Basic information

2011/2193(INI) INI - Own-initiative procedure	Procedure completed
Voluntary and unpaid donation of tissues and cells **Subject** 4.20.01 Medicine, diseases 4.20.02 Medical research 4.20.05 Health legislation and policy	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ENVI Environment, Public Health and Food Safety	YANNAKOUDAKIS Marina (ECR)	20/09/2011
	Shadow rapporteur LIESE Peter (PPE) PRODI Vittorio (S&D) RIES Frédérique (ALDE) AUKEN Margrete (Verts/ALE) MATIAS Marisa (GUE/NGL)	

Committee for opinion	Rapporteur for opinion	Appointed
ITRE Industry, Research and Energy	The committee decided not to give an opinion.	
IMCO Internal Market and Consumer Protection	The committee decided not to give an opinion.	
JURI Legal Affairs	MAŠTÁLKA Jiří (GUE/NGL)	21/11/2011

European Commission

Commission DG	Commissioner
Health and Food Safety	DALLI John

Key events

Date	Event	Reference	Summary
17/06/2011	Non-legislative basic document published	COM(2011)0352	Summary
29/09/2011	Committee referral announced in Parliament		
20/06/2012	Vote in committee		
29/06/2012	Committee report tabled for plenary	A7-0223/2012	Summary
10/09/2012	Debate in Parliament		
11/09/2012	Decision by Parliament	T7-0320/2012	Summary
11/09/2012	Results of vote in Parliament		
11/09/2012	End of procedure in Parliament		

Technical information

Procedure reference	2011/2193(INI)
Procedure type	INI - Own-initiative procedure
Procedure subtype	Initiative
Legal basis	Rules of Procedure EP 55
Other legal basis	Rules of Procedure EP 165
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/7/06547

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE480.608	09/03/2012	
Committee opinion	JURI	PE478.552	26/04/2012	
Amendments tabled in committee		PE489.459	15/05/2012	
Committee report tabled for plenary, single reading		A7-0223/2012	29/06/2012	Summary
Text adopted by Parliament, single reading		T7-0320/2012	11/09/2012	Summary

European Commission

Document type	Reference	Date	Summary
Non-legislative basic document	COM(2011)0352	17/06/2011	Summary
Commission response to text adopted in plenary	SP(2012)766	19/12/2012	

Voluntary and unpaid donation of tissues and cells

2011/2193(INI) - 29/06/2012 - Committee report tabled for plenary, single reading

The Committee on the Environment, Public Health and Food Safety adopted the own-initiative report by Marina YANNAKOUDAKIS (ECR, UK) on voluntary and unpaid donation of tissues and cells in response to the Second Report from the Commission on the subject.

It notes with concern that **half of Member States state that they regularly face a lack of human tissues and cells,** particularly spinal marrow, gametes and tissues such as corneas and skin; believes that the policies and laws in force should therefore be reviewed, as they are not adequate to meet the challenge of self-sufficiency in the European Union. Members recall that while 11 countries have official policies in place to endeavour to promote self-sufficiency of tissues and cells, 17 other countries have bilateral agreements with the same aim of ensuring national supplies of human tissues and cells.

Non-remuneration, consent and safeguarding health: the report states that the removal of tissue and cells must be subject to the following principles: anonymity (except in the case of removal from a living person for a relative), non-remuneration, consent, the obligation to share organs for transplant fairly among patients, and safeguarding the health of donors and recipients.

Members go on to stress that donation should be **voluntary, unpaid and anonymous** (except in the case of procurement from a living person for a relative), governed by protective legal and ethical rules that respect the integrity of the person. They call on the Commission to

- report on current national practices and criteria for compensation of living donors, especially as regards egg cell donation;
- carefully monitor developments in the Member States, to examine carefully any reports from civil society or in the media about **violation of the principle of unpaid donation,** and to take appropriate action, including, if necessary, infringement proceedings.

Member States are asked to clearly define the conditions under which fair and proportionate financial compensation may be granted, bearing in mind that **compensation is strictly limited** to conditions making good the expenses incurred in donating tissues and cells, such as travel expenses, loss of earnings or medical costs related to the medical procedure and possible side effects, thereby prohibiting any financial incentives and avoiding disadvantages for a potential donor. Such compensations must be transparent and regularly audited.

