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on the implementation of the principle of voluntary and unpaid donation for 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**

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ABBREVIATIONS

ART	= Assisted reproductive technologies
BM	= Bone marrow
EC	= European Commission
EEA	= European Economic Area
EU	= European Union
IFA	= Illegal and fraudulent activities
HFEA	= Human Fertility and Embryology Authority
HSC	= Haematopoietic stem cells
HTA	= Human Tissue Authority
PBA	= Price base amount
PBSC	= Peripheral blood stem cells
SOP	= Standard operating procedures
VUD	= Voluntary and unpaid donation
WMDA	= World Marrow Donor Association

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, is based on the responses to a questionnaire sent to the Member States' tissue and cell competent authorities in 2014. All Member States submitted their replies to the Commission. In addition, Liechtenstein and Norway provided answers to the survey.

This document aims to map the implementation of the principle of voluntary and unpaid donation (VUD) of tissues and cells in the European Union. Besides addressing the legislative provisions and guidelines existing at national level, the report presents the Member States' practices vis-à-vis donors and provides data on tissue and cell donation and anonymity, on promotion and advertising, as well as on donation-related practices in the national healthcare systems. The main findings of the VUD survey have been presented to the Member States' tissue and cell competent authorities during their regular meetings with the Commission.

2. IMPLEMENTATION OF THE PRINCIPLE OF VOLUNTARY AND UNPAID DONATION FOR HUMAN TISSUES AND CELLS

2.1. Legislative provisions, guidelines and policies

Twenty-seven of the 30 reporting countries reported that VUD of human tissues and cells is mandatory in their countries (AT, BE, BG, CY, CZ, DE, DK, EL, ES, FI, FR, HR, HU, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI, SK, UK and NO) (Figure 1). Ireland and Liechtenstein reported that the VUD of human tissues and cells is not mandatory in their countries. Additionally, one Member State (Estonia) indicated that payment for reproductive cells is not prohibited and there are no national requirements on the amount of the remuneration, which is merely decided by the operators.

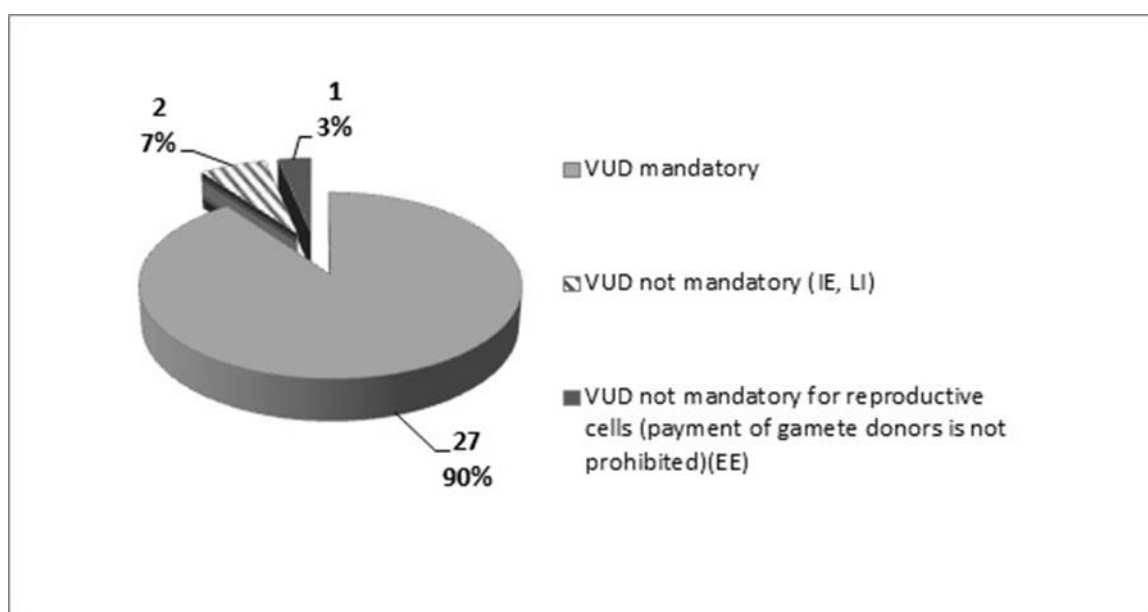


Fig. 1. The application of the VUD principle by EU and EEA countries (2014 data)

Legislative provisions or guidelines regarding VUD of tissues and cells have been subject to change in a number of countries. Since the last report, six Member States made changes in their legislation on VUD of tissues and cells:

- Bulgaria (2011) – prohibition of commercialisation of donated reproductive cells, prohibition of financial gain for donating reproductive cells, provisions allowing donor compensation (reimbursement of costs related to travel and accommodation and compensation for potential temporary disability, pain/discomfort and for specific loss of time and daily income);
- Greece (2011) – provisions regarding compensation of donors, prohibition of donor remuneration, penalties for illegal removal of human tissue and organs, for offering for sale human tissue and organs or mediating transactions involving human tissues and cells;
- Lithuania (2013) – prohibition of commercial transactions involving tissues, cells and organs, penalties for illegal removal or for offering for sale human tissue and organs;
- Latvia (2012, 2013) – provisions concerning consent for donating reproductive cells, provisions regarding anonymity of donations;
- Slovakia (2012) – provisions allowing donor compensation and prohibiting any financial profit related to the procurement and transplantation of tissues, cells and organs;
- United Kingdom (2012) – provisions regarding donation of gametes and embryos (compensation provided to oocyte and sperm donors, benefits in kind in the case of oocyte donation).

In addition, six Member States declared having plans to update or change their legislative provisions, guidelines or administrative practices regarding the application of the VUD principle. Four Member States indicated that new legislative provisions are under preparation: a national interpretation of “compensation” and “incentive” (Bulgaria); clarifications and transposition of Directive 2012/25/EU (Estonia); definitions of donor compensation in the assisted reproductive technologies (ART) sector (Spain); implementation of Directive 2012/39/EU (Sweden). Ireland specified that guidelines for tissue and cell donations need to be drafted, whereas Slovenia reported planning an administrative change.

Penalties for infringements of the legislative provisions on VUD of tissues and cells have been introduced in 25 Member States (AT, BE, BG, CY, CZ, DE, DK, EE, ES, FR, HR, HU, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI, SK, UK). One country (Latvia) defined penalties after 2009 when the second VUD survey was launched. Ireland and Liechtenstein have not defined such penalties.

A summary of the type of penalties for infringements of the legislative provisions on VUD of tissues and cells included in the national legislations is presented in Figure 2. Of the 13 countries in which penalties include fines for the hospital/company not respecting the national legal provisions, 11 also provided the amounts of these fines, which range from EUR 25 to 1 000 000 (Figure 3). Spain reported that regional health authorities are competent to establish the penalties and sanction procedures, including the amount of fines and Denmark specified that the amount is decided by the police or courts. All countries which penalise hospital or company managers also provided the amount of the fines established at national level, which vary from EUR 500 to 300 000 (Figure 4).

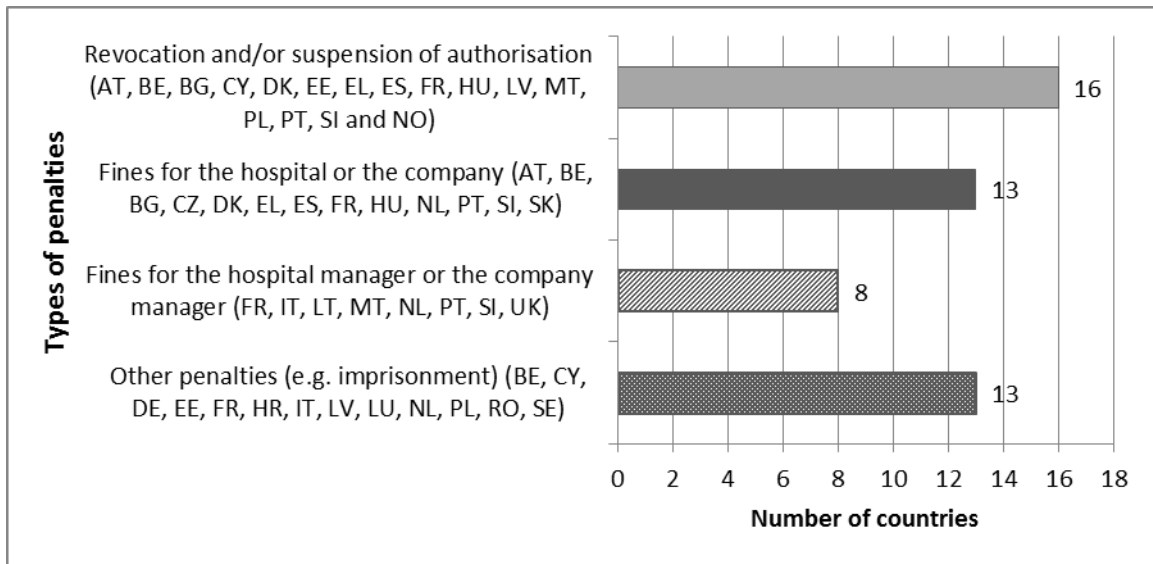


Fig. 2. Type of penalties defined by the EU and EEA countries for infringements of the legislative provisions on VUD of tissues and cells (2014 data)

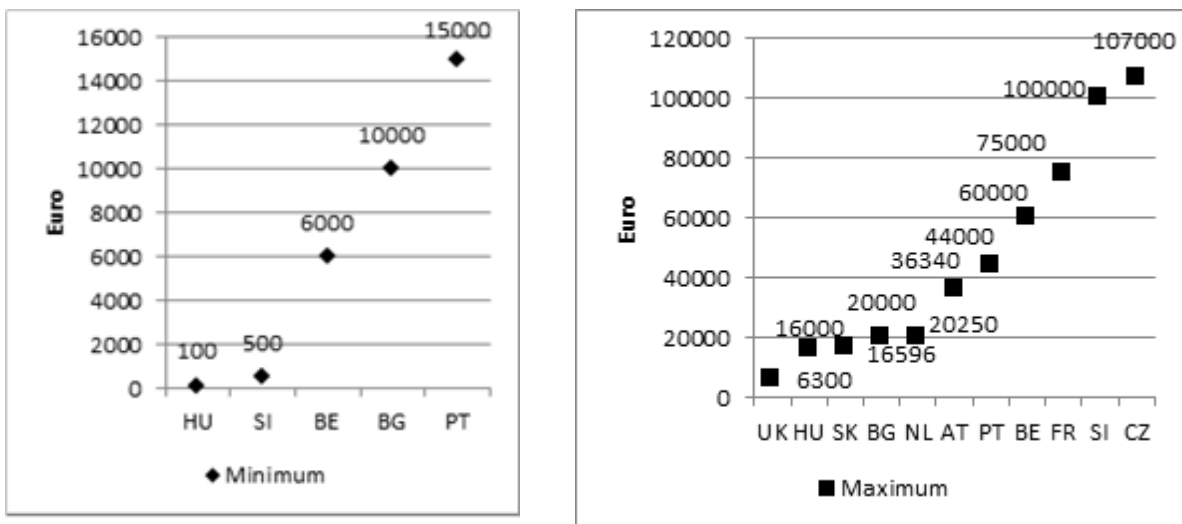


Fig. 3. Fines for the hospital/company not respecting the national legal provisions concerning VUD of tissues and cells (2014 data)

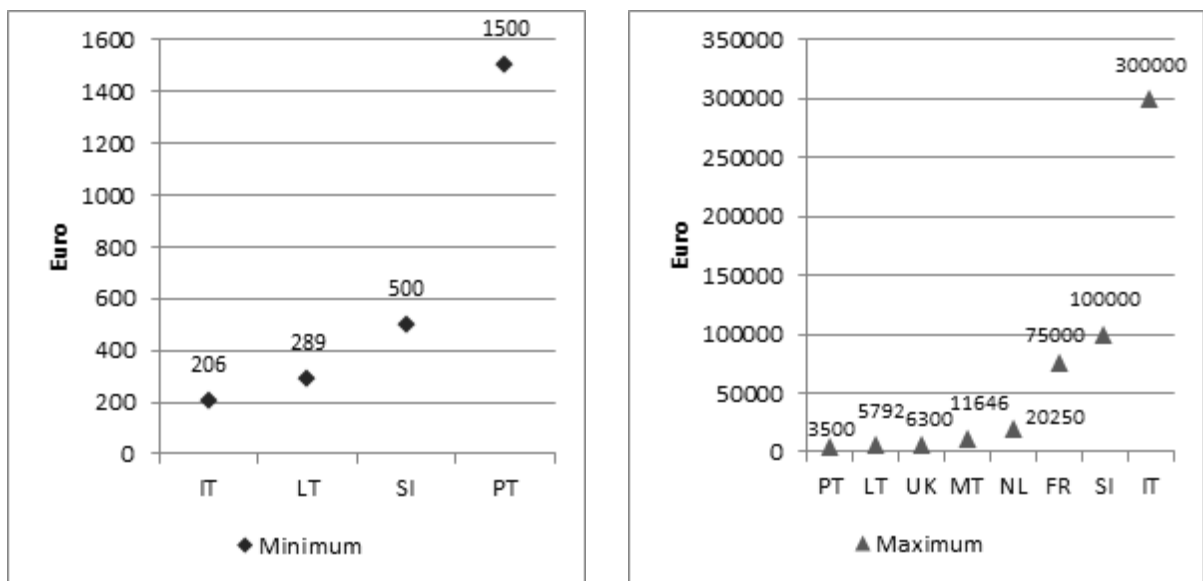


Fig. 4. Fines for the hospital/company manager not respecting the national legal provisions concerning VUD of tissues and cells (2014 data)

It should be underlined that, as of now, only one country (Germany) has reported having imposed penalties for the infringement of criminal provisions laid down in the national law. Individual convictions related to organ and tissue trafficking however are not recorded separately.

In terms of planned changes, Slovenia reported planning to adopt new legislative provisions defining penalties when the application of the VUD principle is not respected.

As regards measures taken at national level to ensure that donations are voluntary and unpaid, half of the reporting countries (AT, BG, DE, DK, HU, IE, LT, LU, LV, NL, PL, RO, SK and LI, NO) acknowledged that no additional measures are in place besides verifying donor consent.

