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Meeting of the Competent Authorities for Tissues and Cells

3 – 4 December 2012

Summary Report

The meeting of the Competent Authorities on Tissues and Cells was convened on 3 and 4 December 2012. The previous meeting of National Competent Authorities (CAs) took place on 7 and 8 June 2012.

PARTICIPATION:

All Member States, except Denmark and Romania, were present at the meeting of the CAs. Croatia, Norway and Turkey, as well as the European Directorate for the Quality of Medicines and Health Care (EDQM) of the Council of Europe (CoE) and the European Centre for Disease Prevention and Control (ECDC) attended the meeting.

European Commission:

Chairman: Mr D. SCHNICHELS (SANCO)

Ms I. SISKA, Ms H. LE BORGNE, Mr P. CATALANI, Mr M. KLAMERT, Mr R. MCGEEHAN and Mr S. VAN DER SPIEGEL (SANCO)

Administrative assistant: Ms A. CORNEA

1. ADOPTION OF THE AGENDA

The agenda was adopted without changes.

The DE representative requested the Commission to clarify why not all the comments to the draft minutes of the previous meeting of Competent Authorities on Tissues and Cells as provided by the Paul Erlich Institute were not taken into account. He also questioned the inclusion in the agenda of the interpretation question on autologous serum eye drops manufactured from plasma and asked why not all meeting' documents were uploaded in CIRCABC well in advance. The Commission clarified that a written answer will be sent concerning the minutes of the previous meeting, and that all interpretation questions from MS are usually discussed by the group. It was also noted that documents sent by the Member States representatives for the CAs meetings are uploaded by the Commission upon their receipt.

2. LEGAL BASIS FOR THE MEETINGS OF THE TISSUES AND CELLS COMPETENT AUTHORITIES

During the June meeting of the Tissues and Cells CAs, the DE representative requested the Commission to clarify the legal basis for the meetings of the CAs according to Directive 2004/23/EC and also to present the set of Rules of Procedure for these meetings.

Following this request, the Commission informed that the Group of Competent Authorities for Tissues and Cells is part of the Competent Authorities on Substances of Human Origin Expert Group (E01718) which operates on a permanent basis. Its mission and tasks are available at:

http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=1718

This expert group does not have a formal legal basis in the Tissues and Cells Legislation nor in the form of a Commission Decision which would be the case if it were a formal expert group. As an informal expert group its role is to provide advice and expertise to the Commission including in relation to the implementation of existing EU legislation and to facilitate coordination and cooperation with Member States in this regard. As no formal voting procedures leading to binding decisions take place, meetings of this group can take place without specific rules of procedure as is the standard practice for groups of this kind. In the absence of a formal legal basis and specific rules of procedure, the creation and operation of this group falls under the rules outlined in Commission Communication C(2010) 7649 final (http://ec.europa.eu/transparency/regexpert/PDF/C_2010_EN.pdf).

The DE representative noted that rules of procedure would be desirable in order to clarify the roles of CAs and the outcome of CAs meetings. This position was supported by AT. It was agreed that the DE and AT representatives will present the Commission with a draft version of the rules of procedure for the Tissues and Cells CAs meetings based on the accompanying document to the Commission Communication C(2010) 7649 final (http://ec.europa.eu/transparency/regexpert/PDF/SEC_2010_EN.pdf), in due time to be discussed by the group during the next meeting to be held in June 2013.

3. EUROPEAN PARLIAMENT OWN-INITIATIVE REPORT ON THE TISSUES AND CELLS DIRECTIVE – UPDATE

Following the publication by the Commission of the 2nd Report on Voluntary and Unpaid Donation of Tissues and Cells in June 2011, the ENVI Committee of the European Parliament has decided to prepare an own-initiative report. During the June meeting, the draft ENVI Report was presented and it was agreed that during the next CAs meeting the Commission would present the final version of the report as adopted by the EP.

The report was adopted as the European Parliament Resolution of 11 September 2012 on voluntary and unpaid donation of tissues and cells (2011/2193(INI)) (http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P7-TA-2012-0320+0+DOC+XML+V0//EN). The recommendations in this resolution, as well as the follow-up actions envisaged by the Commission were presented.