Any compensation provided to donors must be compatible with ethical principles. The committee advises that particular attention should be paid to this issue where the compensation is given not to the donor, but **to the donor's family after death.** Four countries provide forms of compensation or incentives to relatives of deceased donors;

Anonymity, traceability, transparency and information: the committee calls on all Member States to:

- set up rules for ensuring the traceability of tissues and cells of human origin from donor to patient and vice versa, as well as a system for the regulation of imports of human tissues and cells from third countries, ensuring that equivalent standards of quality and safety will apply.
- step up their public information and awareness-raising campaigns to promote the donation of tissues and cells and to ensure the provision of medical information that is clear, fair, scientifically based and conclusive and of data enabling the public to make informed choices;
- take coordinated actions to prevent the development of a black market in gametes on the Internet, as such a market risks both undermining the quality and safety of tissues and cells and raises legal, ethical and public health problems.

Exchanging best practice and reinforcing European and international cooperation: the report calls on Member States to step up exchanges of good practices, particularly with regard to the supply of tissues and cells, the protection of the quality of tissues and cells while they are being transported, raising awareness of donating and training health staff. The Commission and Member States should consider the possibility of setting up a Europe-wide database of donors and potential recipients in order to manage supply in the general interest and avoid shortages where possible. Members particularly applaud the role in this field of Eurocet, which has played a crucial role in acting as the central European database for the collection of data on tissue and cell donation and transplantation activities. They call on Member State authorities to reinforce their collaboration with Eurocet in order to agree further common standards in the donation of cells and tissues and thereby enable healthcare professionals to improve the matches offered to European citizens.

Cord blood and stem cells: Members recognise the significant scientific advances made in the cord blood field, which is a very promising therapeutic alternative in the treatment of many diseases, including children’s illnesses. They call therefore on the Commission and Member States to take appropriate measures to establish a regulatory framework which could stimulate increased availability of umbilical cord blood stem cells.

The committee regrets that at present, stem cells from umbilical cord blood are only stored at 1% of total births in the EU. Member States are asked to raise awareness of public cord blood banking through information campaigns that may take place, for example, during antenatal classes, and proposes that in compliance with the provisions of the Charter of Fundamental Rights of the European Union.

Furthermore, comprehensive, objective and accurate information should be provided about the advantages and disadvantages of cord blood banks. The report proposes that Member States consider adopting and enforcing operational and ethical standards for public and private cord blood banks that uphold the principle of non-commercialisation of the human body and its parts, for example, and ensure traceability. It expects all Member States to **establish at least one public stem cell bank, and calls for European standards and requirements for private stem cell banks.**

Members note that collaboration models and opportunities between public and private sectors already exist in some Member States, and they encourage public and private cord blood banks to collaborate closely in order to increase the availability and exchange of national, European and international cord blood and tissue samples. They call on Member States to appropriately regulate both public and private banks to guarantee the

fullest transparency and safety of cord blood, and also highlight the development of non-intrusive procedures of harvesting stem cells using peripheral blood stem cell collection (PBSC).

Whilst emphasising that it is for the Member States to decide whether to allow, prohibit or regulate research with human embryonic stem cells and in vitro fertilization, Member States must respect the rules set out in Directive 2004/23/EC,

The Commission is asked to:

- propose a revision of Directive 2004/23/EC in order to bring it into line with the principles governing organ donation laid down in Directive 2010/45/EU, and to take into account the new legal situation after the entry into force of the Lisbon Treaty, scientific developments, the practical experience of those involved in the sector and the recommendations of this report;
- propose a revision of Regulation (EC) No 1394/2007 in order to include a provision that guarantees the application of the principle of unpaid donation similar to that referred to in Directive 2010/45/EU and to take into account the problems that have occurred in respect of the implementation of the regulation, especially for SMEs.

Voluntary and unpaid donation of tissues and cells

2011/2193(INI) - 11/09/2012 - Text adopted by Parliament, single reading

The European Parliament adopted by 551 votes to 15, with 81 abstentions, a resolution on voluntary and unpaid donation of tissues and cells in response to the Second Report from the Commission on the subject.

