without delay where any discrepancy relating to such information is identified; and (c) is held securely and subject to safeguards against unauthorised additions, deletions, modifications and transfer of information." |
| 5.10. Did you carry out inspections of third parties? | No |
| 5.10.2. If no, why not? | The Designated Individual is responsible for oversight of any third parties. Third party agreements (TPAs) are to be reported to the HTA, although this is not authorised by the HTA at the time of submission. TPAs are reviewed during inspection. |
| 5.11. Do you use at national level the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections (Commission Decision 2010/453/EU)? | No |
| 5.11.1. If no, which guidelines/regulations are used for inspections at national level? | We do not use the Operational Manual for Competent Authorities on inspection of tissue and cell procurement and tissue establishments - Guidelines for inspections, however our inspection guidelines are based on this document. For example, we have adopted the preparation process dossier template. We provide establishments with the 'Guide to the quality and safety assurance of human tissues and cells for patient treatment' on our website, to assist them with inspection preparation. We use internal standard operating procedures to provide guidance for Regulation managers on how to conduct an inspection including: - REG-SOP-103 Preparing for a routine HTA site visit inspection; - REG-SOP-105 Scheduling and preparing for a joint inspection with the MHRA; and - REG-SOP-106 Conducting a joint inspection with the MHRA. |
| 5.11.2. If no, please provide a hyperlink to these guidelines/inspections. | http://www.hta.gov.uk/_db/_documents/Annex_-_Guide_to_Quality_and_Safety_Assurance_for_Tissues_and_Cells_for_Patient_Treatment.pdf |
| 5.12. Did you send any of your inspectors to the training courses organised by EU-funded projects (e.g. EUSTITE, SOHO V&S)? | Yes |
| 5.12.1. If yes, how would you rate the usefulness and efficacy of these training courses on a scale from 1 to 5 (1 = not important, 2 = sufficient, 3 = good, 4 = very good, 5 = essential)? | 5 |
| 5.13. Did you request/organise an inspection of a tissue establishment in another MS in collaboration with the NCA in that MS (Art 7(6))? | Yes |
| 5.13.1. Could you please explain why? | A Regulation Manager observed an inspection in Germany in 2012 following allegations made against a German tissue establishment about procurement without consent. The HTA participated in this because of potential effects on UK establishments importing tissue from Germany. |
| 5.14. Did you receive/organise an inspection of a tissue establishment in your country at the request of another MS in collaboration with the NCA in that MS (Art 7(6))? | No |
| 5.15. Did you organise any inspections of procurement centres or tissue establishments in third countries from which tissues and/or cells were imported in your country (as recorded by 31/12/2011)? | No |
| 5.16. Have you asked another MS, or have you been requested by any other MS, on the results and control measures of your inspections, as part of an enquiry/investigation? | Yes |
| 5.16.1. If yes, please specify. | We do not keep records on the number of requests from or to other member states. We frequently liaise with other competent authorities over issues of mutual interest, such as the results and control measures of inspections, as part of general enquiries or investigations. |
| 5.17. Would you be interested in developing joint inspections? Joint inspections should be understood as inspections of tissue establishments conducted jointly by two or more Member States' | Yes |

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| Competent Authorities on their territory or in third countries. | |
| 5.18. Do you have any additional comments on inspections? | From 5.2.1: There are a number of other UK healthcare regulatory agencies with work adjoining that of the HTA. In particular, we carry out joint inspections with the Medicines and Healthcare products Regulatory Agency (responsible for blood, devices and medicines) at establishments who are developing Advanced Therapy Medicinal Products. We are also developing similar arrangements with the Human Fertilisation and Embryology Authority which regulates embryos and gametes. For example, establishments where hESCs are derived from embryos and establishments that procure,test, process, store ovarian / testicular tissue. We also inspect sites such as laboratories and hospitals that are also inspected by other accreditation organisations, such as JACIE, NetCord-FACT and the Clinical Pathology Accreditation organisation. Other interactions include work with NHS Blood and Transplant, where work intersects with the MHRA's regulation of the Blood Directives. There has been some engagement with the US Food and Drug Administration to exchange information about establishments. |
| **6. Import/export (Article 9 Directive 2004/23/EC)** | |
| 6.1. Do you have a register of authorised tissue establishments that are explicitly authorised to perform import/export of tissues and celles from/to third countries? | Yes |
| 6.2. Please specify the number of tissue establishments authorised to import tissues and cells from third countries (recorded by 31/12/2011). | 63 |