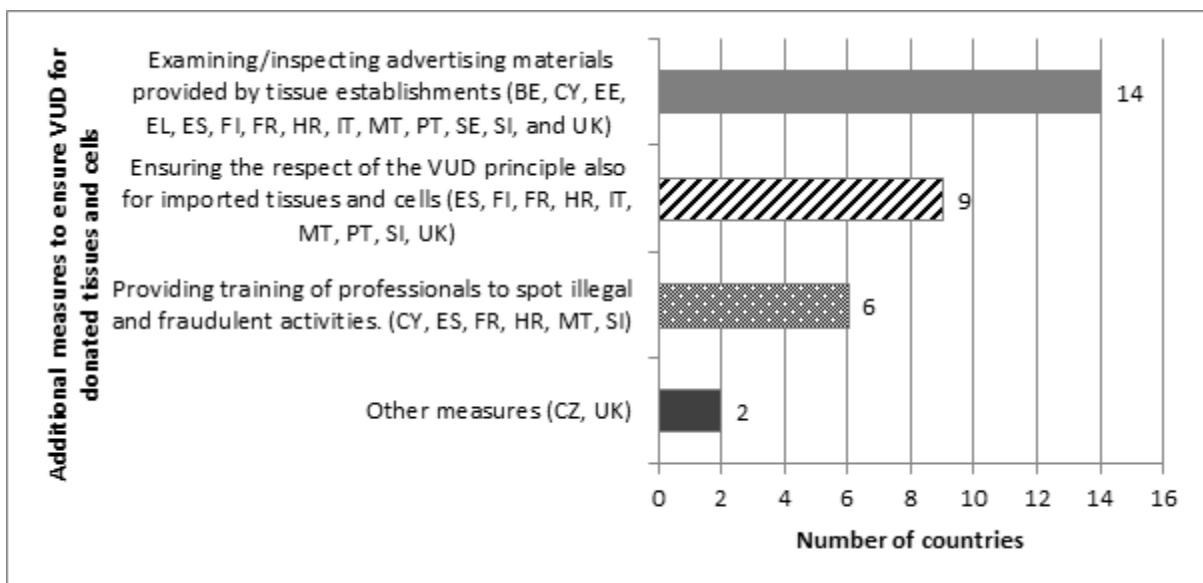


Fig. 5. Additional measures taken by the reporting countries to ensure that donations are voluntary and unpaid (2014 data)

Additional measures to ensure that donations are voluntary and unpaid were reported by 15 Member States (BE, CY, CZ, EE, EL, ES, FI, FR, HR, IT, MT, PT, SI, SE, UK) (Figure 5). These measures include training of professionals to spot illegal and fraudulent activities (IFA), verification that the VUD principle is also respected for imported tissues and cells (e.g. through inspection of the documentation), examination/inspection/approval of advertising materials (e.g. flyers, website information) provided by tissue establishments. Verification of the standard operating procedures (SOPs) prepared by the tissue establishments during inspections (Czech Republic, France), and inspecting patient and donor information provided by licensed fertility clinics (UK-HFEA) were also reported.

2.2. Practices vis-à-vis donors

In order to have a better understanding of the practices vis-à-vis donors across the EU, the questionnaire proposed definitions for compensation and incentive, which are not defined in Directive 2004/23/EC. Compensation was defined as reparation strictly limited to making good the expenses and inconveniences related to the donation, whereas incentive was defined as an inducement/stimulus for donation, with a view to seeking financial gain or comparable advantage. The abovementioned definitions do not constitute an interpretation of the EU Tissues and Cells Directives, and were proposed in order to facilitate a consistent interpretation of these concepts for the purpose of this survey.

Nineteen Member States reported having guiding principles regarding the possibility of giving compensation to donors of tissues and cells (BE, BG, CZ, DE, EL, ES, FI, FR, HU, IT, LT, LU, MT, NL, PL, PT, SI, SK, UK) (Figure 6). Compared with the situation in 2009, six additional Member States (BE, BG, LU, PL, PT, SK) have introduced such guiding principles.

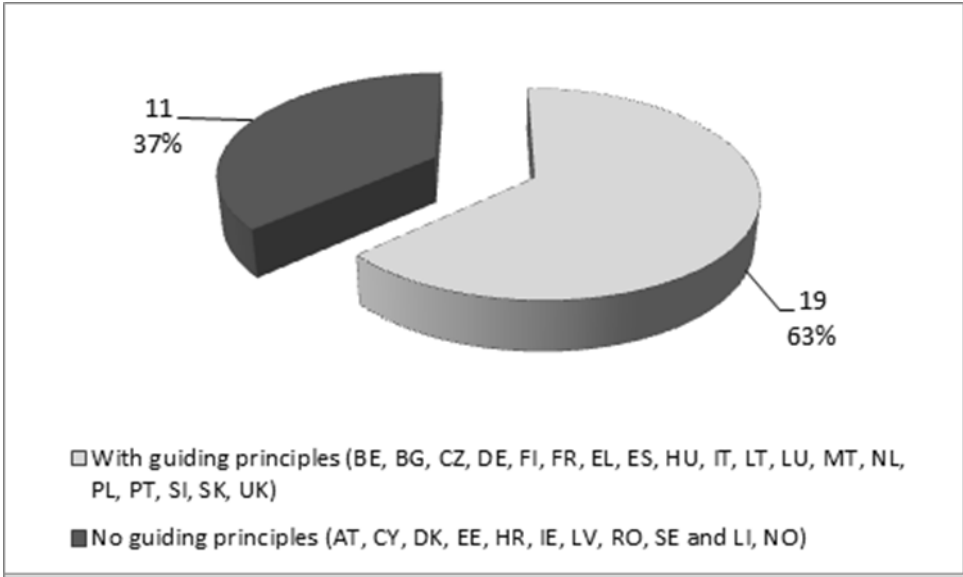


Fig. 6. Guiding principles for giving compensation to donors of tissues and cells in EU and EEA countries (2014 data)

There is a large variation between Member States regarding the content of the guiding principles. Malta reported following WHO guidelines and nine Member States (BE, CZ, DE, EL, FR, HU, LU, NL, UK/HTA) stated that compensation is provided for costs directly related to the donation. France indicated that guiding principles are included in the national legislation. Italy indicated that according to their national legislation, stem cell donors cannot be remunerated, but they are allowed to take time-off from work on donation day(s), with costs being covered by the public social security system. In addition, for unrelated donors, an

insurance coverage is provided for cases in which donation-related serious adverse reactions (including invalidity or death) occur. Lithuania mentioned that donors are entitled to medical leave for the day(s) required for donating cells, tissues or organs. Poland specified that donors are given awards (Transplant Donor or Distinguished Transplant Donor Award). Portugal reported that the compensation for loss of earnings and inconvenience for gamete donation is set in relation to the social support index (1/10 for sperm donors and 1.5/10 for oocyte donors). Slovakia indicated that compensation is based upon the principle that the donor should not lose money. France also indicated financial neutrality as a legal principle.

As set out in Article 12(1) of Directive 2004/23/EC, donors may receive compensation, which is strictly limited to making good the expenses and inconveniences related to the donation. Sixteen countries confirmed having a national interpretation of what is meant by “making good the expenses and inconveniences related to the donation” (Figure 7). Most of these countries consider it acceptable to provide a financial compensation covering the justifiable expenses related to the donation (e.g. travel, loss of income, medical expenses). Estonia specified that both donors and recipients are entitled to subsidies for temporary incapacity from work by the Estonian Health Insurance. Italy referred to their national law which allows time off work and provides insurance coverage for stem cell donors. Lithuania reiterated that donors are entitled to medical leave for day(s) required for donating cells, tissues or organs.

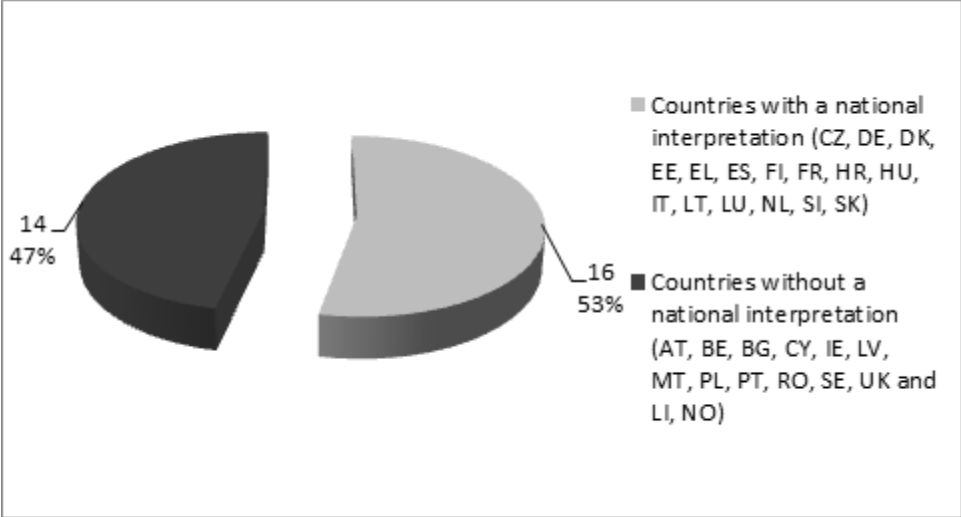


Fig. 7. National interpretation of what is meant by “making good the expenses and inconveniences related to the donation” (2014 data)

2.2.1. Practices vis-à-vis living donors of non-reproductive tissues and cells

Twenty-two countries reported providing some form of **compensation for living donors** of non-reproductive tissues and cells (e.g. peripheral blood stem cells, bone marrow, cord blood) (Figure 8).

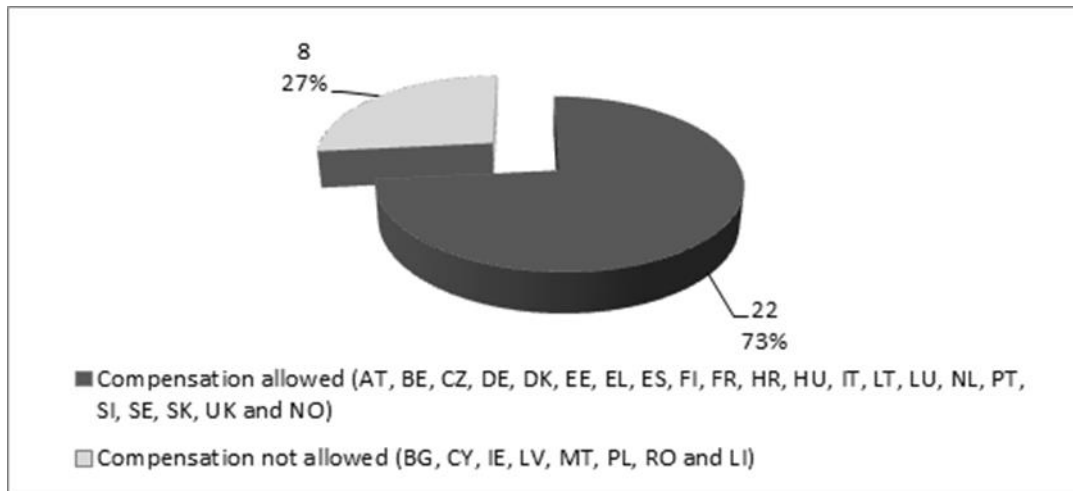


Fig. 8. Countries providing compensation to tissue and cell living donors (2014 data)

An overview of the practices vis-à-vis donors of non-reproductive tissues and cells is detailed in Figure 9.

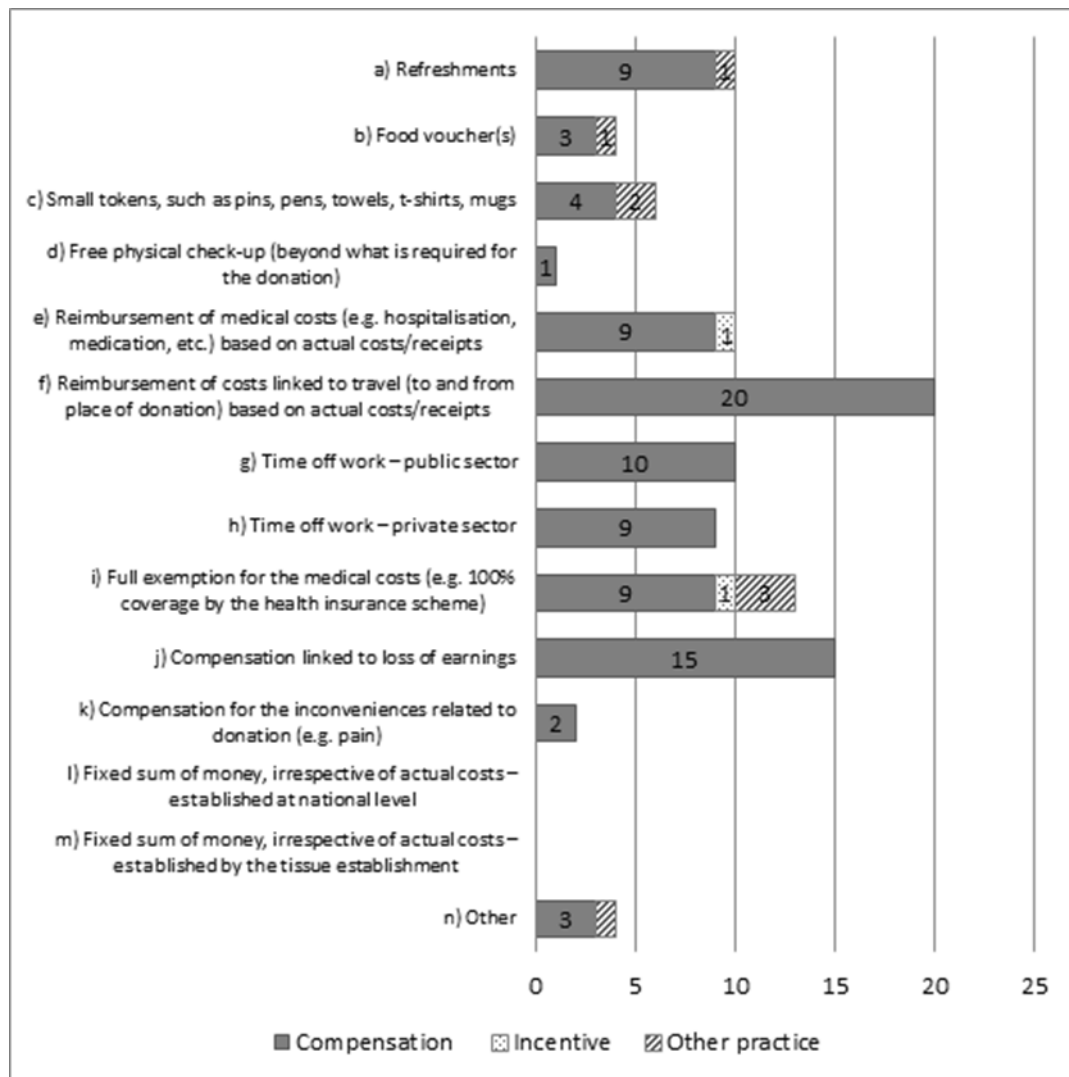


Fig. 9. Overview of the practices vis-à-vis donors and their interpretation by the responding countries (2014 data)

As reported by 19 Member States (AT, BG, CZ, DE, DK, EE, EL, ES, FR, HR, HU, IT, LT, NL, PT, SE, SI, SK, UK) and Norway, the most common practice vis-à-vis donors of non-reproductive cells is the reimbursement of the costs linked to travel to and from the place of donation. In second place, compensation linked to loss of earnings was reported by 15 Member States (BE, CZ, DE, DK, EE, EL, FI, FR, HR, HU, LU, NL, SE, SK, UK). Third, in 13 reporting Member States, is the full exemption of donation-related medical costs of living donors (AT, CZ, DE, EL, FI, FR, HR, HU, LT, SE, SI, SK, UK). Nine Member States (CZ, DK, EL, ES, IT, PT, SE, SI, UK) and Norway reported offering refreshments. With regard to time off work, ten Member States (CZ, DE, DK, EL, FR, IT, LT, LU, NL, SI) reported that this practice is used in both public and private sectors and only one Member State (Slovakia) reported that time off work is accepted only in the public sector.