DE enquired about the application of the new proposal for the Clinical Trials Directive to the area of tissues and cells for transplantation. The Commission stated that this

Directive applies only to medicinal products and a potential revision of the Directive 2004/23/EC may also address the issue of experimental practices in this field. Presently it is for the Member States to decide on how to tackle such matters at national level. Clinical trials that involve the application of human tissues and cells to humans do fall within the scope of 2004/23/EC (Recital 11).

4. DEBRIEF FROM THE PRESIDENCY COMPETENT AUTHORITIES MEETING (PCAM) - VIENNA, 20 NOVEMBER 2012

The outcome of the meeting was briefly presented by CY.

The first informal Tissues and Cells Competent Authorities meeting took place in Vienna on 20 November 2012 under the auspices of the CY Presidency. 14 Competent Authorities, European Commission and Council of Europe attended the meeting. A special session was attended by representatives of the European Society for Human Reproduction and Embryology (ESHRE), European Group for Blood and Marrow Transplantation (EBMT), European Association of Tissue Banks (EATB) and European Association of Eye Banks (EAEB), who provided input from a professional society perspective.

The participants discussed issues for a potential review of the EU Tissues and Cells legislation. Comments and suggestions were made in relation to the potential revision of Directive 2004/23/EC (e.g. revision of definitions used in the Directives and possible addition of others; increase inspection time interval to more than 2 years; propose a set of generic principles to apply to all Member States for the protection of potential donors from receiving falsified information, promotion control and strict advertising prohibition, etc.) and the amendment of the implementing Directives (e.g. clarification about storage time and donor retesting; explicit inclusion of oocyte donation, requirement of interview with a person that knew the deceased donor, etc.).

Taking into account the technical and scientific advances, the participants also suggested new areas which may entail legal requirements at EU level (e.g. authorisation of procurement organisations when TE is located in a different Member State; definition of procurement, donation, testing issues when tissues and cells are further manipulated and become ATMPs; innovative processes authorised after clinical trials; good practices implementation for partner IVF treatment; archiving samples of donors' tissue/cells for future testing and data verification, etc.).

The CY presidency will make a report on the main outcomes of the Vienna meeting and the Commission will make it available over CIRCA-BC.

Participating CA's expressed their intention to organise such informal meetings regularly, if possible once a year.

Following the presentation, several Member States expressed their hope that some of the suggestions will be taken forward by the Commission. The Commission explained that a decision on the potential revision of Directive 2004/23/EC will be taken only after concluding the surveys on the transposition and implementation of the current Tissues and Cells legislation, and that all stakeholders will be consulted, including CAs.

5. DEBRIEF FROM THE MEETING OF THE IMPORT WORKING GROUP (26/09/2012)

The Commission had called for a new WG for Import-Export during the CAs meeting in December 2011. The first meeting was held on 26 September 2012 and representatives of the following countries were present: AT, DK, ES, FR, HR, NL, PL, PT, and UK.

The purpose of the WG was presented: identifying the main topics to be included and developed in a future legislative proposal from the Commission regarding procedures for verifying the equivalent standards of quality and safety for imported/exported tissues and cells from/to third countries.

Following discussions, it was agreed that the following topics should be developed and debated by the group during the next WG meeting. Member States representatives agreed to look into more detail at the following matters: (1) what activities and actors are to be subject to verification of equivalent safety and quality? (2) Which competent authority is responsible for overseeing what? (3) Common requirements/criteria/checklist on these actors (4) How to inform each other amongst CA's? How to share outcomes of import authorisation and inspections? Mutual recognition.

The Commission informed that regular updates will be provided during CA meetings and also enquired whether other Member States may be interested in joining this WG. It was agreed that Member States interested in joining the Import-Export WG will send their expressions of interest in writing.

6. UPDATE ON THE TRANSPOSITION OF THE TISSUES AND CELLS DIRECTIVE

Member States are under the legal requirement to transpose the Directives into national law by the deadline set in the legislation and the Commission has the duty to check the transpositions.