| 6.3. Please specify the number of tissue establishments authorised to export tissues and cells from third countries (recorded by 31/12/2011). | 54 |
| 6.4. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of skin from third countries. | We verify equivalent standards of quality and safety for importation of all tissues and cells from third countries is in place through the initial licence application assessment and inspections. |
| 6.5. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of musculo-skeletal (bone, tendons, fascia etc.) tissues from third countries. | We verify equivalent standards of quality and safety for importation of all tissues and cells from third countries is in place through the initial licence application assessment and inspections. |
| 6.6. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of ophtalmic (cornea, sclera, etc) tissues from third countries. | We verify equivalent standards of quality and safety for importation of all tissues and cells from third countries is in place through the initial licence application assessment and inspections. |
| 6.7. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cardio vascular tissues from third countries. | We verify equivalent standards of quality and safety for importation of all tissues and cells from third countries is in place through the initial licence application assessment and inspections. |
| 6.8. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of haematopoietic stem cells (HSC) (other than cord blood) from third countries. | We verify equivalent standards of quality and safety for importation of all tissues and cells from third countries is in place through the initial licence application assessment and inspections. |
| 6.9. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of cord blood from third countries. | We verify equivalent standards of quality and safety for importation of all tissues and cells from third countries is in place through the initial licence application assessment and inspections. |
| 6.10. Please specify which procedures you have in place for verifying the equivalent standards of quality and safety for importation of reproductive cells (sperm, egg cells) from third countries. | This is only relevant in the case of ovarian or testicular tissue. Sperm, egg cells and embryos fall within the remit of the HFEA. We verify equivalent standards of quality and safety for importation of all tissues and cells from third countries is in place through the initial licence application assessment and inspections. |
| 6.11. Did you import tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | Yes |
| 6.11.1. If yes, please provide the data concerning the number/volume of imported tissues and cells by country of origin. | We do not collect data on specific country of origin. The total number of tissues and cells imported during 2011 was 22539. |
| 6.12. Did you export tissues/cells from 3rd countries during 2011 (01/01/2011-31/12/2011)? | Yes |
| 6.12.1. If yes, please provide the data concerning the number/volume of exported tissues and cells by country of | We do not collect data on specific country of destination The total number of tissues and cells exported during 2011 was 216. |

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| destination. | |
| 6.13. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on imports/exports of tissues/cells between your country and other third countries? | No |
| 6.14. What is the relation between import/export of tissues and cells and self-sufficiency? (more than 1 answer possible) | C. Export of tissues/cells is authorised irrespective of national needs<br>F. Other |
| Please specify 'other': | We are not responsible for determining national needs, when authorising tissue establishments to import and export tissues and cells. Certain licensed establishments do however take national need into account, for example, NHS Blood and Transplant and the Anthony Nolan Trust, a charity involved in collection and allocation of cord blood cells to address national needs. |
| 6.15. Did you authorise direct imports of tissues/cells to hospitals/clinics in your country? | Yes |
| 6.15.1. If yes, please specify the number of cases and for which type of tissues/cells. | We have directly authorised one import of a cranial flap autograft from the USA. |
| 6.16. Do you have any additional comments on import/export? | We provide guidance for TEs in the form of the 'Guide to the quality and safety assurance of human tissues and cells for patient treatment' at: http://www.hta.gov.uk/_db/_documents/Annex_-_Guide_to_Quality_and_Safety_Assurance_for_Tissues_and_Cells_for_Patient_Treatment.pdf Specific guidance on import and export is available from paragraphs 203 - 210. We also provide FAQs on distribution, import and export on our website at: http://www.hta.gov.uk/licensingandinspections/sectorspecificinformation/tissueandcellsforpatienttreatment/distributionandimportexportfaqs.cfm Further guidance which we provide to all our sectors regulated under the Human Tissue Act 2004 is available in the form of the code of practice 8: import and export of human bodies, body parts and tissue: http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code8importandexport.cfm For 6.9 specifically: Guidance on import and export related to cord blood is also provided