Other practices, such as providing non-cash items (small tokens, T-shirts, etc.), reimbursement of medical costs based on actual costs/receipts and granting time off work, are allowed in less than a third of the Member States. For instance, small tokens are provided to donors in five Member States (CZ, DK, PT, SE, UK) and Norway, whereas nine Member States (DE, DK, EL, FR, HR, HU, LT, PT, SK) reimburse medical costs connected with donation based on receipts. Additionally, food vouchers are provided in four Member States (CZ, DK, ES, UK), a free physical check-up for donors is provided in one Member State (Czech Republic), and two Member States (Greece, Italy) compensate donors for the inconveniences related to donation (e.g. pain). Additional practices were reported by three Member States: reimbursement of hotel costs (Netherlands), accommodation fees which are not included in the hospitalisation cost and travel expenses the donor has sometimes to pay to express his consent (France) and costs associated with the recovery period (Germany). No Member States reported practices such as providing a lump sum irrespective of actual costs, either established locally or at national level.

Of the 21 countries compensating donors of non-reproductive tissues and cells, only three Member States and Norway were able to provide data on the value of the practices allowed at national level (Table I).

Furthermore, it has to be emphasised that in a few cases the same practice has a different interpretation from one country to another (Figure 10). Providing refreshments, food vouchers or small tokens was interpreted either as compensation or other type of practice.

Practices	Croatia	Lithuania	Norway	Spain
a) Refreshments			average 5€	average 2€ maximum 2€
b) Food voucher(s)				average 7€ maximum 7€
c) Small tokens, such as pins, pens, towels, t-shirts, mugs			average 5€	
d) Free physical check-up (beyond what is required for the donation)				
e) Reimbursement of medical costs (e.g. hospitalisation, medication, etc.) based on actual costs/receipts	average 4000€; maximum 6400€	NAV		
f) Reimbursement of costs linked to travel (to and from place of donation) based on actual costs/receipts	average 230€; maximum 470€	maximum 100€	average 75€	average 20€; maximum 30€
g) Time off work – public sector		100% coverage by health insurance system		
h) Time off work – private sector		according to the rules of the health insurance system		
i) Full exemption for the medical costs	NAV	100% coverage by health insurance system		
j) Compensation linked to loss of earnings	NAV			
k) Compensation for the inconveniences related to donation (e.g. pain)				
l) Fixed sum of money, irrespective of actual costs – established at national level				
m) Fixed sum of money, irrespective of actual costs – established by the TE				
n) Other				NAV

Table I. Average and the maximum value of the practices vis-à-vis donors of non-reproductive tissues and cells (2014 data; NAV = data not available)

Concerning the responsibility for establishing the form and value of the compensation for living donors of non-reproductive tissues and cells, the survey shows that the responding countries have varied approaches, with some countries entrusting this task to operators (i.e. tissue establishments) and others where the decisions are taken by the national government or national/local government or by authorities in collaboration with health insurance schemes (Figure 10). In three Member States other bodies are also involved in the decisional process: the private insurance scheme (Germany), the hospital where the donation and transplantation occurs (Lithuania) or the employer and the social insurance agency (Sweden). In some Member States, the decision process is shared between national organisations and tissue establishments. For example, in Denmark, donation-related travel costs are decided at national

level, costs of food and accommodation are covered by the hospital and small tokens (flowers, chocolate) are offered by the tissue establishment. In Austria, travel costs are reimbursed by the tissue establishments and the cost of medical service is covered by the national insurance scheme. Only in four Member States (BE, NL, PT, UK) and Norway do tissue establishments have the sole responsibility for deciding on the form and value of compensation for living donors of non-reproductive tissues and cells.

Five Member States impose specific conditions for providing compensation to living donors of tissues and cells (DK, FR, HR, SI, UK). Four Member States (DK, FR, HR, SI) require donors to provide supporting documents when claiming reimbursement of expenses related to donation. In addition, the United Kingdom (HTA) further specified that compensation is restricted to expenses and inconveniences related to the donation.

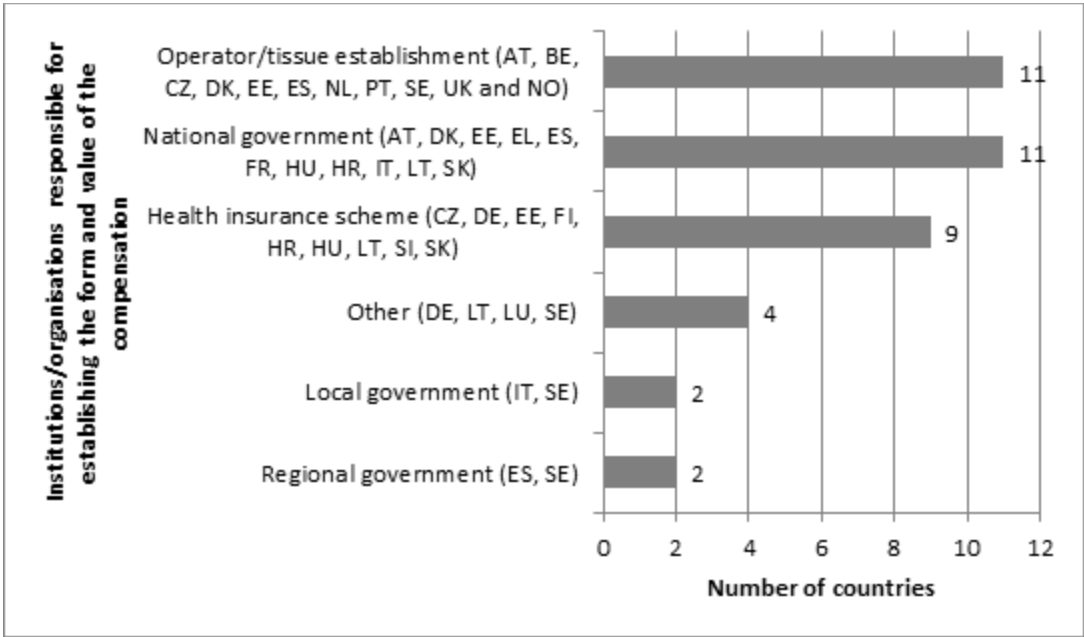


Fig.10. Institutions/organisations responsible for establishing the form and value of the compensation provided to living donors of non-reproductive tissues and cells (2014 data)

Eighteen Member States (CY, CZ, DK, ES, FI, FR, HR, HU, IE, IT, LT, LV, NL, PL, PT, RO, SI, SK) and Norway reported having a follow-up registry or a database of bone marrow and peripheral blood stem cell (PBSC) donors.

The information provided is presented in Table II, which shows that Member States have differing approaches, with donor follow-up performed in the five to ten years following donation, with examinations performed at the donor/transplantation centre, by the general practitioner or via a questionnaire. The other reporting countries indicated that such registries are not required by law (Austria, Bulgaria) or that follow-up of donors is ensured in a different manner. For instance, in Belgium, donors are followed for one year after donation and notification of serious adverse reactions to the competent authorities is mandatory. Estonia reported that its haematopoietic stem cell donors are registered with the Finnish Bone Marrow Donor Registry. Germany indicated that a follow-up registry is not in place but traceability is ensured by allocating a unique number to each donation. In Sweden, regional/university hospitals are responsible for the follow-up schemes of living donors. United Kingdom specified that individual licensed tissue establishments may have arrangements in place to follow-up donors.

Member State	Information on the registry(ies) for the follow-up of PBSC and BM donors
Croatia	Clinical and laboratory evaluation of the donor on the day of discharge from the hospital, on the last day of apheresis and 30 days after donation. Complete blood count to be performed one year and five years after donation. Ten years after the donation the Register must contact donors through questionnaires. SARs and SAEs must be reported immediately.
Cyprus	According to WMDA guidelines
Czech Republic	Regular check-ups: after 1 week, 1 month, 6 months, 1 year, 4 years blood tests
Denmark	The registry contacts donors 1 week after donation by telephone. If they have symptoms the follow-up is continued on individual basis. After 6 weeks blood tests are performed (haemoglobin, leukocytes, platelets, liver and kidney parameters). The two tissue establishments in Denmark where donation takes place have not yet implemented long-term follow-up, but they are planning to do this in accordance to WMDA standards.
Finland	For the bone marrow registry, the licence holder is the Finnish Red Cross Blood Service
France	The follow-up of related donors is directly managed by transplant physicians. The follow-up of unrelated donors is managed by the national registry and the correlated donor centres: since 1994 for BM donations and since 2000 for PBSC donations (yearly follow up).
Hungary	The Hungarian Bone Marrow Donor Registry is maintained by the Hungarian National Blood Transfusion Service (HNBTS).
Ireland	Historically PBSC donors were followed up annually for 10 years and BM donors were followed up until fully recovered. In accordance with WMDA, guidelines were amended by the national establishment as follows: <ul style="list-style-type: none"> - PBSC donors - one week, one month, one year and annually for 10 years - BM donors - one week, one month, one year and annually for 10 years The registry/database has been in place since 09/01/2013 and has a compliance rate of approximately 95%.
Italy	The follow-up of unrelated donors is carried out by the Donors Centre at periodic intervals after donation. After PBSC donation controls are performed after 2 and 7 days, after 1 month, 6 months and one year. After BM donation controls are performed at 1 month, 3 months, 6 months and 1 year. For both types of donations an annual check-up is expected in the next 10 years. These controls include a physical examination, blood tests and other exams.
Latvia	Tissue establishments keep the register for autologous stem cells transplantations.
Lithuania	The donor is invited for check-up (interview and full blood test) at the donation and transplantation centre 1 month after donation. Then donor is contacted by phone once per year with questions about his health condition, and if needed he is invited again for check-up. Duration of follow-up is 5 years.
Netherlands	Guidelines/protocols are locally implemented and maintained
Poland	The frequency, duration and parameters followed of check-ups are not established at national level. Each bone marrow donor centre has its own standard operating procedures created usually in co-operation with the procurement centre and accepted by the National Consultant in Haematology and the National Centre for Tissue and Cell Banking. The Unrelated bone marrow and cord blood donors' registry has been created in its present form in 2010 and is continuously developed and upgraded.
Portugal	Follow-up inquiry one day after donation. Testing and written inquiry one month after donation. Written inquiry one year after donation. Data are centralized on the CEDACE (national registry of bone marrow donors) database
Romania	National Registry of HSC Donors
Slovakia	Bone marrow donor registry performs the follow-up at 3months intervals, 1 year up to minimum 5 years at the general practitioner and data are sent to registry.
Slovenia	Regular examination after donation (6 months, 1 year, more if necessary). All steps shall be in accordance with legislative provisions and expert standards.
Spain	The Spanish Register of Bone Marrow (REDMO) is responsible for the donor follow up, via telephone, few days after the donation. Each donation centre has their own rules to monitor the donors. The REDMO accepts this fact when the minimum checks are ensured in those centres, i.e. one month after the donation and once a year during five years (for PBSC); and one month and one year after the donation (for bone marrow).

Table II. Follow-up of haematopoietic stem cell donors (2014 data)

One Member State (Malta) and Liechtenstein explained that patients in need of stem cell transplantations are referred to other countries, so follow-up of both donors and recipients is expected to be performed abroad.

2.2.2. Practices vis-à-vis donors of reproductive cells

Regarding reproductive cells, 17 Member States (AT, BE, BG, CZ, DK, EE, ES, FI, FR, HU, LV, NL, PT, SE, SI, SK, UK) and Norway reported providing some form of compensation for living donors of reproductive cells. Greece did not provide replies to the section concerning donors of reproductive cells (Figure 11). Of the 11 countries not providing compensation to gametes donors, four Member States (DE, IT, LT, LU, MT) and Liechtenstein indicated that, at the time of the survey, non-partner donation is not allowed at national level and one Member State (Germany) reported allowing non-partner donation of sperm, but not oocyte donation. One Member State (Poland) reported that gamete donation was not yet regulated.

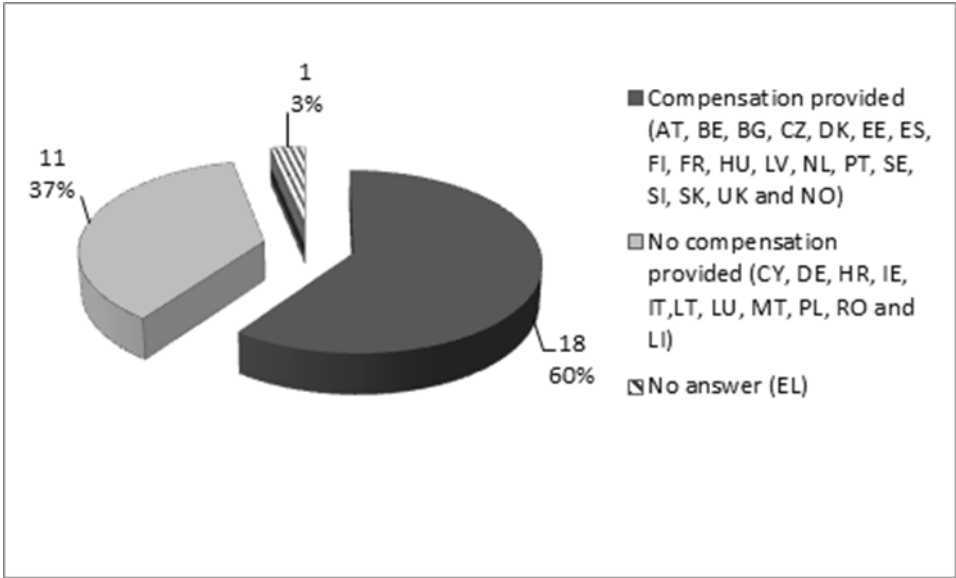


Fig. 11. Countries providing compensation to donors of reproductive cells (2014 data)

An outline of the practices vis-à-vis donors of reproductive cells is presented in Figure 12.