The Commission launched the web-based questionnaire on 1 July 2011. The deadline for submitting replies to the questionnaire was 15 October 2011. The deadline was extended by a month, and all submissions were received by January 2012.

The Commission already presented an overview of the replies submitted, based only on the yes/no answers during the CA meeting in December 2011. Following the in-depth analysis of the Member States replies, it was concluded that the transposition check was completed without further issues only for 4 Member States, while the Commission requested clarifications and additional information from 23 Member States. The main issues which were potentially not appropriately transposed by some Member States were outlined separately for the three sections of the questionnaire, general provisions, provisions related to Competent Authorities and provisions for tissue establishments.

The Commission informed that after analysing the clarification replies from the Member States, it is expecting to close the transposition check for most Member States. However, in cases of inappropriate transposition or non-transposition, the Commission shall request amendments to the current national legislation and, if necessary, will launch infringement procedures. The Commission will update the group on the status of the transposition check during the Competent Authorities meeting in June 2013.

7. IMPLEMENTATION OF THE TISSUES AND CELLS DIRECTIVE – 2012 SURVEY

The Commission recalled its legal obligation to transmit to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions a report on the implementation of Directive 2004/23/EC, in particular as regards inspection and monitoring (Article 26).

The results of the first implementation survey were published in January 2010 - COM (2009) 0708 Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions on the application of Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.

The Commission informed that the second implementation survey should be launched as a web-based questionnaire in the first months of 2013. The survey should provide an overall picture of tissue and cell regulation in EU (achievements, practices, implementation, difficulties) and also identify areas/opportunities for exchanging best practices, as well as for a potential future revision of the Tissues and Cells Directives.

The deadline for submitting replies will be 3 months after the launch. Analysis of the replies and a first draft report should be made available during the next meeting in December 2013. UK suggested that such surveys should be communicated to the Member States well in advance in order to allow appropriate planning at CA level.

8. DONOR REGISTRIES FOR HSC – LEGAL QUESTIONS

During the CA meeting in June 2012 the issues surrounding the activities of private donor registries (based on the activities in Spain of DKMS – a private non-profit donor recruitment organisation established in Germany) were presented by ES. Following the discussions on this issue the Commission was asked to provide legal clarifications in terms of the compatibility of such activities with the requirements of the EU tissue and cells legislation, and also on the compatibility of national measures linked to donor drives with EU Treaty provisions.

Following this request the Commission has gathered the necessary information from the parties involved and has asked its Legal Service to clarify certain questions concerning the above points.

Several Member States underlined that in many countries donor registries are under the direct responsibility of Competent Authorities and this may be considered a matter of national competence. It was also noted that practices developed by such private recruitment organisations may increase the donor pool and finding a collaborative approach may be of interest for both patients and regulatory authorities. The group of Competent Authorities welcomed the Commission initiative to clarify the above mentioned issues with the Legal Service. Based on the feedback from the Legal Service, the Commission will report back to the group during the next CA meeting (June 2013).

9. INTERPRETATION QUESTIONS

9.1. Embryonic stem cell lines (UK)

In the UK, several universities and companies are developing new therapies based on "rest-embryos". Such embryos were originally created through IVF for the purpose of fertility treatment, but are no longer needed by the partner/couple. Years after their creation, these embryos can be donated by the partner couples to research and development. This second donation raises some specific questions: (a) Are the original tests of partner donors, relevant if the embryos are now donated to third parties, potentially for allogeneic use?; (b) Are these donated embryos intended for human application?; (c) Due to the time window between 2 donations, additional testing might be needed to check on potential contaminations in processing/storage. As time windows might be around 10 years, national requirements from before transposition of Directive 2004/23/EC might need to be considered.

UK's view to this question was presented together with a proposal to amend donor testing requirements in the Directive 2006/17/EC, allowing testing to be performed on material other than donor serum (i.e. cell lines) under specific circumstances.