through our guidance document on cord blood: http://www.hta.gov.uk/_db/_documents/Cord_Blood_Guidance_Document_final_draft.pdf We have also directly authorised two exports to date: one heart valve to Egypt and one PBSC autologous sample to the USA. We have seen an increase in the level of oversight required to ensure that products imported from the US meet equivalent standards. HTA is organising meetings with the American Association of Tissue Banks and FDA in October with the aim of starting to address some of the issues. HTA is involved in the Import / Export Working Group and considers that many of the current difficulties of ensuring equivalence will be addressed by the introduction of the proposed Implementing Directive. We also consider that there is scope to explore the value of establishing an EU inspectorate for third countries. |
| **7. Distribution/intra community exchanges (Article 23 Directive 2004/23/EC)** | |
| 7.1. Do you have intra-community exchanges of tissues and cells? | Yes |
| 7.1.1. If yes, how do you address the possible more stringent quality and safety measures established by other Member States? Please specify. | Tissue establishments are required to put into place service level agreements with licensed establishments in other member states to define the obligations for complying with relevant requirements across jurisdictions. |
| 7.1.2. If yes, do you have more stringent quality and safety measures than in other Member States? | No |
| 7.2. How do you ensure that tissues establishments fulfil the requirements of Art. 23 of Directive 2004/23/EC regarding quality of tissues and cells during distribution? Please specify. | Tissue establishments are required to put into place service level agreements with licensed establishments in other member states to define the obligations for complying with relevant requirements across jurisdictions. |
| 7.3. Do you allow direct distribution to hospitals/clinics in your MS from TEs in another MS? (only 1 answer possible). | Other |
| Please specify 'other'. | We do allow direct distribution to end users, without requiring a |

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| | licence, provided tissues and cells will not be stored for longer than 48 hours. |
| 7.4. Have you authorised direct distribution to the recipient of specific tissues and cells (Art. 6, Directive 2006/17/EC)? | No |
| 7.5. Do you collect data regarding the cross-border exchange of tissue/cells between your country and other EU MS? | Yes |
| 7.5.1. Please provide us with data (country of destination, type of tissue/cell and number of units distributed) concerning distribution to other MS in 2011 (01/01/2011-31/12/2011). | We do not collect information on country of destination. The total number distributed to other MS in that period was 41271. |
| 7.5.2. Please provide us with data (country of origin, type of tissue/cell and number of units distributed) concerning distribution to other MS in 2011 (01/01/2011-31/12/2011) | We do not collect information on country of origin. The total number distributed from other MS in that period was 238244. Please note - the question wording above says "to other MS" this would be the same response as 7.5.1. We have assumed that the question should have read "from other MS". |
| 7.6. Are you aware of any significant changes in 2012 which may invalidate the 2011 data on cross-border exchanges of tissues/cells between your country and other EU MS? | No |
| 7.7. Do you allow brokerage companies for either distribution in EU and/or import/export of tissues/cells? In this context, a brokerage company means a body that arranges transactions between a supplier (tissue establishment/company selling tissues or cells) and a buyer (a tissue establishment/a hospital or clinic/an individual) without undertaking activities of processing, preservation or storage. | Yes |
| 7.7.1. Please describe the legal requirements and your role (if any) as a Competent Authority, in their authorisation/monitoring or inspection. | There are organisations that operate in the UK as intermediaries obtaining tissue for end users, however most of these are licensed as they are engaged in an intermediate storage step. Our role is therefore to authorise these and monitor them through inspection. We currently license one broker, Cryolife. It is only licensed for distribution, import and export, without storage. We have licensed another broker in the past engaged in the activities of distribution, import and export, however storage was also listed on that licence. The licence is now inactive. |
| 7.8. Are brokers actively supplying health professionals/establishments in your country? | Yes |
| 7.8.1. Where are the brokers located? | Your country |
| 7.9. Do you have any additional comments on distribution? | |
| **8. Register of tissue establishments and reporting obligations (Article 10, Directive 2004/23/EC)** | |
| 8.1. Do you have an annual report model/template on the activities of tissue establishments in your Member State? (Article 10(1)). If yes, please upload the template. | Yes |
| 8.2. How many tissue establishments submitted annual reports of their activities during 2011. Please provide an estimation. (1 answer possible) | 100% (all) |
| 8.3. Are these reports publicly available? (Article 10(1)) | No |