In ranked order, the most common practices are the reimbursement of costs related to travel to and from the place of donation (BE, BG, CZ, DK, FI, FR, HU, SI, SK, and NO), providing compensation related to loss of earnings (BE, BG, CZ, EE, FR, NL, SE, SK), providing donors a fixed sum of money/lump sum irrespective of actual costs, either established/decided by the tissue establishments themselves (AT, BE, CZ, EE, NL, SE, SK) or at national level (CZ, DK, FI, HU, SI, UK), reimbursing medical costs (e.g. hospitalisation, medication) (DK, ES, FI, PT, UK) and compensating for the inconveniences related to donation (BG, CZ, DK, LV).

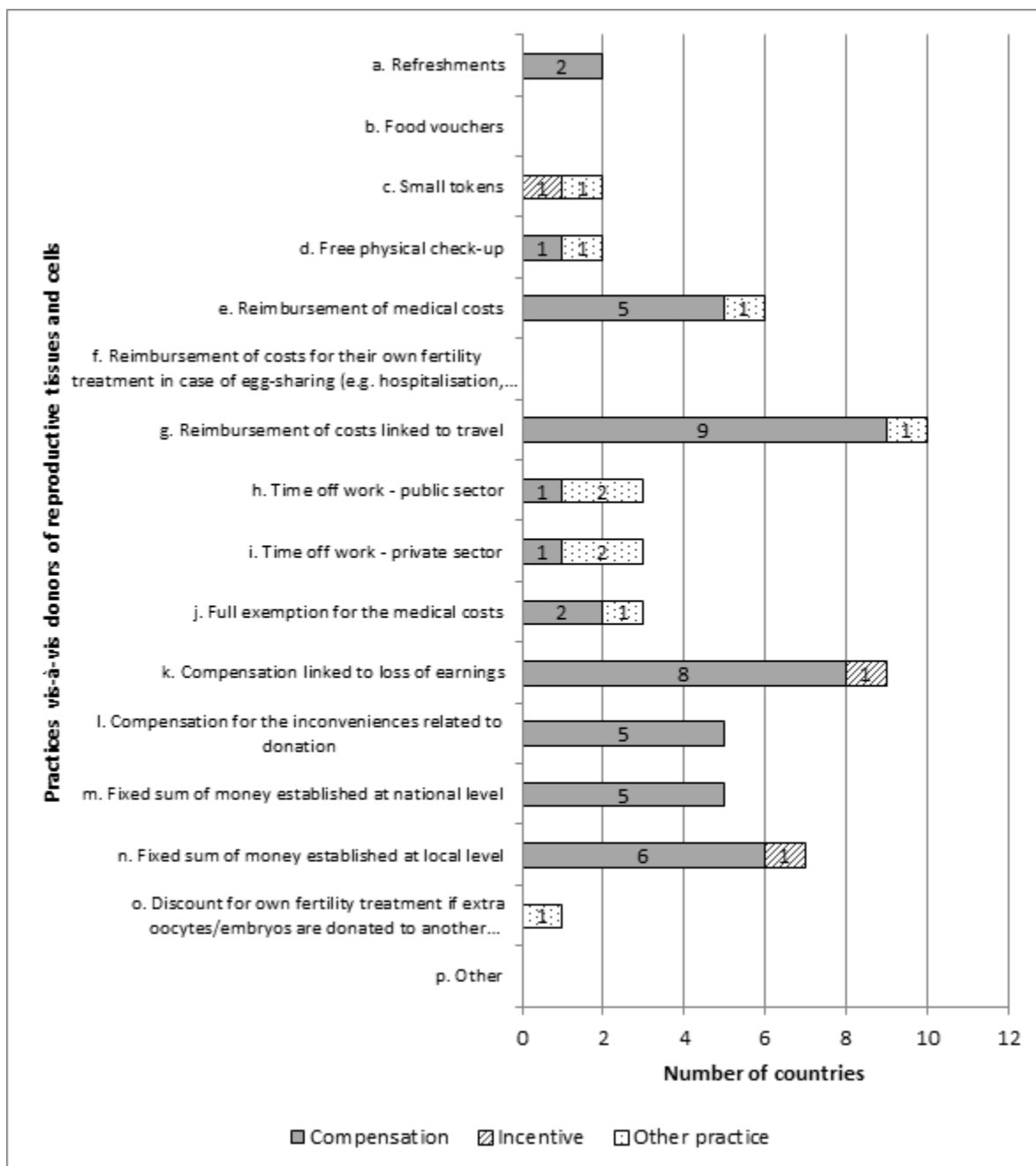


Fig. 12. Practices vis-à-vis living donors of reproductive cells and their interpretation by the responding Member States (2014 data)

Some practices were reported by just two or three Member States. For instance, offering time off work in both private and public sectors and providing refreshments was reported by three Member States (Bulgaria, Latvia, Slovenia), whereas two Member States (Bulgaria, Latvia) described providing small tokens. A physical check-up beyond what is required for the donation was reported by two Member States (Bulgaria, Slovenia). Two Member States (Czech Republic, France) indicated fully exempting donors from the medical costs associated with donation.

Only one Member State (United Kingdom) reported that donors may receive a discount for their own fertility treatment if unused oocytes/embryos are donated to another individual/couple (described as egg or embryo sharing). Food vouchers are not given to

donors of reproductive cells in any of the reporting countries. No “other practices” were reported.

As is the case for living donors of non-reproductive tissues and cells, it has to be underlined that the same practice may have different interpretations across the EU (Figure 12). For example practices such as providing a free physical check-up, reimbursement or full exemption of medical costs, reimbursement of costs associated with travel to the donation centre, and providing time off work were considered either compensations or incentives.

A small number of Member States provided information on the average/maximum equivalent of money corresponding to each practice applied at national level. For instance, Slovenia reported that medical costs covered by health insurance per single medical procedure were estimated to range from EUR 900 to 1800 for oocyte donation and up to EUR 135 for sperm donation. In Bulgaria, expenses related to travel to and from the site of donation are reimbursed up to EUR 40 for oocyte donors. In Slovenia, this can be up to EUR 250 for oocyte donors and EUR 125 for sperm donors. Latvia indicated that compensation for the inconveniences related to donation ranges from EUR 751 to 854 for oocyte donors and from EUR 113 to 280 for sperm donors. In addition, the figures reported by eight Member States regarding the lump sums provided to oocyte and sperm donors established both locally (by the tissue establishments responsible for procurement) and at national level are presented in Figure 13.

a)

Fixed sum of money (lump sum) established at national level				
COUNTRY	OOCYTE DONATION		SPERM DONATION	
	Average amount (€)	Maximum amount (€)	Average amount(€)	Maximum amount(€)
Denmark	320	320	40	67
Finland	250	250		
Portugal	628,83	628,83	41,92	41,92
Spain		900		100
United Kingdom		898		42

b)

Fixed sum of money (lump sum) established at local level				
COUNTRY	OOCYTE DONATION		SPERM DONATION	
	Average amount (€)	Maximum amount (€)	Average amount(€)	Maximum amount(€)
Slovakia	500	500	50	50
Sweden*	700	1200	200	400
Bulgaria	1000	1500	50	200

* The maximum value provided by Sweden refers to an on-going project in the Skåne region offering a higher compensation for oocyte donation (25 % of the PBA) than the other regions. The lump sum for sperm donation is provided for 4 to 10 donations

Fig. 13. The average and maximum amount of the lump sums provided as compensation to oocyte and sperm donors: a) established locally (by the tissue establishments responsible for procurement) and b) decided at national level (2014 data)

With reference to the responsibility for taking decisions specifying the form and value of such compensations, in half of the reporting countries this task was entrusted to the tissue

establishments (Figure 14). A small number of Member States described the decision-making process for establishing the form and value of the compensation for donors of reproductive cells.

- Latvia and Slovenia indicated that compensation is established on a case by case basis by either the tissue establishments or the national ART Committee, respectively;
- In Sweden, the decision-making process varies from county to county. In 2013, a recommendation was produced by the National Tissue Council in cooperation with representatives from all university hospitals. The recommendation targets non partner donors and urges that compensation is only offered for the expenses linked to the donation. This compensation is connected to the price base amount (PBA) which is updated annually. For sperm, the compensation was set at 1.25 % of the PBA and for egg donation the sum is 15 % of the PBA. If the donor has expenses that exceed these amounts, the compensation can be increased to cover these extra expenses. The compensation is paid after performing a donation including handing in a screening test 180 days after the donation. The United Kingdom specified that the form of compensation was decided by the competent authority (HFEA) following a public consultation.

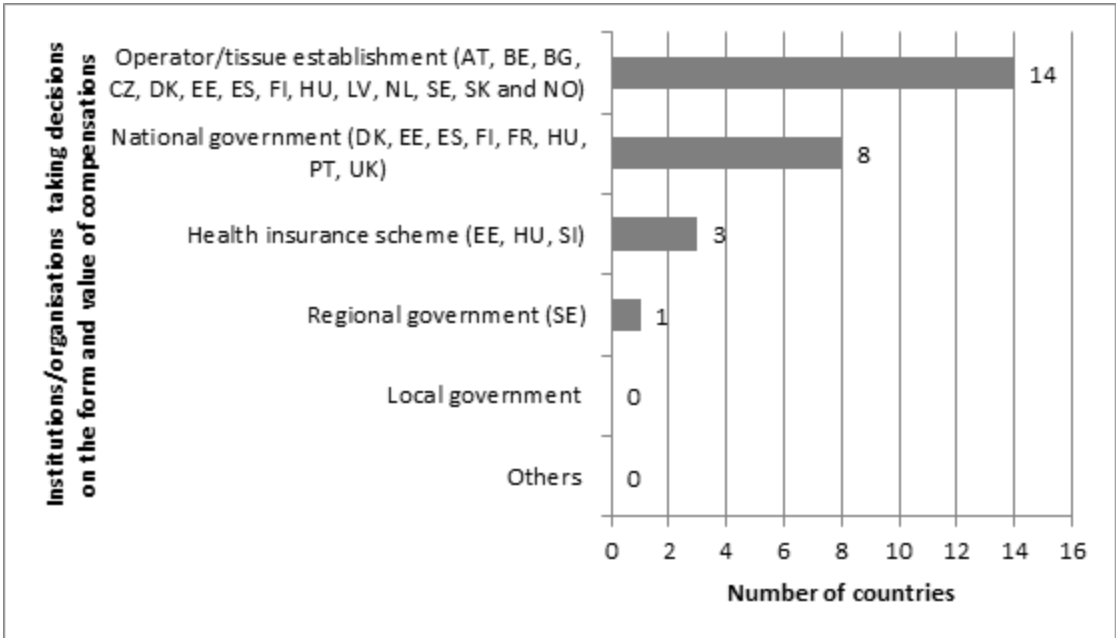


Fig. 14. Institutions/organisations responsible for deciding the form and value of the compensation given to donors of reproductive cells (2014 data)

As regards the possibility for couples/individuals requesting fertility treatments with donated oocytes or sperm to bring/recruit potential donors, 12 Member States (AT, BE, BG, DE, DK, EE, FI, NL, RO, SE, SK, UK) reported allowing such a practice. In five Member States (BG, DK, NL, SE, UK), bringing a potential oocyte donor gives some advantages to the recruiting couple/individual. In four of these countries (BG, DK, NL, SE), this practice moves the recruiting couples/individuals up the waiting list. Bulgaria further specified that when recipients are not in a position to wait to find an anonymous non-partner oocyte, oocyte donors can be recruited among relatives (e.g. siblings, cousins). Denmark reported that oocyte donors recruited by a couple/individual are included in an oocyte donor pool, while the recruiting couple/woman will receive an oocyte from another donor in the pool ("cross-donation"). Cross-donation was also reported by Sweden. Furthermore, Bulgaria and Sweden admitted having difficulties in ensuring that in such cases donation remains voluntary and

unpaid. United Kingdom (HFEA) informed that recruiting couples/individuals can benefit from certain advantages but these are decided at clinic level in line with the HFEA Direction 0001.

Three Member States (Croatia, Netherlands and Slovenia) declared imposing specific conditions to couples/individuals from other EU MS/non-EU countries requesting fertility treatments with donated sperm or oocytes on their territory. Croatia specified that in accordance with the national Medically Assisted Fertilisation Act, a child conceived and born by means of ART with donated sperm, oocytes or embryos, is entitled to review the data concerning his biological origin after he or she has reached the age of 18, including the identity of the sperm/oocyte/embryo donor(s). The latter information is recorded in the State Register of Medically Assisted Reproduction maintained by the national competent authority. The Netherlands indicated that only gametes from non-anonymous donations can be used. Slovenia underlines that the special conditions refer only to pricing and reimbursement from the health insurance company(ies) in the patients’ countries of origin. Additionally, Malta reiterated that according to the Embryo Protection Act 2012, non-partner donation of gametes is not allowed.

Three Member States (Finland, Netherlands and Slovenia) and Norway reported having a national registry or database for the follow-up of donors of oocyte and/or sperm intended for non-partner donation. In this context, the Netherlands explained that in case of a child born through IVF, data on the sperm/egg donor and mother are kept in a central database and specific data can be requested by general practitioners, the child and the parents. France indicated that the Biomedicine Agency has the mission to follow oocyte donors and children born subsequent to ART procedures through the public national health insurance database.

2.2.2.1. Special provisions for non-partner oocyte donation

In regard to non-partner oocyte donation, the vast majority of countries reported having some **restrictions** in place, as defined by Directive 2006/17/EC (Figure 15). However, nine Member States (BE, CY, CZ, DK, FI, IE, PL, RO und UK) stated having no such restrictions.

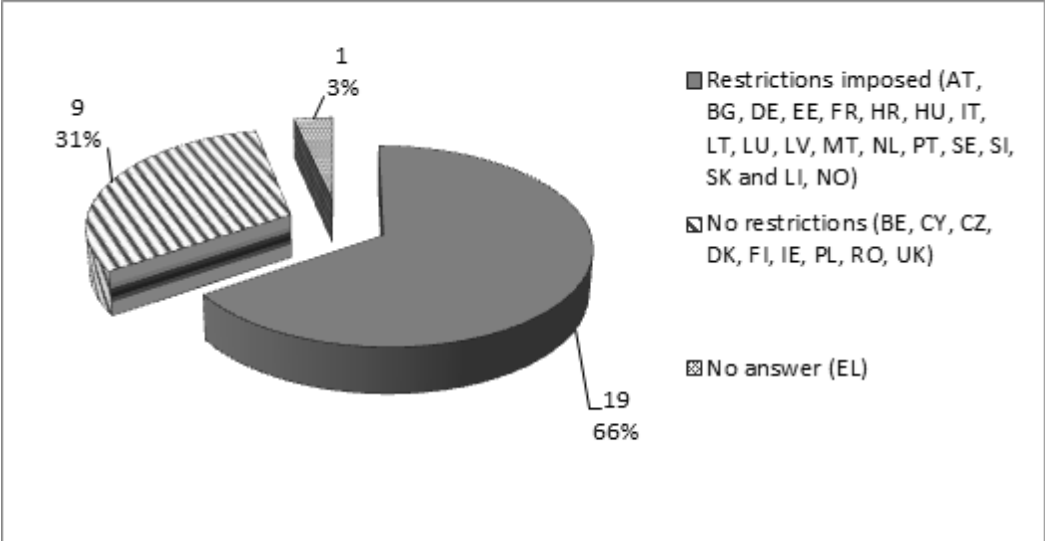


Fig. 15. Member States and EEA countries’ approaches towards non-partner oocyte donation (2014 data)

Most of the respondents noted that the restrictions for non-partner oocyte donation are laid down in the national legislation (Figure 16).