Following discussions it was agreed to further reflect on the proposed amendment. Member States were requested to consult their experts and provide comments to the UK Competent Authority before the end of the 2012. An update on this topic should be presented during the Competent Authorities meeting in June 2013.

9.2. Transplantation of face – Update after the meeting of Competent Authorities for Organ Transplantation (13-14 September 2012)

In December 2011, the Swedish CA had asked whether composite tissues, such as facial transplants should fall under the Organs or Tissues and Cells Directive. This question was already discussed at the meeting of Tissues and Cells Competent Authorities in October 2009, however without reaching a conclusion. In the meantime the Directive 2010/53/EU was adopted and provides for a definition for "organs" in Art 3 (h).

Several NCAs considered that facial transplants require no processing. Several NCAs considered that the process of face donation and transplantation is very analogous to that of organ donation and transplantation and the safety issues are similar. It was suggested that the Commission should have the same interpretation for other multi-tissue transplantation procedures (e.g. hand transplantation).

In June 2012, after consulting the SANCO legal team, the Commission confirmed that the "organ" definition in Directive 2010/53/EC prevails, which suggests including composite tissues under the Organs Directive. However, there are important technical issues to be clarified by professionals in the field, so an opinion from the Organs CAs is also needed.

The issue was brought again to the attention of the CAs for organ transplantation and during their meeting in September 2012 it was agreed that the face is a vascularised composite tissue requiring similar processing and safety issues to organ transplantation.

The group of the Tissues and Cells CAs agreed with this view and concluded that vascularised composite tissues, such as the face, should be covered by the Organ

transplantation Directives and should be explicitly excluded from the scope of Directive 2004/23/EC during its next revision.

9.3. NAT HCV testing for tissues imported from third countries and distributed in EU Member States (AT)

The Commission introduced a question received from the AT CA, concerning practices in Member States with more stringent safety and quality requirements than those requested by the EU legislation when importing tissues from third countries (e.g. USA). In most Member States, imported tissues are tested according to EU Directives, but cannot report a HCV NAT test which is mandatory for tissue distributed in AT. Therefore, some Austrian TEs receive such tissues imported from third countries via other TEs located in EU Member States where HCV NAT is not required. In this regard, AT demanded clarifications on whether an EU Member State is allowed to prohibit an import when the quality meets minimum requirements of the EU Directives but not the national higher safety standards and whether a tissue released in one EU Member State is allowed to be distributed in all EU Member States despite additional local requirements.

Several Member States with more stringent testing requirements stated that they already have in place methods to check these additional requirements and in some countries tissues/cells distributed from other EU countries are treated like tissues/cells imported from third countries.

Since Directive 2004/23/EC lays down only minimum safety and quality requirements, it was concluded that it is the responsibility of the Member States with more stringent testing requirements (6-7 EU Member States) to check whether tissues/cells distributed from other EU Member States fulfil their national requirements**.**

9.4. Hospital Exempt Advanced Therapy Medicinal Products (IE)

The IE representative referred to the requirements of Art. 28 in the Advanced Therapies Medicinal Product (ATMP) Regulation 1394/2007/EC concerning Hospital Exempt ATMPs (HE-ATMPs) which are exempt from the formal requirements of a centralised Marketing Authorisation.

Because the ATMPs can be manufactured from human tissues and cells, and because of the variable approaches in the Member States, it was suggested that a common overview of the hospital exempt regulatory models in different Member States would be of interest also for Tissues and Cells Competent Authorities. In order to get this overview, the IE representative will circulate a questionnaire in December to all Tissues and Cells Competent Authorities, as well as to Member States with a CAT delegate at EMA, with a deadline for replies by 4 January 2013.

It was mentioned that anonymized data will be collected for a Master thesis by a representative of the IE Competent Authority. It was agreed that the outcome of this survey will be presented by the IE Competent Authority during the next CA meeting in June 2013.