| 8.4. Do you publish a national annual report of the consolidated activities of all tissue establishments in your country? | No |
| 8.4.2. If no, why not? | Currently the data are not publicly available, but we direct enquiries about these data to the Eurocet site. UK licensed establishments do not want potentially sensitive commercial information to be made publicly available. |
| 8.5. Is there a publicly accessible register of authorised tissue establishements in place? (Article 10(2)) | Yes |
| 8.5.1. If yes, please provide us with the link to the register's web site. | http://www.hta.gov.uk/_db/_documents/Licensing_Reports_-_HA_201307021659.pdf |
| 8.6. Do you provide data regarding tissues and cells activities to the EUROCET registry (non-mandatory reporting)? | Yes |
| 8.6.1. If yes, what data are provided to EUROCET? Please specify. | We supply annual activity data to the EC and we assume this information then goes to the EUROCET registry. We complete all mandatory reporting. |
| 8.7. Do you have any additional comments on reporting? | |

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| **9. Traceability (Article 8, Directive 2004/23/EC; and Directive 2006/86/EC)** | |
| 9.1. Was the donor identification system (Art. 8(2)) implemented in your country? | Yes |
| 9.2. Who assigns the unique code for each donation? (only 1 answer possible) | Other |
| Please specify 'other'. | Tissue establishment or procurement centre. |
| 9.3. How is the data storage for traceability purposes organised in your tissue establishements (Art 8(4))? (only 1 answer possible) | Both paper records and electronic forms |
| 9.4. How do you ensure that the 30 years data storage requirement is respected (Directive 2006/89/EC, Art. 9)? Please specify. | We require a records retention policy to be in place. We check this is in place both at the initial licence application stage and during inspections. |
| 9.5. Do you have any additional comments on traceability? | |
| **10. Notification of serious adverse events and reactions (Article 11 Directive 2004/23, Article 6 Directive 2006/86)** | |
| 10.1. Do you have a national vigilance system in place (for the reporting of serious adverse events and reactions (Article 11(1))? | Yes |
| 10.1.1. If yes, which CA/institution is responsible? | HTA |
| 10.1.2. If yes, please provide a short description of its organisation. | The HTA is a government sponsored regulator and the UK Competent Authority for Tissues and Cells and the Competent Authority under the EU Organ Donation Directive. We are an independent watchdog which ensures human tissues and organs are used safely and ethically and with proper consent. We regulate organisations that remove, store and use tissue for research, anatomy, medical treatment, post-mortem examination, teaching and display in public. We also give approval for organ and bone marrow donations from living people. |
| 10.2. Annual reporting (Article 6.4, Dir. 2006/86/EC). Do you use the SAR/E (to the CA (2006/86 art 6.4)) templates developed to the Annual reporting ot the EC also at national level? | No |
| 10.2.1. If no, what template do you use? You are welcome to upload the template if you wish. | Licensed establishments in the tissues and cells for patient treatment sector are required to report SAREs to the HTA within 24 hours of them being discovered. Establishments report via our web Portal and reports are assigned to an HTA Regulation Manager (RM) who reviews the establishment's investigation of the matter. Establishments are asked to provide a copy of their internal investigation report within 90 days of submitting the notification. All communication and RM notes about the SAREs are stored against the licence record on our licence management system, CRM. |
| 10.3. Do you use the Common Approach Document developed for the Annual reporting to the EC also at national level? | No |
| 10.3.1. If no, please specify what guidelines you use. | We signpost establishments to the EUTITE V&S Tools for reference when they report SAREs. Information and guidance about SAREs reporting is also provided by RMs on inspection and in our Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment on our website, on pages 40-41 and in Annexes C and D. http://www.hta.gov.uk/_db/_documents/Annex_-_Guide_to_Quality_and_Safety_Assurance_for_Tissues_and_Cells_for_Patient_Treatment.pdf |
| 10.4. Do you have a dedicated vigilance officer in charge of collecting SAR/E from all TEs? | No |
| 10.4.1. Why not? | The HTA has a dedicated team of Regulation Managers in place who assess SAREs from establishments. The team have monthly meetings and promote SAREs reporting and learning across the HTA and when on inspection. A Regulation Officer acts as the administrator and data manager for the team and the reporting system is monitored by the team on a 24 hour basis, and any reports received are responded to within 24 hours. |
| 10.5. How many tissue establishments provided in 2011 the SAR/SAE data as requested (please provide the % from the total number of TEs authorised in your country). | 100% |
| 10.6. Do you have a mandatory procedure for the transplantation centres when reporting SAR/SAE to the TEs which distributed the | No |

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| tissues/cells (Art 11.2)? | |