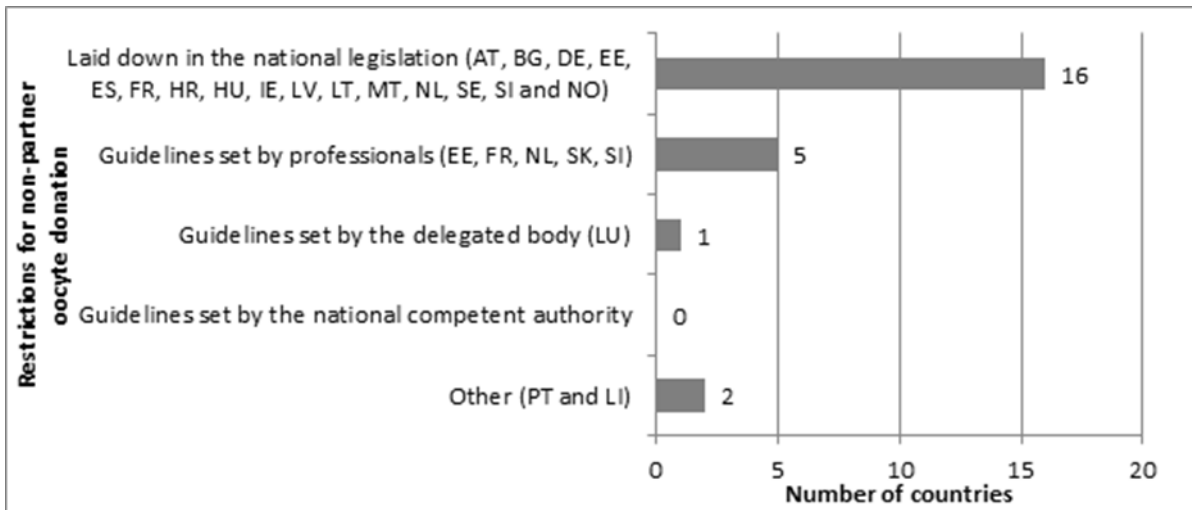


Fig. 16. Legal status of the restrictions put in place for non-partner oocyte donation by the reporting Member States and EEA countries (2014 data)

In addition, Liechtenstein reported that restrictions are included in a governmental decision and Portugal specified that they are set by the ART national competent authority. It should be noted that although Ireland does not provide any restriction, no ART clinics are currently authorised for non-partner oocyte donation.

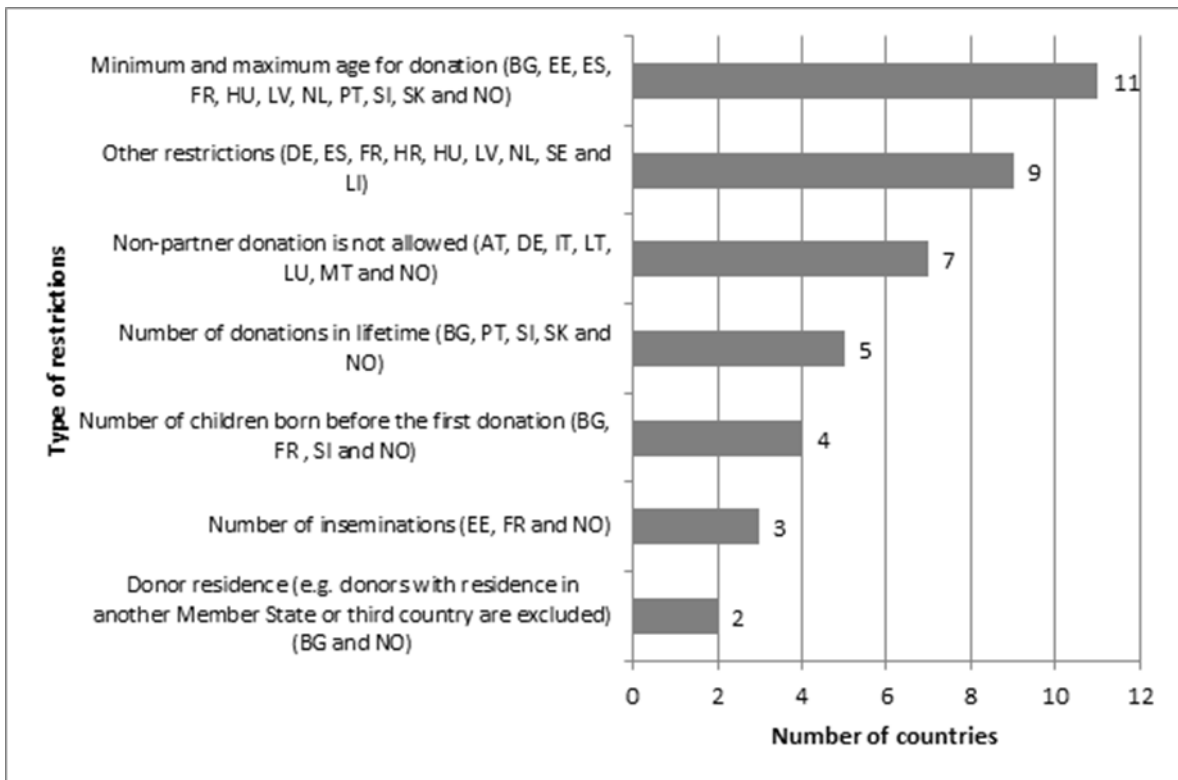


Fig. 17. Type of restrictions for non-partner oocyte donation as defined by the reporting Member States and EEA countries place (2014 data)

In terms of specific restrictions, oocyte donation is prohibited in one Member State (Germany) and non-partner oocyte donation is not allowed in six Member States and one EEA country (Figure 17). Regarding this issue, Lithuania stressed that partner donation of gametes is allowed only between married partners. Eleven Member States (BG, EE, ES, FI,

FR, HU, LV, NL, PT, SI, SK) and Norway reported having criteria to be fulfilled by oocyte donors (e.g. minimum and maximum age for oocyte donation, number of children born before donation, maximum offspring born from an individual oocyte donor) (Table III). Additionally, in Sweden, only university hospitals are allowed to use oocytes from non-partner donors.

Furthermore, six Member States (BG, FI, HU, PT, SI, UK) confirmed having a national registry or database for non-partner oocyte donors. In addition, Croatia specified that such a national registry is currently under development.

Member State	Oocyte donor' age limits (years)	Minimum number of children born before donation	Maximum of children born from a donor
Bulgaria	18-34 for unrelated non-partner donation; 18-38 for relatives of women requiring oocyte donation	1	5
Croatia	Legal age	1	2
Estonia	<35		6
France	20-37	1/0*	10
Hungary	< 35		4
Latvia	18-35		3
Netherlands	25-40	1	
Portugal	18-35		maximum 3 donations
Slovakia	21-34	0	
Slovenia	adult	1	2
Spain	>18		

Table III. Criteria to be fulfilled by oocyte donors as reported by the responding Member States (2014 data)

*France indicated that before 2011, the law on bioethics stipulated that only women having a child before donation were allowed to donate oocytes. In 2011 the law on bioethics has been changed and even women without a child can now donate their oocytes. The same regulation applies to sperm donors.

Regarding the organisation of national registries of oocyte donors, the answers provided show a variety of approaches with the databases serving different purposes:

- In Bulgaria, a registry has been in place since 2011. The following data are collected: the number of the donors, the tissue establishment where the donation took place, unique ID number, number of own children, the unique identification number of the cells and the donor, the number of ART procedures, children born or pregnancies by ART. The aim is to not exceed the number of permitted live-born children by ART and to ensure traceability from the donor to the recipient;
- Finland indicated that the National Supervisory Authority for Welfare and Health is responsible of their registry;
- Hungary specified that according to a Government decree, the National Institute for Quality and Organizational Development in Healthcare and Medicines (NIQODHM) maintains the Database for Reproductive Technologies. Healthcare providers provide

data for the NIQODHM and among other data, information on oocyte donors are also collected;

- In Portugal, the registry has the purpose of registering encrypted identification data of donors and to process a national donation code for each donation;
- In Slovenia, the registry includes personal and medical data, dates of donation, storage and use, follow-up results and birth date. Data are stored for 50 years;
- In the United Kingdom, the HFEA has a record of all births as a result of assisted conception treatments from licensed UK fertility clinics since 1 August 1991. The information includes details of everyone who has donated sperm, eggs or embryos that were used at licensed UK fertility clinics. Donor information is shared with parents and patients in order to allow parents to be open with their children about their donor-conceived origins from an early age.

2.2.2.2. Special provisions for non-partner sperm donation

In regard to non-partner sperm donation, the majority of the responding countries reported having some restrictions, whereas seven Member States declared having no such restrictions (Figure 18). Although Ireland does not provide any restrictions, it should be noted that no ART clinics are authorised for non-partner sperm donation.

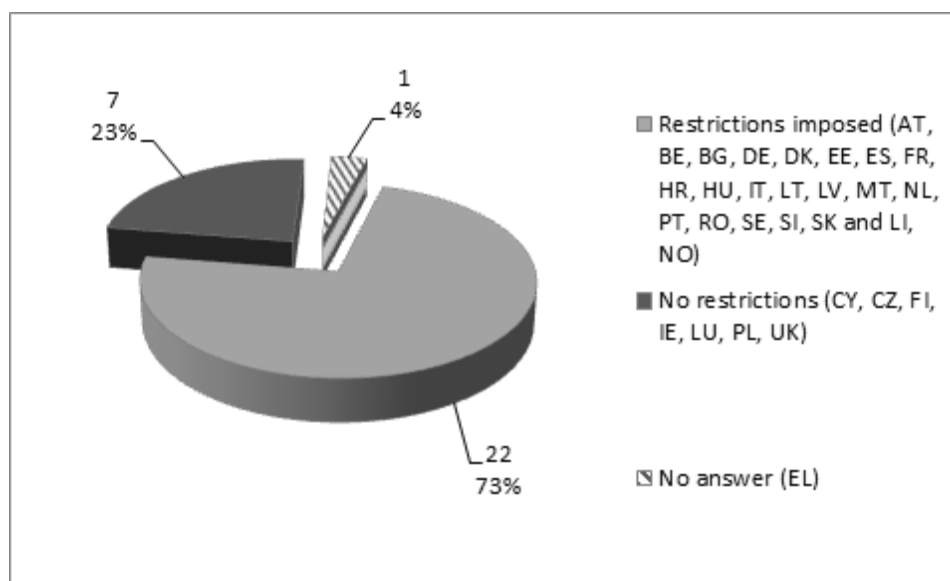


Fig. 18. Member States and EEA countries' approaches towards non-partner sperm donation (2014 data)

An overview of the legal status and type of restrictions defined by the Member States for non-partner sperm donation is presented in Figure 18 and 19. Most of the responding countries reported that restrictions related to non-partner sperm donation are laid down in their national legislation. Six Member States declared that such restrictions are included in guidelines developed by professional associations and in two Member States they are covered by the guidelines issued by the national competent authorities. Liechtenstein reported that such restrictions are taken by governmental decision and Portugal indicated that they are included in a relevant regulation issued by the national competent authority.

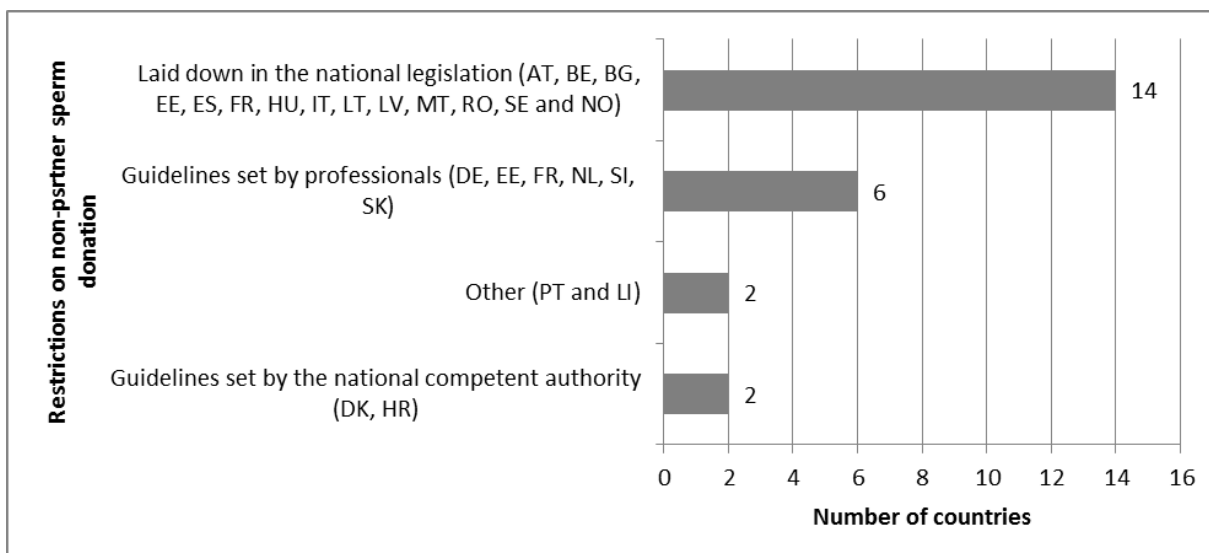


Fig. 19. Legal status of the restrictions put in place for non-partner sperm donation by the reporting Member States and EEA countries (2014 data)

Regarding the type of restrictions, they range from number of donations and number of children born from the same donor to complete prohibition of non-partner sperm donation (Figure 20, Table IV). Liechtenstein confirmed having no establishments using donated sperm. Additionally, Lithuania specified allowing ART procedures in which donated sperm is used only between married partners.