9.5. Autologous serum eye drops manufactured from whole blood (BE)

The question was introduced by the BE CA following a similar question addressed by FI to the group of Blood Competent Authorities. The questions referred to the eye drops made of autologous serum, for which blood is collected in a clinic, transported and centrifuged in a hospital pharmacy, then delivered to the patient for (30) daily doses. The patient stores the doses in a private freezer. The preparation process is performed outside the hospital blood banks and cannot be easily integrated as a blood establishment procedure.

During the Blood Competent Authorities meeting in October 2012, three countries presented their views on this matter. Both Ireland and UK apply the GMP requirements for the measures implemented considering the eye drops as pharmaceutical product, but a marketing authorisation is not required. Austria has the same approach, but there is a magisterial procedure and no market authorisation is required.

During discussion, some Member States considered this matter is of interest only for the blood sector, while others stated that such products may be also produced by tissue establishments.

Taking into account also the opinion of the SANCO legal team which stated that the scope of Directive 2002/98/EC needs to be reviewed (Art.2) to make clear which procedures should fall under its scope, it was also suggested that an appropriate revision of some articles in the Directive 2004/23/EC (e.g. definition of tissue establishment, scope) would be also needed.

10. SURVEILLANCE AND VIGILANCE

10.1. Update on infectious disease risks

10.1.1. Debrief from the "Expert consultation on a priority setting for the risk assessment of communicable diseases transmissible through SoHO" - Stockholm, 20-21 September 2012- ECDC

ECDC presented activities on SoHO, and summarized the outcomes of the meeting on prioritisation of communicable diseases for risk assessment on SoHO (Stockholm 20-21 September). The report is available at http://www.ecdc.europa.eu/en/publications/publications/diseases-communicable-by-substances-of-human-origin-soho.pdf

Six arthropod-borne diseases have already been prioritized (including malaria, dengue and WNV), and prioritisation criteria to identify additional diseases of interest have also been laid down. Further discussion is needed on which elements should be covered by the risk assessments: (1) risk of the disease, (2) probability of transmission through transplantation/transfusion, (3) risk/benefit analysis of disease transmission versus transfusion/transplantation benefits, and (4) potential preventive and corrective measures.

It was recalled that the work plan would need to address communicable diseases not only for the field of tissues and cells, but also for the fields of blood and organs. ECDC explained that the current list of prioritised diseases is a result of threats identified in the past years, and that other relevant diseases may be added to

the initial priority list. The Commission asked Member States to provide comments or proposals for additional diseases to be considered in the preparation of risk assessments in the following years.

10.1.2. Epidemiological update – ECDC

ECDC presented a summary of the relevant epidemiological information received in the last 6 months. Short presentations were given on the 2012 outbreaks of WNV in EU (IT, EL and RO) and malaria in Greece. ECDC also reported about the status of the outbreak of dengue in Madeira, PT (November 2012 data); it was mentioned that a recommendation for blood donor deferral for 28 days after return from the Autonomous Region of Madeira has been posted on the rapid alert system for blood.

10.1.3. Other – Member States will be asked whether they have additional information or updates to report

No additional information was reported by the Member States.

10.2. Update on the development of the new European code for tissues and cells – EUROCET128 tender

EUROCET128 is the consortium (CNT Italy, ICCBBA and Artman Technologies) which won the public procurement procedure launched by the EAHC/2011/Health/03 concerning the reference compendia for the application of a single European coding system for human tissues and cells. These compendia follow the coding structure presented and unanimously supported during the NCA meeting of June 2011. A representative of the coordinator (CNT) updated the group on the status of the work regarding two of the main deliverables, the EU tissue establishments' compendium and the product compendium, as well as on the dissemination activities. Competent Authorities were informed that they will have to fill out the template for all tissue establishments authorised in their country by June 2013, and that the draft EU generic list of products will be also presented during the next Competent Authorities meeting. It was also mentioned that a user manual will be provided by the consortium.

The Commission clarified that EMA was informed about this work and there is no overlap with the catalogue developed by the agency. Concerning some questions raised by Member States regarding the dissemination activities of EUROCET128 (e.g. presentation to scientific conferences) it was clarified that such activities are requested in the contract with EAHC and were scheduled and carried out in agreement with DG SANCO. It was noted that after the adoption of the new legal requirements on the application of the code across EU a transitional period may be granted in order to allow an appropriate implementation in all EU Member States. Dissemination and follow-up of implementation by the Tissue Establishments will be in hands of the respective national competent authority(ies).