| 10.6.2. If no, how do you ensure that SAR/SAE are reported to the TEs? | The SAREs reporting requirement is outlined in HTA standards and when establishments initially apply for a licence in the tissues and cells for patient treatment sector. Establishments licensed by the HTA are required to have end-user agreements in place with transplantation centres, which include the requirement to report SAREs. Incident reporting is promoted and monitored on inspection. |
| 10.7. Do you give feedback to the TEs regarding SAR/SAE recorded at national level? | Yes |
| 10.7.1. Please specify. | The HTA provides feedback during inspections, to suggest better practice through lessons learned from SAR/Es. We notify establishments about any SAR/E implications in a regular e-newsletter. We are currently organising a SAREs workshop for October 2013 which will share learning and best practice. It will include interactive sessions to allow staff from licensed establishments to discuss SAREs reporting. We are also considering how we can provide further guidance on our website, e.g. by publishing case studies. |
| 10.8. Do you give feedback to the TEs regarding SAR/SAE recorded at EU level? | Yes |
| 10.8.1. Please specify. | The HTA provides feedback during inspections, to suggest better practice through lessons learned from SAREs. We notify establishments about any SARE implications in a regular e-newsletter. We are currently organising a SAREs workshop for October 2013 which will share learning and best practice. It will include interactive sessions to allow staff from licensed establishments to discuss SAREs reporting. |
| 10.9. Do you require your TEs to have a recall procedure? | Yes |
| 10.10. How many recalls related to safety and quality of tissues/cells were issued in your country in 2011? Please specify the number and which tissues were recalled and why (e.g. missing consent, quality defects etc). | The HTA did not issue any recalls related to the quality and safety of tissues and cells in 2011. We are aware that three establishments issued recalls as follows in 2011: -Recall of heart valves due to faulty packaging. -Recall of corneas due to microbiological contamination. -Recall of corneas which had been released prematurely from quarantine. |
| 10.11. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites in case of a national rapid alert? | Yes |
| 10.11.1. If yes, please give a short description of the system/procedure. | Our process is formalised in REG-SOP-033-Preparing and Issuing a Regulatory Alert. A decision to issue a regulatory alert can be made for a number of reasons, including: information from the EU, another CA/regulator, a serious adverse event or reaction or other regulatory action. Once a decision is made to issue an alert, the alert is added to the regulatory alert register. The Head of Media/Communication and Communications Officers are informed and a distribution list and lines to take are prepared. The distribution list is based on data we hold about the activities of potentially affected UK establishments and the tissues/cell types they work with. The alert wording is approved by a Head of Regulation or Director of Regulation and reviewed by the Head of Media/Communication. Once the alert is approved, we issue a statement on our website and email all establishments on the distribution list. The Head of Regulation or Director of Regulation reviews all responses to the alert. |
| 10.12. Do you have in place a system/procedure to notify Tissue Establishments and procurement sites when a rapid alert is issued via the EU RATC platform? | Yes |
| 10.12.1. If yes, please give a short description of the system/procedure. | A RATC is one of the reasons we may make a decision to issue a regulatory alert. If we believe UK establishments are affected by the RATC, we will issue a rapid alert following our formal process in REG-SOP-033-Preparing and Issuing a Regulatory Alert. Once a decision is made to issue an alert, the alert is added to the regulatory |

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| | alert register. The Head of Media/Communication and Communications Officers are informed and a distribution list and lines to take are prepared. The distribution list is based on data we hold about the activities of potentially affected UK establishments and the tissues/cell types they work with. The alert wording is approved by a Head of Regulation or Director of Regulation and reviewed by the Head of Media/Communication. Once the alert is approved, we issue a statement on our website and email all establishments on the distribution list. The Head of Regulation or Director of Regulation reviews all responses to the alert. |
| 10.13. Do you provide data regarding SAR/SAE to the EUROCET registry (non-mandatory reporting)? | No |
| 10.13.2. If no, please specify why not. | Reporting not mandatory. We report all mandatory information. |
| 10.14. Do you notify alerts communicated via these tissues and cells national vigilance system also to other national vigilance/alert systems? | Yes |
| 10.14.1. If yes, please specify which of the following systems are usually contacted. (more than 1 answer possible) | Haemovigilance<br>Pharmacovilance<br>Medical devices<br>Other |