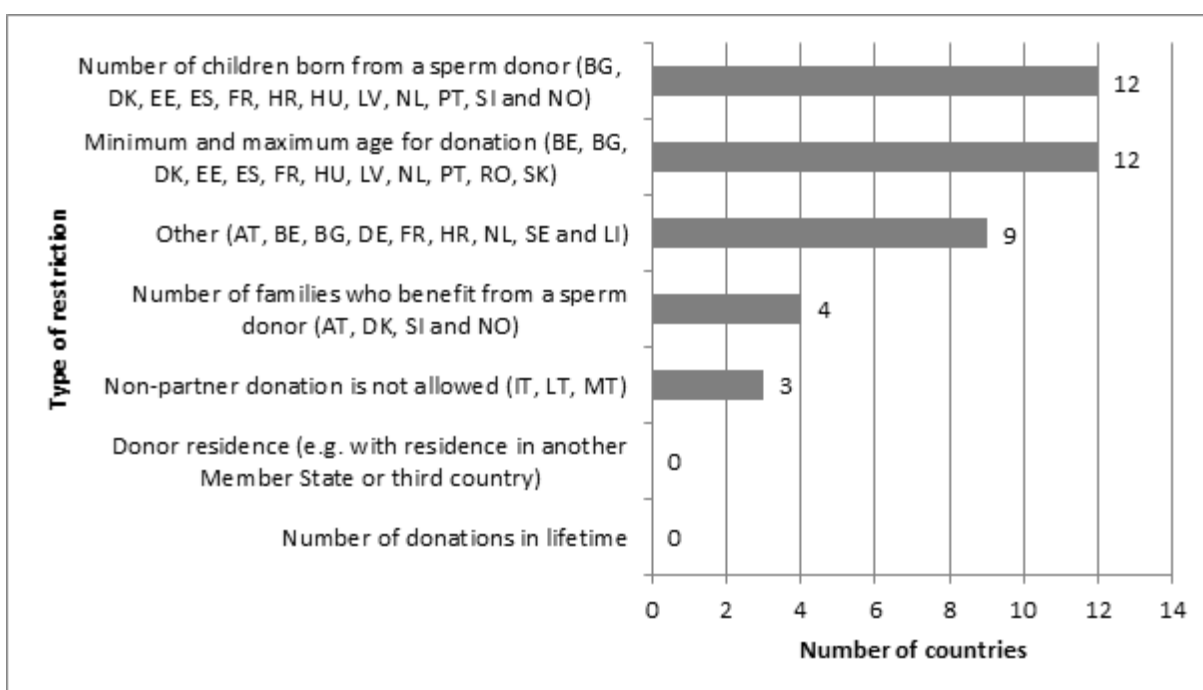


Fig. 20. Type of restrictions for non-partner sperm donation as defined by the reporting Member States and EEA countries place (2014 data)

Member State	Sperm donor' age limits (years)	Number of inseminations/ pregnancies	Maximum of children born from a donor	Number of beneficiaries
Austria				Max. 3 partnerships. Donation restricted to one clinic.
Belgium				Max. 6 women
Bulgaria	18-40	Max 20 inseminations	5	
Croatia			3 in 3 different families	
Denmark	>18		Max 12 children for recipients living in Denmark except when families already have children born with sperm from the same donor	
Estonia	<40		6	
France	<45		Max 10 children	
Germany		Max. 10 pregnancies		
Hungary	<35		4	
Latvia	18-45		3 (except multiple pregnancies)	
Netherlands	20-45	25		
Norway			Max 2 children per 4 families or one child per 6 families	
Portugal	18-45		8	
Slovakia	<35			
Slovenia			Max.2 children born in 2 different families	
Spain	>18			
Sweden	Adult age		Max. children born in 6 families	

Table IV. Criteria for sperm donation as reported by the responding Member States (2014 data)

Five Member States (BG, FI, PT, SI, UK) and Norway reported having a national registry/database for non-partner sperm donors. While Hungary reported having a national registry or database for oocytes donors, there is no similar registry for sperm donors. On the other hand, Norway has a national registry for sperm donors, but not for oocyte donors. Croatia and Latvia indicated that such national registries are currently under development.

With regard to the purpose of the registry for non-partner sperm donors, Bulgaria indicated that the national registry allows verification of compliance with the provisions on the maximum number of children conceived through ART procedures and to ensure appropriate traceability. The Bulgarian registry contains data such as the number of donors, tissue establishments where donations take place, personal data, number of own children, donor code, codes of the donated samples, number of inseminations, pregnancies and live-born children. Portugal specified that their national registry ensures the central allocation of donor and donation numbers. The registry in Norway serves the same purpose as in Portugal. In Slovenia, the registry includes donor medical and personal data as well as testing results. The

United Kingdom stated that HFEA has been keeping track of results of assisted reproduction since 1991 and includes information on donors whose cells were used in national clinics. People conceived as a result of a donation have a legal entitlement to apply to the HFEA for information about their origins, including details the donor provided at the clinic. Patients seeking treatment with donor gametes and parents of donor-conceived children will also be able to access anonymous donor information. Donor information is shared with parents and patients in order to help people be open with their children about their donor-conceived origins from an early age.

Countries who declared not having a national registry of sperm donors explained that either non-partner donation of sperm is not allowed (IE, IT, LT, MT) or there is no legal requirement to develop such a registry (AT, DE, HU, PL). Croatia, Latvia and Slovakia indicated that a national registry is under development. Nine Member States (BE, CY, DK, EE, FR, HU, NL, RO, SE) and Norway reported that registries are maintained by the operators (e.g. mostly private ART clinics).

2.2.3. Practices vis-à-vis relatives of deceased donors of tissues and cells

Concerning practices vis-à-vis relatives of deceased donors of tissues and cells, only three Members States (Bulgaria, Romania and Spain) reported giving some form of compensation. A summary of the practices accepted in these three countries is presented in Figure 21. Compared with the previous Commission survey, one Member State has stopped paying donors, namely Slovenia, who stressed that tissue donation from deceased donors is provided without any financial or material compensation.

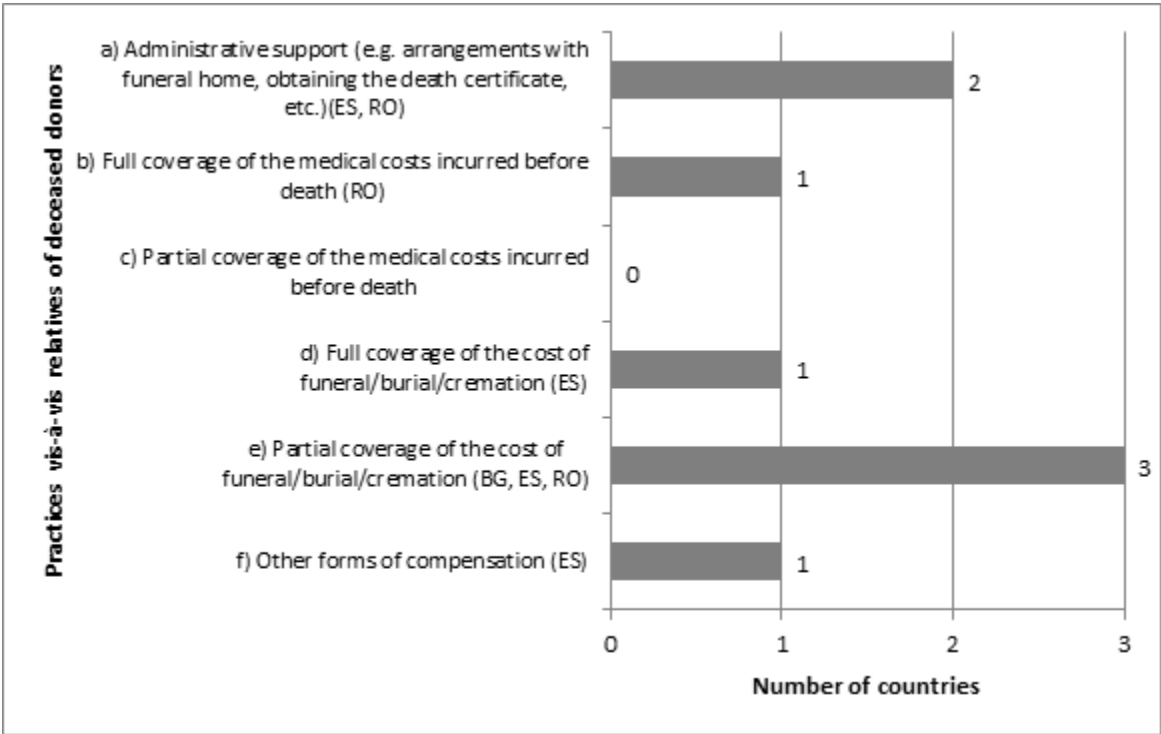


Fig. 21. Practices vis-à-vis deceased donors (2014 data)

All the practices outlined above are considered by the Member States concerned as compensation provided to the family or relatives of deceased donors. The decision on the form and value of the compensation is taken at different levels. Romania specified that the form of compensation for deceased donors is laid down in the law, but its value is established

by the National Transplant Agency (average value EUR 600), whereas in Bulgaria the decisions are taken by operators (i.e. tissues establishments; average value EUR 300 with a maximum of EUR 750). Spain clarified that compensations are decided at regional/hospital level and only in exceptional cases, when there is no insurance covering the funeral expenses and the family has no resources to afford them, the regional authorities (*Comunidades Autónomas*) may allow the full coverage for the costs of the funeral/burial/cremation or other forms of compensation. No further information was provided on the value of the compensation.

2.3. Tissue and cell donation and anonymity

All reporting countries apart from Ireland and Liechtenstein have legislative provisions regarding anonymity/non-anonymity of donors of non-reproductive tissues and cells. Twenty-four Member States (BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IT, LT, LV, NL, PL, PT, RO, SE, SI, SK, UK) and Norway indicated that donation should be anonymous. Non-anonymous donation of non-reproductive tissues and cells is required in only three Member States (Austria, Luxembourg, and Netherlands).

For donors of reproductive tissues and cells, 24 countries indicated having in place provisions regarding anonymity/non-anonymity. Sixteen Member States (BE, BG, CY, CZ, DK, EE, ES, FI, FR, HU, LV, PT, RO, SE, SI, SK) and Norway reported that donation must be anonymous, whereas seven Member States (AT, DE, HR, LU, MT, NL, UK) indicated that their legislation requires donations to be non-anonymous. Four Member States (IE, IT, LT, PL) and Liechtenstein have no requirements concerning this issue.

Sweden indicated that, even though donation of reproductive cells is anonymous, in special circumstances the donor's identity should be made available to children conceived with donated gametes, when they reach adulthood. Additionally, two Member States (Belgium and Denmark) specified allowing both anonymous and non-anonymous donation of reproductive tissues and cells. In this regard, Denmark specified that non-anonymous donation refers to sperm donors with an extended profile (“known donors”) or donors whose identity is known by the recipient or to “open donors”; the latter refers to situations when the child conceived with the donor has the possibility to contact and meet the donor when he/she turns 18.

An overview of the requirements on donor anonymity/non-anonymity for both reproductive and non-reproductive tissues and cells is presented in Figure 22.

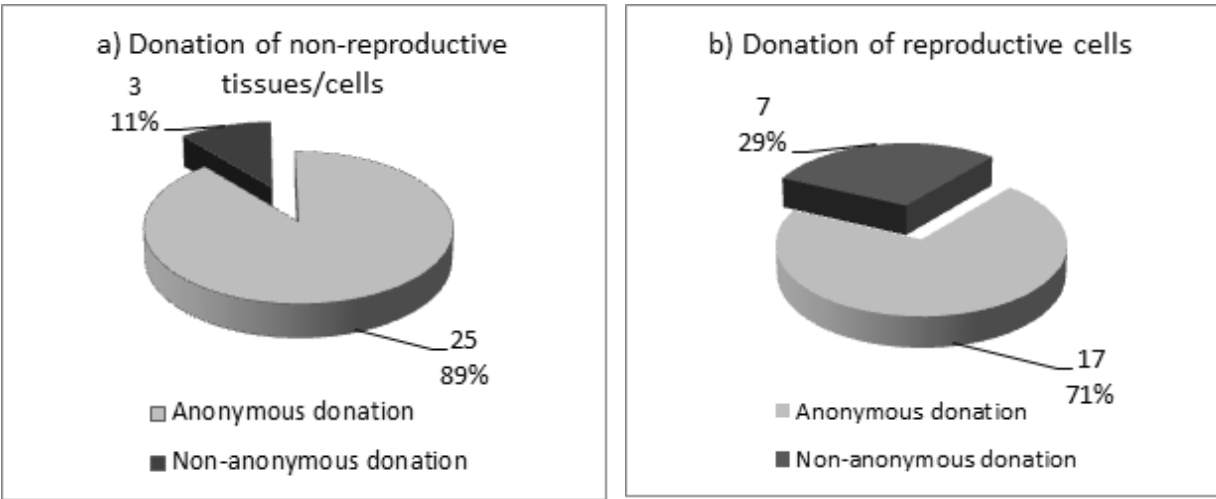


Fig. 22. Donor anonymity for donation of non-reproductive and reproductive tissues and cells as reported by the EU and EEA countries (2014 data)

Two Member States (Latvia and Lithuania) notified changes to the national legislative provisions on donor anonymity since the previous reporting exercise. Latvia reported introducing an obligation for tissue establishments, procurement organisations and sites for human application to ensure anonymity of the tissue and cell donor, as well as protection and confidentiality of donor personal and genetic data. Lithuania indicated that the national law on transplantation of human tissues, cells and organs, was amended in 2013 by adding a provision requiring that human tissue, cell, organ donation and transplantation is voluntary and unpaid in accordance with the principles of anonymity, confidentiality and respect for human dignity. Additionally, Ireland specified that donor identification issues will be addressed in the national provisions and guidelines on VUD currently in preparation.

2.4. Promotion and advertising

Twenty Member States (BE, BG, CY, DE, EL, ES, FR, HR, IE, IT, LT, LU, LV, MT, NL, PL, RO, SE, SI, UK) and Norway confirmed having taken measures to promote VUD of tissues and cells. A summary of the measures reported is shown in Figure 23. Compared to the second Commission report on the application of the VUD principle, three Member States (Croatia, Luxembourg, Romania) and Norway reported starting to promote VUD.