10.3. Rapid alerts for Tissues and Cells (RATC)

10.3.1. Draft RATC report for 2010-2012 (for CIRCA and CIRCABC RATC)

The Commission presented a brief overview of the alerts circulated by Member States in the RATC CIRCA/CIRCABC platform between the launch of the system in 2010 until end of 2012. It was mentioned that a report on this issue will be soon published by the Commission on its website.

10.3.2. Launch of the new RATC platform

The Commission presented the final version of the new RATC system to be launched by the end of 2012. Details were given regarding users' roles, registration, workflow and data protection issues. A Standard Operating Procedures manual was submitted to the CAs for their feedback. The CAs congratulated the Commission for their work on this project.

Following the meeting in June 2012 when CAs requested a hands-on training for RATC users, the Commission informed that besides a first training for national tissues and cells vigilance contact points organised on 5 December 2012, two other courses will be organised in order to allow the training of at least one representative per Member State Competent Authority.

Concerning the timeline, the platform could be operational on 1 January, while CIRCABC RATC will be maintained as back-up system for some months. Following the request of some Member States to postpone the launch of the platform, it was agreed to start working with the new RATC system only on 1 February 2013. There was also a discussion about the principle that the information on the RATC is to be dealt with confidentially between the registered users.

The Commission informed that similar alert systems dedicated to blood and organs CAs may be developed in the next couple of years.

10.3.3. 2012 RATC alerts – debrief

The DE CA presented an updated state of play on the alert launched in RATC concerning the recalls of tissues distributed by Tutogen Medical GmbH in Germany. Clarifications provided by the manufacturer to a number of questions raised by several Member States CAs, were also presented. It is up to each CA to decide on follow-up measures within its territory. The group was informed that a pharmacovigilance inspection of the company's main site in Germany was planned by the regional CAs in collaboration with the UK HTA. The DE CA will keep the colleagues informed of further alerts through the RATC CIRCA-BC system. Further questions from NCA's can be addressed to PEI.

10.4. Serious adverse reactions and events:

10.4.1. 2010 SARE Annual report

Based on the reported data, the number of SAR and SAE reported for 2010 is low, especially when compared to the number of tissues and cells distributed and processed at EU level (0.14% and 0,095%). Nevertheless, these data need to be interpreted with caution (in many Member States it is still difficult to collect accurate data for both SAR/SAE and the two denominators (tissues and cells distributed and tissues and cells processed). Both the Commission and national

Competent Authorities for Tissues and Cells acknowledged that there is an under-reporting due to various causes which need to be further addressed (e.g. different definitions used for data collection at national vs. EU level, raising awareness of end-users of the importance of reporting SARE for the benefit of the entire professional community working in the area of tissues and cells for human application, etc.). It was agreed that CAs should provide their feedback until end of January 2013 for the Commission to finalise the publishable report.

Participants thanked the Commission for the good progress made in this complex exercise.

10.4.2. 2011 SARE Annual report – First analysis

The Commission presented a draft report of the SARE reporting for 2011. SAR, SAE and denominators data for 2011 were presented in comparison with the 2010 numbers. A full report should be presented in June 2013. It was noted that data collection improved after the revision of the template and the update of the Common Approach document, but further suggestions from CAs for the next reporting and/or data analysis are always welcomed. Additionally, the Commission will also correct some minor technical issues in the reporting template to be used for the 2013 SARE reporting.

11. PROJECTS PRESENTATIONS – PUBLIC HEALTH PROGRAMME

11.1. SOHO V&S and NOTIFY

The SOHO V&S project, funded under the second Health Programme, is an active partner in the WHO project NOTIFY, a global initiative in building up a free public database for professionals with the aim to share internationally knowledge on SARE for tissues, cells and organs.