| Please specify 'other'. | We communicate alerts to the Medicines and Healthcare products Regulatory Agency and Human Fertilisation and Embryology Authority. We also share details of SAREs reported to us if we believe they could have an impact on medicines and healthcare products and/or reproductive tissues and cells. |
| 10.15. Did you send a vigilance officer/contact point to the trainings organised by the EU-funded project SOHO V&S? | Yes |
| 10.15.1. If yes, how would you rate the usefulness and efficacy of these trainings on a scale from 1 (insufficient) - 2 (sufficient) 3 (good) - 4 (very good) to 5 (essential)? | 5 |
| 10.16. Do you have any additional comments on SARE reporting? | 10.5 above is actually not applicable for the HTA: Establishments report SAREs within 24 hours of their discovery, and not via an annual report. As a result, we may not receive data from every establishment every year, as serious reactions or events may not take place at every establishment. We received a total of 130 SARE reports in 2011. We found the training excellent. We follow the EC RATC Platform standard operating procedures when reporting an incident on the RATC platform. |
| **11. Consent and personal data protection (Article 13 and 14, Directive 2004/23/EC)** | |
| 11.1. What consent system for living tissue/cell donation do you have in place within your Member State? | Explicit consent (opt-in) |
| 11.1.1. Please specify your choice of consent system for living tissue/cell donation. | Consent or authorisation is given by the donor . If a donor is a child, the child or a person with parental responsibility can give consent. If an adult has mental incapacity, an appropriate person can give consent on their behalf, in line with the Mental Capacity Act. Peripheral Blood Stem Cell donations from children are subject to an approval process by HTA volunteer accredited assessors. This involves interviews with the donor and recipient to ensure there are no potential issues around coercion etc. Any difficult cases can be referred to the HTA Board for a final decision. |
| 11.2. What consent system for deceased tissue/cell donation do you have in place within your Member State? | Presumed (opt-out) and explicit (opt-in) consent |
| 11.2.1. If you have chosen both consent systems for deceased tissue/cell dontation, please specify. | The Welsh national assembly has recently passed a Bill to change the Welsh position to one of presumed (opt-out)consent. This system is not yet in place, but will be different from the rest of the UK, which currently has an explicit (opt-in) system of consent. |
| 11.3. According to your national legislation, in case of deceased donations, please specify who is giving the authorisation for the tissue donation? (more than 1 answer possible) | First degree relatives (including spouse)<br>Other relatives<br>Non-marital partners<br>Friends<br>Other |

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| Please specify 'other'. | In England, Wales and Northern Ireland a person in life or a person's "nominated representative" can give consent. There is no mention of "nominated representatives" under the Human Tissue (Scotland) Act. |
| 11.4. Is the consent system for deceased tissue donation the same as for organs? | Yes |
| 11.5. How is this consent verified during inspections? (more than 1 answer possible) | Analysis of documentation<br>Interviews with personnel<br>Other |
| Please specify 'other'. | We also conduct traceability audits to verify the consent documentation in some randomly selected cases (including matching stored tissue samples to consent files). |
| 11.6. What measures are in place to ensure that donors/relatives/authorising persons on behalf of donors are provided with the appropriate information, as requested by Art. 13(2)? (more than 1 answer possible) | Only trained personnel is allowed to provide such information<br>Information for donors are standardised at national/regional level<br>Other |
| Please specify 'other'. | Ensure correct procedures are in place at the initial application assessment stage. Follow up during two yearly inspections. |
| 11.7. What measures are in place to ensure that both donors and recipients remain unidentifiable when access is given to third parties (Art. 14(1)). Please specify. | Donor and recipient numbers are used to ensure donors and recipients are unidentifiable. |
| 11.8. Please specify what measures are in place to ensure that the identity of the receipient is not disclosed to the donor and vice versa. | Donor details are not stored in recipient notes and vice versa. This may not be the case if the donation is directed and the donor is known to the recipient (e.g. sibling to sibling, parent to child etc.). |
| 11.9. Does your national legislation allows disclosure of donor data in case of gametes donation? | No |
| 11.9.1. If no, please specify the circumstances and measures in place. | This is not applicable - gamete donation is regulated by the HFEA. The HTA does not hold information to confirm this. |
| 11.10. Do you have any additional comments on consent and data protection? | |
| **12. Selection, evaluation and procurement (Article 15 Directive 2004/23; Annexes I-IV Directive 2006/17)** | |
| 12.1. How do you ensure that all requirements related to the evaluation and selection of donors (except donors of reproductive cells) are respected in your country (Art. 15(1), Annex I Directive 2006/17/EC)? (more than 1 answer possible) | Inspections of TEs and procurement sites |