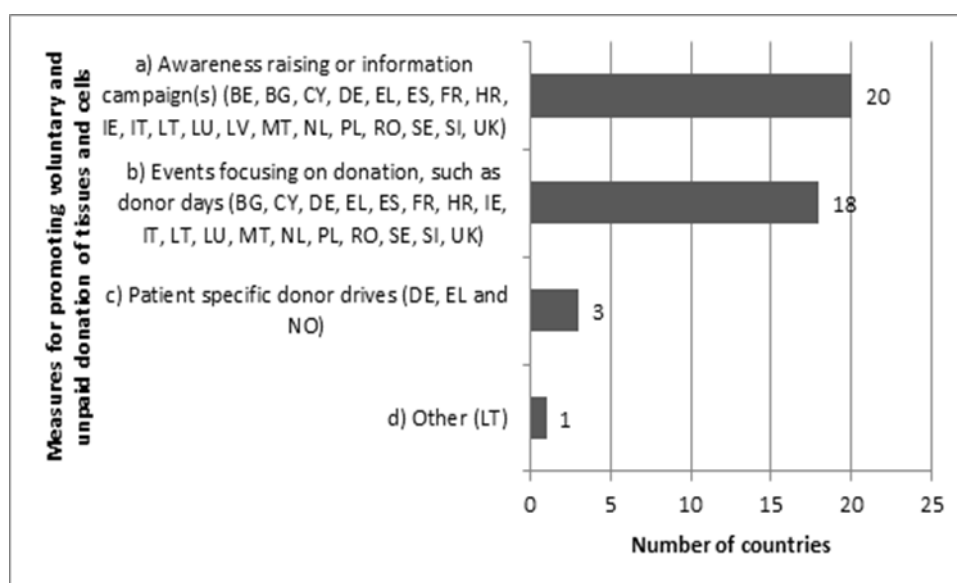


Fig. 23. Measures taken at national level to promote VUD of tissues and cells (2014 data)

The most commonly used measure is the launching of information campaigns organised by public or private actors either at national or local level. The second most commonly used tool is organising donor days/donor weeks, an initiative reported by six Member States (BG, CY, HR, MT, NL, RO). In addition, several countries reported having routine promotional initiatives (Germany - telephone line; Netherlands – website; Sweden - appointed persons at local levels; Lithuania - lectures about VUD in secondary schools, medical faculties and other institutions). Spain specified that its national donation system does not allow promotional campaigns for individual patients and that no specific measures to promote VUD were taken in the ART sector.

As set out in article 12(2) of Directive 2004/23/EC, Member States shall take all necessary measures to ensure that any promotion and publicity activities in support of the donation of human tissues and cells comply with the guidelines or legislative provisions laid down at

national level. Twenty-six Member States (AT, BE, BG, CY, CZ, DE, EE, EL, ES, FI, FR, HR, HU, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI, SK, UK) reported having such restrictions, of which seven (EL, ES, LT, LV, PL, SE, SK) noted that their current binding provisions concerning restrictions or prohibitions of advertising changed since the publication of the second VUD survey.

Specific provisions providing for restrictions or prohibitions of advertising the need for, or availability of particular tissue and cells with a view to offering or seeking financial gain or comparable advantages are in place for:

- Haematopoietic stem cells - in 14 Member States (AT, BE, CZ, DE, EL, ES, FR, HR, HU, LU, NL, PL, SI, SK);
- Gametes and embryos – in 15 Member States (AT, BE, BG, CZ, DE, DK, ES, FR, HR, HU, LU, NL, PT, SK, UK).

Penalties for infringements of the legislative provisions related to Article 12(2) in Directive 2004/23/EC have been defined in 22 countries (AT, BE, BG, CZ, DE, EE, EL, ES, FI, FR, HR, HU, LT, LU, MT, NL, PL, PT, RO, SI, UK and LI). An outline of the type of penalties included in the Member States' legislation is shown in Figure 24. However, no Member State has imposed such penalties.

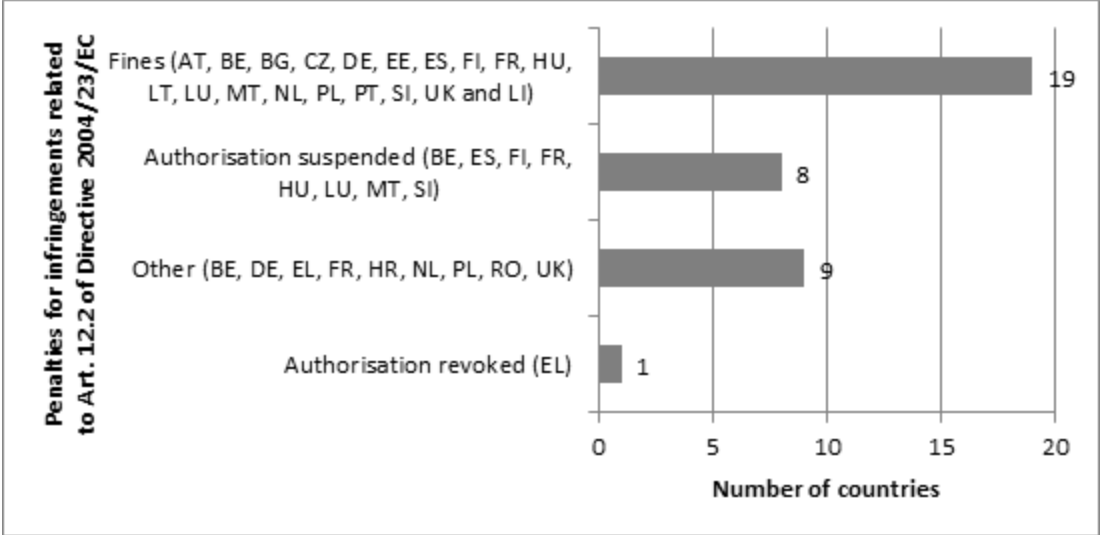


Fig. 24. Penalties for infringements of the legislative provisions related to Article 12.2. in the Directive 2004/23/EC (2014 data)

More than half of the responding countries indicated using only one type of penalty, as following: fines (BG, CZ, EE, LT, PT, SI), imprisonment (Belgium, Croatia, Romania), licence suspension or revocation (Hungary, Spain). Eight countries use a combination of penalties. Fines and imprisonment were reported by four Member States (DE, FR, PL, UK) and Liechtenstein, and fines and licence suspension/revocation were described by three Member States (Austria, Finland, Spain). The duration of imprisonment ranges from six months (Liechtenstein), up to one year (Netherlands, United Kingdom) or five years (France, Germany) and even longer, between one and ten years (Poland). Malta did not provide any information on the type of penalties established at national level.

Seven Member States (BE, CY, DE, EL, FR, NL, SI) reported having legal requirements for tissue establishments/commercial operators when advertising tissues and cells via the internet. Advertising with the purpose of obtaining a financial gain or any other material gain is illegal in Cyprus, Germany, Netherlands and Slovenia. In France, tissue establishments and

commercial operators do not have the right to take any type of advertising initiative, whereas in Belgium advertisements are only allowed as part of public awareness campaigns. In Greece, issuing a brochure or any other form of advertisement for donation requires prior approval by the competent authority.

Legal requirements or guidelines concerning posting donation offers (e.g. donation of sperm or oocytes) by individuals in newspapers, social media or other means are in place in seven countries (BE, DE, EL, FR, HR, PL, SI). In Belgium and France, national legislation prohibits any form of advertising on procurement or activities related to human body material. In Croatia, Germany, Greece and Poland, posting such advertisements is illegal and punishable with imprisonment.

In addition, France and Slovenia indicated that in their countries promotion activities for tissue and cell donation were entrusted only to the national competent authorities. Malta, Greece and Poland underlined that promotion and advertisement activities are supervised and require prior approval from the national competent authorities.

2.5. Donation-related practices in the healthcare system

This section of the survey aims to establish which are the main suppliers of tissues and cells across the EU, whether Member States provide or do not provide incentives to donors and/or healthcare professionals involved in recruiting donors or procuring tissues and cells, and if a sufficiency policy for human tissues and cells has been defined at national level.

An overview of the main suppliers of replacement tissues (e.g. skeletal tissue, ocular tissues, skin, cardiovascular tissue) is presented in Figure 25.

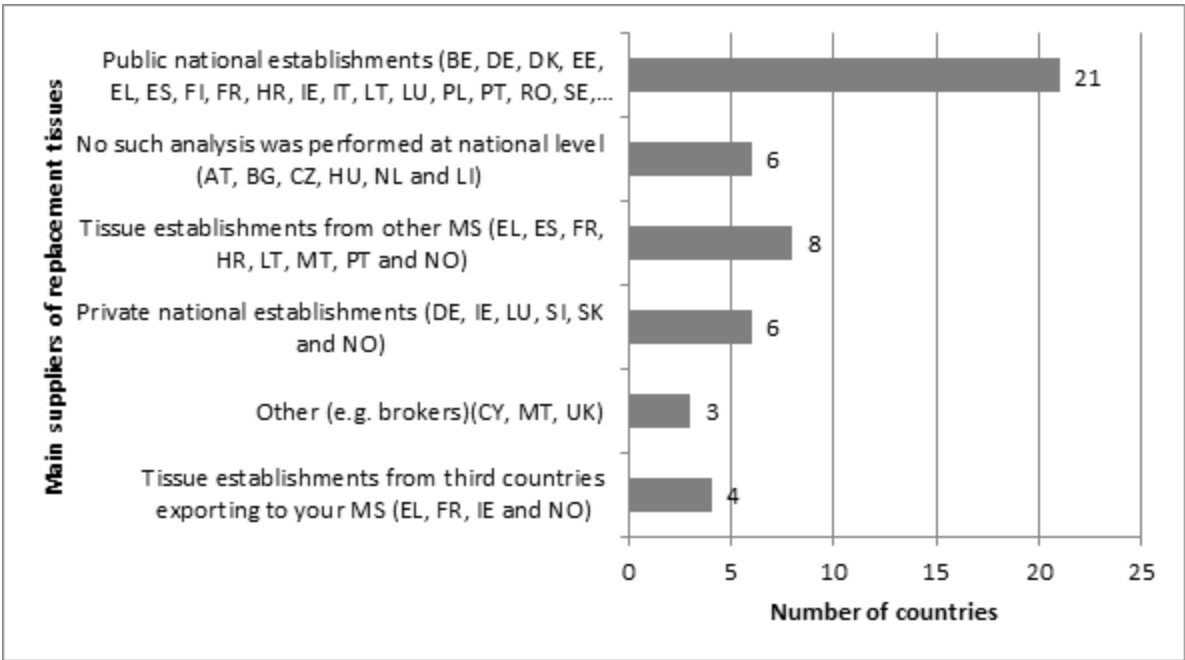


Fig. 25. Main suppliers of replacement tissues in the EU and EEA countries (2014 data)

The survey shows that, for replacement tissues, public tissue establishments prevail. Five Member States (DE, IE, LU, SI, SK) and Norway indicated having a dual system of private and public suppliers. Three Member States, namely Cyprus, Malta and United Kingdom rely entirely on brokers in order to ensure the national supply of replacement tissues. Three Member States (France, Greece and Ireland) and Norway indicated that third country

suppliers are also important for ensuring an adequate national supply. It has to be noted that seven countries did not perform such an analysis.

As shown in Figure 25, with regard to the main registries of haematopoietic stem cell donors (Figure 26), 19 Member States and Norway reported having national registries. However, only two Member States (Croatia and Finland) and Norway rely entirely on them. Most Member States recruit donors from both national and WMDA registries, with four Member States using all available registries (AT, FR, IE, LT). Estonia uses only WMDA accredited registries.

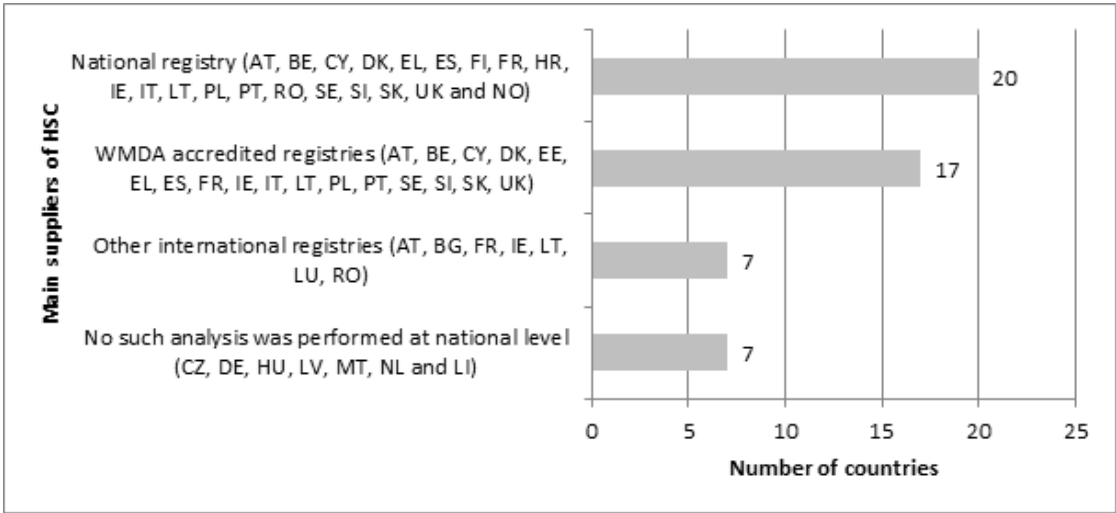


Fig. 26. Main suppliers of haematopoietic stem cells in the EU and EEA countries (2014 data)

Replies concerning the main suppliers of gametes and embryos from non-partner donations are summarised in Figure 27.

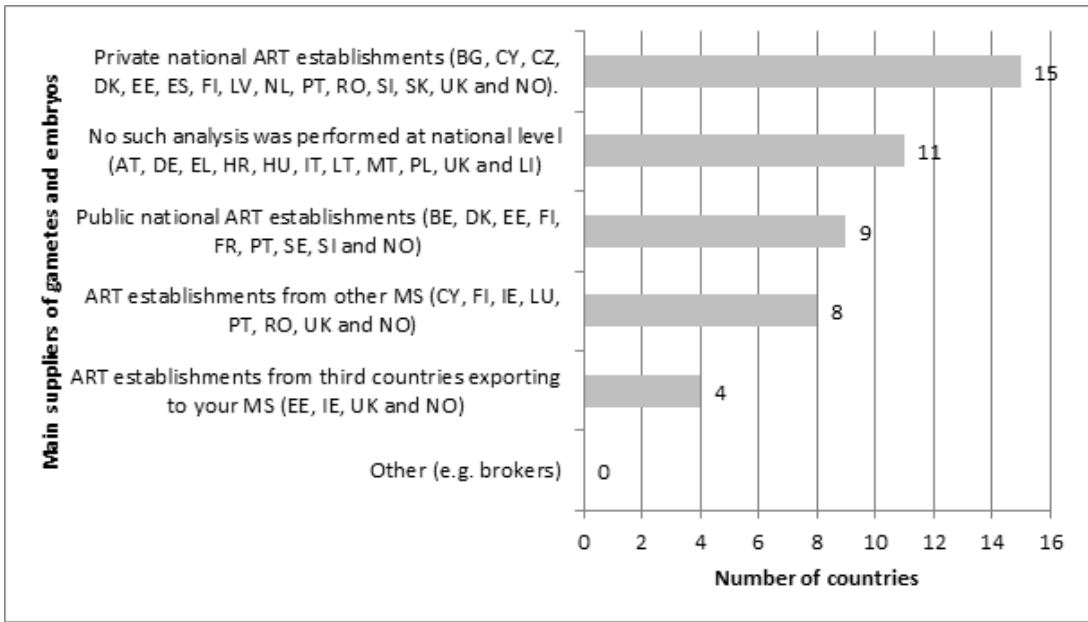


Fig. 27. Main suppliers of gametes and embryos in the EU and EEA countries (2014 data)

The survey shows that the ART sector is dominated by private establishments with 15 Member States indicating they are the main suppliers. Public ART establishments are the only

suppliers in three Member States (Belgium, France, Sweden). In contrast, four Member States (BG, LV, NL, SK) reported that only the private ART establishments provide gametes in their countries. Three Member States (EE, IE, UK) and Norway indicated that establishments in third countries are among their main suppliers for this type of cells. Similar to the sector of non-reproductive tissues and cells, most of the respondents indicated that reproductive cells are supplied by both private and public ART establishments in their countries, but also from other EU Member States. No such analysis was performed at national level in ten of the responding countries.