A representative of the coordinator (CNT Italy) presented the development of the NOTIFY Library and the contribution of the SOHO V&S project to this work. It was clarified that only documented SARE will be included in the library and that access is free for professionals, regulators and public. It was mentioned that a thorough editing process was put in place in order to make sure that all data are made unidentifiable.

The work of CNT and SOHO V&S project were highly appreciated by the group of Competent Authorities.

11.2. 2013 Joint Action on good practices on donation, collection, testing, processing, storage and distribution of gametes for assisted reproductive technologies and of haematopoietic stem cells for transplantation

Following the adoption on 28 November 2012 of the work plan for 2013 for the second programme of Community action in the field of health, the Commission introduced the joint action proposed for the area of tissues and cells (http://ec.europa.eu/health/programme/docs/wp2013_en.pdf).

It was emphasized that the joint action will focus on two very important fields covered by the EU Tissues and Cells legislation: assisted reproductive technologies (ART) and haematopoietic stem cells (HSC). The Commission

informed that already 13 countries expressed interest to participate (CY, AT, GR, SE, HR, LI, SK, NO, ET, FR, MT, IT, CZ, NL), and encouraged all Member States to participate according to their availability and expertise.

Several Member States underlined that there are already guidelines in place, especially in the field of haematopoietic stem cell transplantation, and suggested that the JA should build on existing best practices, should try filling the gaps, without any duplication of work. It was also noted that coordination might be difficult with two very different areas, and that the amount of funding foreseen might not cover all desired tasks (e.g. training of inspectors). It was also suggested to focus on good practices in the area of cord blood banking.

The Commission informed about the workshop organised by EAHC in Luxembourg on 11-12 December 2012 concerning the preparation of joint actions proposals and strongly supported CAs to express interest in coordination or WP leadership, as well as in participating to this first JA in the field of tissues and cells.

12. UPDATE FROM COUNCIL OF EUROPE – CDPTO MEETING, GUIDE TO SAFETY AND QUALITY ASSURANCE FOR TISSUES AND CELLS – UPDATE FROM EDQM SECRETARIAT

Council of Europe updated the group about the development of the first edition of the "Guide to the Quality and Safety of Tissues and Cells". The guidelines will apply only to tissues and cells intended for clinical use or transplantation (including insemination and fertilisation), while tissues and cells used for 'basic' research do not fall under the scope of the present Guide. The work has been coordinated by the Centro Nazionale Trapianti (CNT; tissues) and Agence de la Biomédecine (ABM; cells), with valuable contributions from other countries (BE, BG, CY, EE, ES, GE, IE, PT, RO, SI, TR, UK).

The Guide will address all 47 member states of the Council of Europe and should contribute to the harmonisation of these activities among European tissue establishments, facilitating uniform standards and inspection. The Guide will include exhaustive guidelines for the activities carried out in tissue establishments, in order to ensure high levels of quality and safety standards for procurement, processing, preservation and distribution of tissues and cells of human origin used for transplantation purposes. A comprehensive introduction to legislation and ethics is also provided.

The Guide will be sent for public consultation in the first months of next year and should be published in the first half of 2013.

13. SEMINAR ON ILLEGAL AND FRAUDULENT ACTIVITIES ON ORGANS, TISSUES & CELLS - PARIS 2013 (FR)

The FR representative informed the group about the organisation of a seminar on illegal and fraudulent activities (IFA) in the area of organs, tissues and cells by ANSM in collaboration with the European Commission, Interpol, OCLAESP and the International Institute of Research against Counterfeiting Medicines (IIRACM). The seminar will be held in Paris on 8-10 April 2013 and aims to provide police and customs officials with information on issues related to IFA in

the area of organs, tissues and cells for human application (e.g. the extent of international and national commerce in this area, the nature of IFAs and ways to identify, prevent them and manage any suspected cases in cooperation with established National Regulatory Authorities). It was mentioned that both EU MS and neighbouring countries will be invited and the outcome of the meeting will be presented during the next CAs meeting in June 2013.The Commission co-sponsored the organisation of this event.

DOMINIK SCHNICHELS