It notes with concern that **half of Member States state that they regularly face a lack of human tissues and cells**, particularly spinal marrow, gametes and tissues such as corneas and skin; believes that the policies and laws in force should therefore be reviewed, as they are not adequate to meet the challenge of self-sufficiency in the EU. Members recall that while 11 countries have official policies in place to endeavour to promote self-sufficiency of tissues and cells, 17 other countries have bilateral agreements with the same aim of ensuring national supplies of human tissues and cells.

Non-remuneration, consent and safeguarding health: the resolution states that the removal of tissue and cells must be subject to the following principles: anonymity (except in the case of removal from a living person for a relative), non-remuneration, consent, the obligation to share organs for transplant fairly among patients, and safeguarding the health of donors and recipients.

Parliament calls on Member States to adopt protective measures for living donors and to guarantee that donation is anonymous (except in the case of procurement from a living person for a relative), voluntary, freely agreed to, informed and not remunerated.

It calls on the Commission to

- report on current national practices and criteria for compensation of living donors, especially as regards egg cell donation;
- carefully monitor developments in the Member States, to examine carefully any reports from civil society or in the media about **violation of the principle of unpaid donation**, and to take appropriate action, including, if necessary, infringement proceedings.

Member States are asked to clearly define the conditions under which fair and proportionate financial compensation may be granted, bearing in mind that **compensation is strictly limited** to conditions making good the expenses incurred in donating tissues and cells, such as travel expenses, loss of earnings or medical costs related to the medical procedure and possible side effects, thereby prohibiting any financial incentives and avoiding disadvantages for a potential donor. Such compensations must be transparent and regularly audited.

Any compensation provided to donors must be compatible with ethical principles. The committee advises that particular attention should be paid to this issue where the compensation is given not to the donor, but **to the donor's family after death**. Four countries provide forms of compensation or incentives to relatives of deceased donors.

Anonymity, traceability, transparency and information: Parliament calls on all Member States to:

- set up rules for ensuring the traceability of tissues and cells of human origin from donor to patient and vice versa, as well as a system for the regulation of imports of human tissues and cells from third countries, ensuring that equivalent standards of quality and safety will apply.
- step up their public information and awareness-raising campaigns to promote the donation of tissues and cells and to ensure the provision of medical information that is clear, fair, scientifically based and conclusive and of data enabling the public to make informed choices;
- take coordinated actions to prevent the development of a black market in gametes on the Internet, as such a market risks both undermining the quality and safety of tissues and cells and raises legal, ethical and public health problems.

Exchanging best practice and reinforcing European and international cooperation: Parliament calls on Member States to step up exchanges of good practices, particularly with regard to the supply of tissues and cells, the protection of the quality of tissues and cells while they are being transported, raising awareness of donating and training health staff. The Commission and Member States should consider the possibility of setting up a Europe-wide database of donors and potential recipients in order to manage supply in the general interest and avoid shortages where possible. Members particularly applaud the role in this field of Eurocet, which has played a crucial role in acting as the central European database for the collection of data on tissue and cell donation and transplantation activities. They call on Member State authorities to reinforce their collaboration with Eurocet in order to agree further common standards in the donation of cells and tissues and thereby enable healthcare professionals to improve the matches offered to European citizens.

Cord blood and stem cells: Members recognise the significant scientific advances made in the cord blood field, which is a very promising therapeutic alternative in the treatment of many diseases, including children's illnesses. They call therefore on the Commission and Member States to take appropriate measures to establish a regulatory framework which could stimulate increased availability of umbilical cord blood stem cells.

Parliament regrets that at present, stem cells from umbilical cord blood are only stored at 1% of total births in the EU. Member States are asked to raise awareness of public cord blood banking through information campaigns that may take place, for example, during antenatal classes, and proposes that in compliance with the provisions of the Charter of Fundamental Rights of the European Union.

Parliament takes the view that donations of non-family allogeneic umbilical cord blood, regardless of whether the bank is public or private, should be further developed, so that stored units of umbilical cord blood are registered in the Bone Marrow Donors Worldwide (BMDW) database and made available to any compatible patient who needs them.

Furthermore, comprehensive, objective and accurate information should be provided about the advantages and disadvantages of cord blood banks. Parliament proposes that Member States consider adopting and enforcing operational and ethical standards for public and private cord blood banks that uphold the principle of non-commercialisation of the human body and its parts, for example, and ensure traceability. It expects all Member States to **establish at least one public stem cell bank, and calls for European standards and requirements for private stem cell banks**. Member States are further asked to provide a territorial network of maternity centres authorised to carry out this procurement to guarantee cord blood supply in all population centres.