| 12.2. How do you ensure that all requirements related to the evaluation and selection of donors of reproductive cells are respected in your country (Art 15 (1), Annex III of Directive 2006/17/EC)? (more than 1 answer possible) | Other |
| Please specify 'other'. | Not applicable - this is regulated by the HFEA. |
| 12.3. Do you have more stringent criteria for donor selection than those listed in Annex I of the Directive 2006/17/EC? | No |
| 12.4. What sources are required in your MS for the evaluation of a deceased donor of tissues/cells? (more than 1 answer possible) | Interview with the donor's family or a person who knew the donor well<br>Medical records of the donor<br>Interview with the treating physician<br>Interview with the general practitioner<br>Autopsy report<br>Other |
| Please specify 'other'. | Tissue establishments may use a number of sources to evaluate a donor, including those described in 12.4. We do not specify how to evaluate a deceased donor. |
| 12.5. Do you have more stringent criteria for selection of donors of reproductive cells than those listed in Annex III of the Directive 2006/17/EC? | No |
| 12.6. Do you have more stringent criteria for autologous donation than those listed in Annex I of the Directive 2006/17/EC? | No |
| 12.7. Do you require more information on the donation of tissues/cells than the mandatory one as laid down in the Annex of Directive 2004/23/EC (Art 15(3)? | No |

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| 12.8. How do you ensure that all requirements regarding tissues and cells' procurement, packaging and transport are complied with by tissue establishments in your country (Art 15(1), Annex IV of Directive 2006/17/EC? (more than 1 answer possible)(For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)) | Inspection of tissue establishment<br>Inspection of the centre of human application (e.g. transplantation centre, ART centre)<br>Other |
| 12.8.1. Please specify. | Ensure correct procedures are in place at the initial application assessment stage. Follow up during two yearly inspections. |
| 12.9. Do you have any additional comments on selection, evaluation and procurement? | |
| **13. Quality management, responsible person, personnel (Article 16, 17, 18 Directive 2004/23/EC)** | |
| 13.1. How do you ensure that tissue establishments in your country have in place a quality system respecting the provisions of the Directive 2004/23/EC Art 16.1? (more than 1 answer possible). (For this question "audit" means a documented review of procedures, records, personnel functions, equipment, materials, facilities, and/or vendors in order to evaluate adherence to the written SOP, standards or governments laws and regulations (from Council of Europe Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells, 2011)). | Authorisation requirement<br>Inspections<br>Internal audits<br>External audits |
| 13.2. How do you ensure that tissue establishments have a responsible person fulfilling the requirements of Art. 17(1)? (more than 1 answer possible) | Authorisation requirement<br>Inspections<br>Regular evaluation of personnel<br>Mandatory trainings |
| 13.3. How do you ensure an appropriate training for the personnel directly involved in the activities of tissue establishments? (more than 1 answer possible) | Authorisation requirement<br>Inspections<br>Regular evaluation of personnel<br>Mandatory trainings |
| 13.4. Do you have national/regional/local training programmes for the personnel of tissue establishments? | Yes |
| 13.4.1. If yes, please specify. | We provide e-learning training for designated individuals. All designated individuals are required to undertake this training as a licence condition. It is open for other registrants. This is available here: http://www.hta.gov.uk/trainingandconferences/e-learningcourses.cfm We also run workshops for TE's e.g we recently ran one on authorisation of preparation processes and we are planning another in September on SAREs. |
| 13.5. Any additional comments on quality management, responsible person, personnel? | |
| **14. Reception, processing, storage, labelling and packaging (Art 19-22 Directive 2004/23/EC)** | |
| 14.1. How do you ensure that tissue establishments in your country fulfill the requirments of the Art. 19 (Tissue and cell reception) of Directive 2004/23/EC and Annex IV of Directive 2006/17/EC? (more than 1 answer possible) | Inspections of tissue establishments<br>Internal audits of tissue establishments<br>External audits of tissue establishments (e.g. ISO) |
| 14.2. How do you ensure that tissue establishments in your country fulfill the requirements of the Art. 20 (Tissue and cell processing) of Directive 2004/23/EC? (more than 1 answer possible) | SOPs for all processes affecting quality and safety are mandatory for authorisation<br>Inspections of tissue establishments<br>Internal audits of tissue establishments<br>External audits of tissue establishments (e.g. ISO) |
| 14.3. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 21 (tissue and cell storage conditions) of Directive 2004/23/EC? (more than 1 answer possible) | SOPs for procedures associated with storage of tissues and cells are mandatory for authorisation<br>Inspections of tissue establishments<br>Internal audits of tissue establishments<br>External audits of tissue establishments (e.g. ISO) |