As regards the policy to provide financial incentives to the tissue establishments, recruitment organisations or professionals in procurement organisations, only four Member States (HR, LT, PL, SE) reported giving some form of financial incentive. Croatia provides financial incentives to hospital administration, recruitment organisations and tissue establishments, whereas Lithuania and Portugal indicated motivating only hospital administrations and Sweden providing inducements only to tissue establishments. The existing incentives are provided especially for the donation and procurement of tissues and cells (Lithuania and Portugal), for organising donor drivers (Croatia and Sweden) and for organising awareness campaigns (Croatia and Sweden). Both Croatia and Sweden reported that resources for providing financial incentives were allocated by the national government (i.e. in Sweden ten million euros have been allocated over a period of 10 years for the implementation of the tissue and cells Directives; in Croatia 0,6 million euros are allocated for such activities).

The types of tissues and cells for which the four Member States grant such incentives are shown in Figure 28.

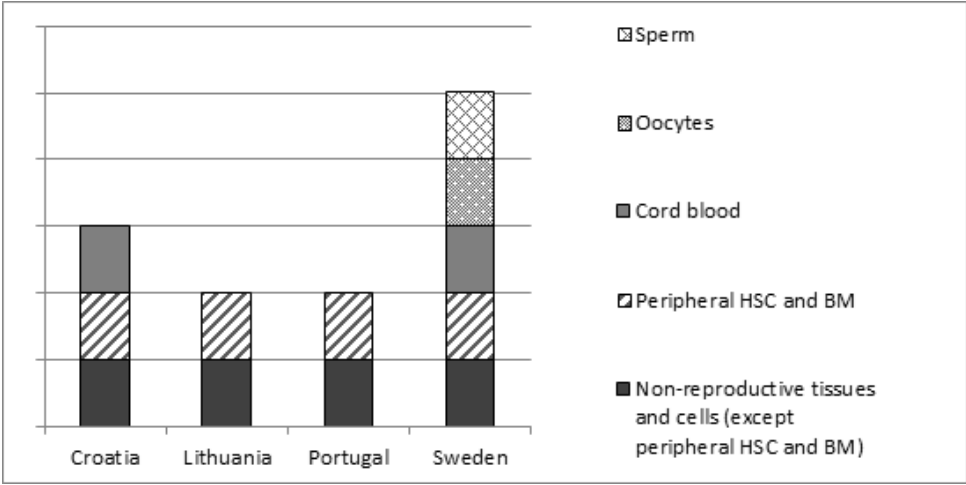


Fig. 28. Tissues and cells for which incentives to professionals are provided by the Member States (2014 data)

Only Portugal¹ notified a change in its national practices since the previous survey, specifying that incentives provided to healthcare professionals for the procurement of tissues and cells have been increased in order to stimulate procurement activities. Additionally, Bulgaria declared foreseeing a change of its national policy in this area. Croatia indicated that besides financial incentives, educational support to professionals in the tissue banking sector is also provided. Lithuania provides tissue establishments with information on the tissues transplanted, acknowledging their contribution to the transplantation therapies, thus ensuring the motivation of the personnel working in this sector.

¹ Despacho no. 1886/2014

All Member States reported that stimulating donations by remunerating the donors of tissues and cells is not allowed. Estonia, which is the only Member State not prohibiting remuneration of gamete donors, specified that the sum offered is not considered to be an incentive, but there are no national requirements on the amount of the remuneration, its value being decided solely by the operators.

2.6. National sufficiency and shortages of tissues and cells

The current survey proposed definitions for sufficiency, self-sufficiency and shortage, terms which are not defined in Directive 2004/23/EC. The abovementioned definitions do not constitute an interpretation of the EU Tissues and Cells Directives, and were proposed in order to facilitate a consistent interpretation of these concepts for the purpose of this survey. *National self-sufficiency* was defined as fulfilling the needs of human tissue and cell products for medical application (e.g. transplantation, ART procedures) of the resident population by accessing resources from within the country’s population. *National sufficiency* was defined as fulfilling the needs of human tissue and cell products for medical application (e.g. transplantation, ART procedures) of the resident population by accessing resources from within the country and through regional/international cooperation. *Shortage* means a relative deficiency in the supply with human tissue and cell products for medical application, which requires creation of waiting lists or makes a certain therapy temporary unavailable at national level.

In relation to the supply-demand balance, 18 Member States (AT, BE, BG, EE, EL, ES, HR, IE, IT, LT, LV, MT, PL, PT, SE, SI, SK, UK) and Norway reported experiencing regular shortages of tissues and cells on a national level (Figure 29). Shortages were reported mostly for bone marrow and haematopoietic stem cells (11 countries), corneas (11 countries) and musculoskeletal tissues (9 countries).

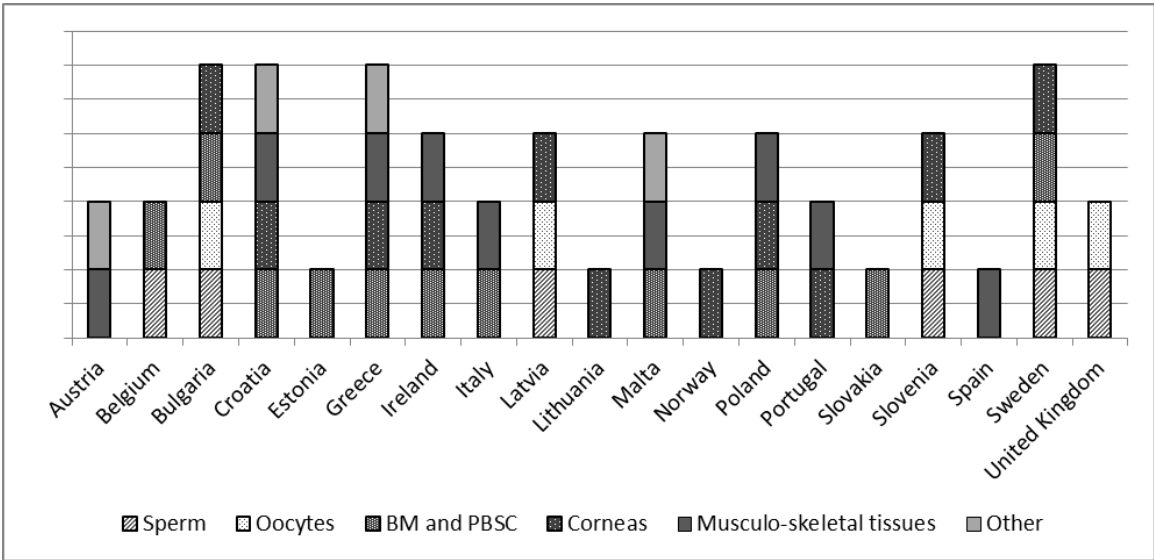


Fig. 29. Type of tissues and cells for which shortages were reported (2014 data)

Other tissues and cells subject to shortages include skin (Croatia, Malta), heart valves (Malta) and trachea (Austria).

The main reasons for shortages are summarised in Figure 30. It should be emphasised that the main cause for shortages is the lack of donors, followed by insufficient procurement capacity at national level and other reasons. Among these additional reasons, practical difficulties in finding a compatible match for patients in need of an HSC transplantation and insufficient

cooperation between healthcare professionals were mentioned. An insufficient processing capacity was reported by three Member States. Malta indicated that there are no tissue establishments.

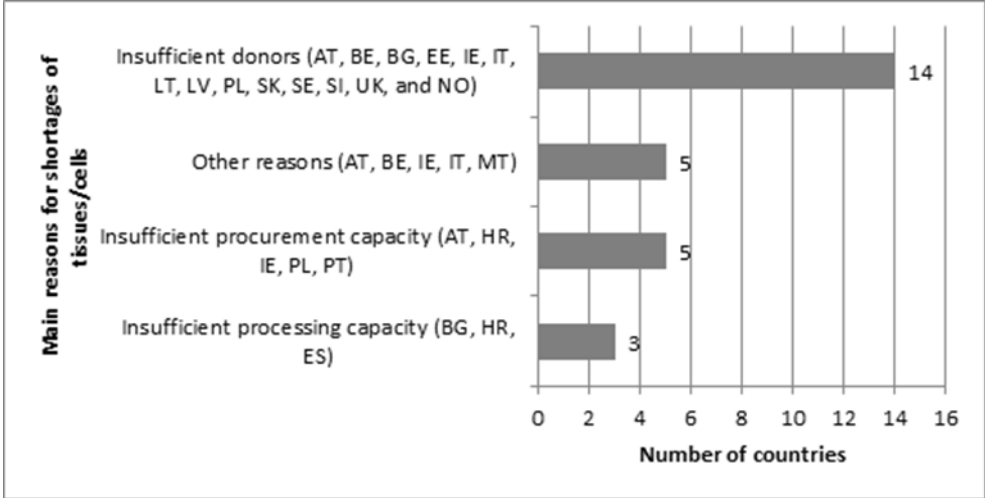


Fig. 30. Main reasons for shortages of tissues and cells in the Member States and EEA countries (2014 data)

Ten Member States (EL, ES, FR, HR, IT, LT, MT, NL, PT, SI) and Norway indicated having policies in place to promote self-sufficiency for tissues and cells. It should be highlighted that Member States have various understandings of self-sufficiency and/or sufficiency.

Four Member States (FR, LT, MT, NL) have defined the concept in relation to the extent that national supply meets national demand. The same criterion is used by Spain for non-reproductive tissues and cells, but it doesn't apply for bone marrow and PBSC donors, who also need to be recruited from international registries. Finally, Slovenia referred to waiting lists, reporting that self-sufficiency and/or sufficiency requires that there are no long waiting lists and no long waiting time on lists. Other countries referred to their national policies or estimations of national needs. In this regard, Croatia and Poland mentioned national programmes which include promotion of donation, but also development of registries, support for upgrading tissue establishment facilities and promotion of the use of new types of tissue and cell grafts. Italy stated that national needs of human tissues and cells are based on the number of tissue/cell transplantation procedures performed and reported the previous year.

Since 2009, four of the above-mentioned Member States (Greece, Lithuania, Malta and Poland) have changed their policy on self-sufficiency and/or sufficiency. Since 2011, Poland has been promoting bone marrow donations by creating bone marrow donor centres, building a national registry of unrelated donors of bone marrow and cord blood, and finally by developing new tissue and cell processing and transplantation techniques. Malta indicated having plans to set up the first tissue establishment in the country. Greece indicated that the new law adopted in 2011 places special emphasis on public information in order to increase organ, tissue and cell donation.

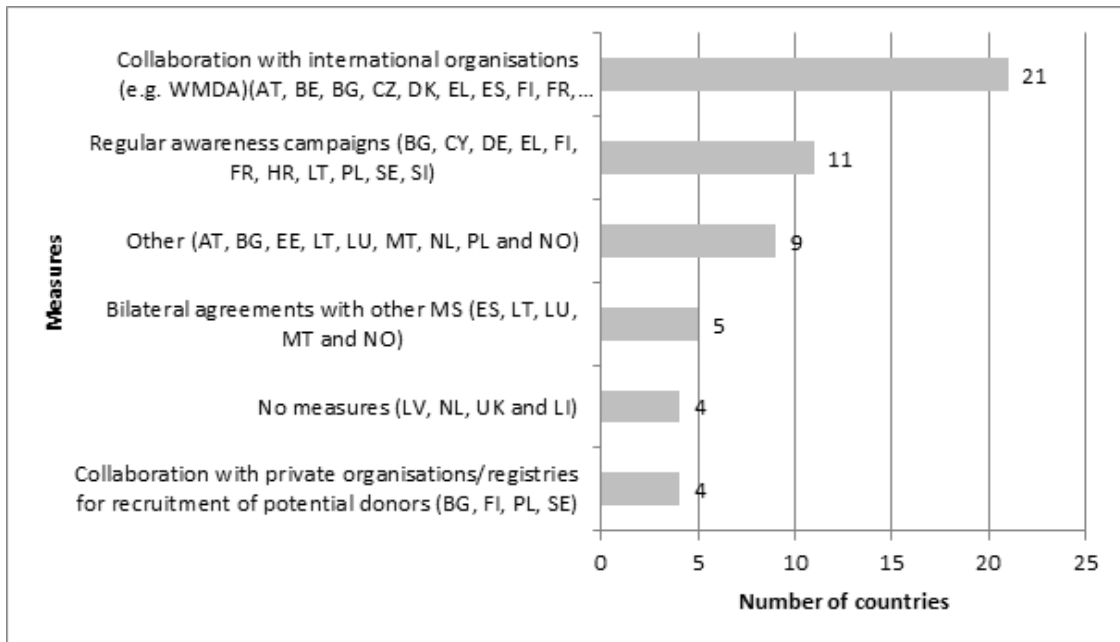


Fig. 31. Measures for ensuring an adequate supply of human tissues and cells in EU and EEA countries (2014 data)

In cases where self-sufficiency is not a feasible aim, due to the need to ensure compatibility between donor and recipient (e.g. bone marrow, peripheral blood stem cells), most of the responding countries indicated organising various activities from awareness campaigns to bilateral agreements and cooperation with recruitment organisations. An outline of these measures is shown in Figure 31.

Seventeen Member States (AT, BE, BG, CY, CZ, DE, DK, EE, FI, HU, IE, LU, LV, PL, RO, SE, SK) as well as Liechtenstein and Norway declared having no policy for promoting self-sufficiency/sufficiency for tissues and cells.

Five Member States (ES, FR, HR, NL, SI) indicated having no intention to change their current policy on sufficiency, whereas one Member State, namely Italy, stated that initiatives for defining self-sufficiency for haematopoietic stem cells are ongoing. Five Member States (CY, CZ, FI, RO, SE) reported that there is no need to address this issue at national level because they don't experience major shortages. Bulgaria and Slovakia indicated that such policies are in preparation, whereas Austria, Estonia and Ireland specified that no change of policy is foreseen because the self-sufficiency concept has not been defined at national level. France indicated that in the field of ART, their objective is to reach self-sufficiency for non-partner oocyte donation.