Members note that collaboration models and opportunities between public and private sectors already exist in some Member States, and they encourage public and private cord blood banks to collaborate closely in order to increase the availability and exchange of national, European and international cord blood and tissue samples. They call on Member States to appropriately regulate both public and private banks to guarantee the fullest transparency and safety of cord blood, and also highlight the development of non-intrusive procedures of harvesting stem cells using peripheral blood stem cell collection (PBSC).

Whilst emphasising that it is for the Member States to decide whether to allow, prohibit or regulate research with human embryonic stem cells and in vitro fertilization, Parliament notes that Member States must respect the rules set out in Directive 2004/23/EC. It points out that the EU has limited competence in this area and, when applying this competence, needs to respect the principles of the EU Charter of Fundamental Rights and the principles applied in the judgments of the Court of Justice.

The Commission is asked to:

- propose a revision of Directive 2004/23/EC in order to bring it into line with the principles governing organ donation laid down in Directive 2010 /45/EU, and to take into account the new legal situation after the entry into force of the Lisbon Treaty, scientific developments, the practical experience of those involved in the sector and the recommendations of this resolution;
- propose a revision of Regulation (EC) No 1394/2007 in order to include a provision that guarantees the application of the principle of unpaid donation similar to that referred to in Directive 2010/45/EU and to take into account the problems that have occurred in respect of the implementation of the Regulation, especially for SMEs.

Voluntary and unpaid donation of tissues and cells

2011/2193(INI) - 17/06/2011 - Non-legislative basic document

PURPOSE: presentation by the Commission of its **Second Report** on Voluntary and Unpaid Donation of Tissues and Cells in accordance with Directive 2004/23/EC.

CONTENT: the report is based on the Members States' responses to a report template on voluntary and unpaid donation of tissues and cells. All Member States submitted a report to the Commission. In addition, Liechtenstein and Norway submitted a report (in total 29 reporting countries).

The report aims to provide an overview of the practice of voluntary and unpaid donation of tissues and cells, focusing on (1) legislative provisions, guidelines and policies; (2) compensation and incentives; (3) promotion and advertising, and (4) procurement and supply.

Compliance: the report shows that Member States overall comply with Article 12 of Directive 2004/23/EC, requiring Member States to take the necessary measures to endeavour to ensure voluntary and unpaid donations of tissues and cells. Largely in line with the findings of the first report on voluntary and unpaid donation of tissues and cells (issued in 2006), this report shows that legislative provisions and guidelines on voluntary and unpaid donation of tissues and cells are well established across the EU. 27 out of the 29 reporting countries have such legislative provisions or guidelines in place.

Compensation: 19 of the reporting countries have some form of compensation or incentive structures for donors of tissues and cells (excluding reproductive cells), such as reimbursement of travel and medical costs. For reproductive cells, about half of the countries provide some forms of compensation or incentives, including reimbursement of travel costs, refreshments and compensation linked to loss of earnings. In addition, four countries give some form of compensation or incentives to relatives of deceased donors.

Promotion: 19 countries have undertaken some form of measures to promote voluntary and unpaid donation of tissues and cells, such as awareness raising and information campaigns. In addition, 23 countries have restrictions or prohibitions on advertising the need for, or availability of, human tissues and cells with a view to offering or seeking financial gain or comparable advantage (in line with article 12 of Directive 2004/23/EC).

Procurement and supply of tissues and cells: the report shows that the majority of the countries have public collectors/suppliers or a dual system of public and private collectors/suppliers. With regards to supply, 11 countries report having policies in place to endeavour to promote self-sufficiency of

tissues and cells, and 17 countries have bilateral or other forms of agreements/collaboration structures to ensure national supply of tissues and cells. However, almost half of the countries report some form of shortages of tissues and cells, including bone marrow and gametes.

As set out in Article 12 of Directive 2004/23/EC, the Commission shall inform the European Parliament and the Council of any necessary further measures it intends to take in the field of voluntary and unpaid donation of tissues and cells. Based on the findings of this report, the Commission will now, together with the Member States, reflect on the potential need for further measures, keeping in mind that the Commission's legal mandate is limited to quality and safety of tissues and cells.