| 14.4. How do you ensure that tissue establishments in your country fulfill the requirements of Art. 22 (labelling, documentation and packaging) of Directive 2004/23/EC and Annex IV of Directive | SOPs for procedures associated with labelling and packaging are mandatory for authorisation<br>Inspections of tissue establishments |

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| 2006/17/EC? (more than 1 answer possible) | Internal audits of tissue establishments<br>External audits of tissue establishments(e.g. ISO) |
| 14.5. Any additional comments on reception, processing, storage, labelling and packaging? | |
| **15. Third party agreements (Art. 24 Directive 2004/23/EC)** | |
| 15.1. Are third party agreements foreseen/allowed in your national legislation? | Yes |
| 15.1.1. If yes, have tissue establishments in your Member State notified third party agreements? | Yes |
| 15.1.1.1. Under which circumstances and for which responsibilities? | To conduct licensable activities other than storage. |
| 15.1.1.2. How are third party agreements controlled (Art 6.2) by the Competent Auhtority(ies) in your MS? Please specify. | The Human Tissue (Quality and Safety for Human Application) Regulations 2007 (the Regulations) define a third party agreement (TPA) as: "An agreement in writing between a licence holder (or the designated individual on behalf of the licence holder) and another person, which is made in accordance with any directions given by the Authority under section 23(1) of the 2004 Act for the purpose of securing compliance with the requirements of Article 24 of the first Directive (relations between tissue establishments and third parties), and under which the other person: (a) carries out licensed activity (other than storage) on behalf of the licence holder; or (b) supplies to the licence holder any goods or services which may affect the quality or safety of tissue or cells." A TPA may be used to provide a third party with the authority to undertake licensable activities on behalf of a licensed establishment. For this reason, there are stringent criteria that a TPA must meet, set down in paragraph 118 of HTA's Directions 002/2007. For TPAs where a person or establishment is supplying to the licence holder any goods or services which may affect the quality or safety of the tissues or cells, the requirements for the TPA are contained in paragraph 119 of HTA's Directions 002/2007. The HTA has powers to enter and inspect third party premises.The HTA has powers to direct a licensed establishment to put in place a TPA with a supplier of goods or services where it considers this necessary. The HTA equally has powers to direct an individual licensed establishment not to use a named supplier of either goods or services. Under extreme circumstances the HTA may give details of suppliers from whom no licensed establishment may receive goods or services. The term TPA is used for non-licensed establishments contracting with licensed establishments in the UK. The term 'service level agreement' is used for agreements between HTA licensed establishments and for agreements with parities from the EU or third countries. We provide FAQs and a 'third party agreement submission form' on our website: http://www.hta.gov.uk/licensingandinspections/sectorspecificinformation/tissueandcellsforpatienttreatment/thirdpartyagreementfaqs.cfm#SLA . We have further information available about TPA content and HTA powers in our 'Guide to the quality and safety assurance of human tissues and cells for patient treatment' at: http://www.hta.gov.uk/_db/_documents/Annex_-_Guide_to_Quality_and_Safety_Assurance_for_Tissues_and_Cells_for_Patient_Treatment.pdf |
| 15.2. Any additional comments on third party agreements? | |
| **16. General comments - implementation** | |
| 16.1. Do you have at national level more stringent quality and safety requirements than those requested by the EU legislation in this field (e.g. restrictions concerning the donation/use of certain tissues/cells, mandatory unpaid donation etc.)? | No |
| 16.2. Has your Member State encountered any difficulties in implementing the requirements in the EU Tissues and Cells Directives? Please choose from the options below. | No difficulties |
| 16.2.1. For all selected options in question 16.2., please provide a | No specific difficulties to report. |

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|---|---|
| short description. | |
| 16.3. In your opinion, in which of the following Directives are there shortcomings (if any)? (more than 1 answer possible) | Directive 2006/17/EC |
| 16.3.2. How would you suggest to solve these issues in Directive 2006/17/EC? | We would like to see a revision of this Directive and in particular Annex 11. We consider that the technical nature of this Directive requires that is reviewed on a regular basis to ensure that it continues to reflect scientific development. In particular, we consider that there is a reasonable basis to consider making NAT testing mandatory in certain situations (i.e multiple donors, one recipient and no storage), product testing instead of serum testing in certain proscribed situations and a review of the requirement for HTLV testing for all tissue types e.g should terminally sterilised products be excluded from the requirement? |