

P7_TA(2012)0320

Voluntary and unpaid donation of tissues and cells

European Parliament resolution of 11 September 2012 on voluntary and unpaid donation of tissues and cells (2011/2193(INI))

The European Parliament,

- having regard to Article 184 of the Treaty on the Functioning of the European Union,
- having regard to the Charter of Fundamental Rights of the European Union, and in particular Article 1 on human dignity and Article 3 on the right to the integrity of the person, which refers to the “prohibition on making the human body and its parts as such a source of financial gain”,
- having regard to the Second Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on Voluntary and Unpaid Donation of Tissues and Cells (COM(2011)0352),
- having regard to Directive 2010/53/EU of 7 July 2010 of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation¹,
- having regard to its resolution of 19 May 2010 on the Commission Communication: Action Plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States²,
- having regard to Regulation (EC) No 1394/2007³ of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004,
- having regard to Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells⁴,
- having regard to Directive 2006/17/EC of 8 February 2006⁵ implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells,
- having regard to the World Health Organization’s Guiding Principles on Human Cell, Tissue and Organ Transplantation,
- having regard to the Council of Europe Convention on Human Rights and Biomedicine, and its Additional Protocol concerning Transplantation of Organs and Tissues of Human Origin,

¹ OJ L 207, 6.8.2010, p. 14.

² OJ C 161 E, 31.5.2011, p. 65.

³ OJ L 324, 10.12.2007, p. 121.

⁴ OJ L 102, 7.4.2004, p. 48.

⁵ OJ L 38, 9.2.2006, p. 40.

- having regard to the Oviedo Convention on Human Rights and Biomedicine, and the additional protocol thereto on transplantation of organs and tissues of human origin,
 - having regard to the European data on Tissues, Haematopoietic and Reproductive Cells donation and transplantation activities of the 2010 Report of the European Registry for Organs, Tissues and Cells,
 - having regard to its resolution of 10 March 2005 on the trade in human egg cells¹,
 - having regard to Rule 48 of its Rules of Procedure,
 - having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinion of the Committee on Legal Affairs (A7-0223/2012),
- A. whereas donated tissues and cells, such as skin, bones, tendons, corneas and haematopoietic stem cells, are increasingly used in medical therapies and as starting material for advanced therapy medicinal products (ATMP); whereas Directive 2004/23/EC stipulates that Member States shall endeavour to ensure voluntary and unpaid donations and shall also endeavour to ensure that the procurement of tissues and cells as such is carried out on a non-profit basis; whereas this is a clear legal obligation, and if a Member State does not comply with the principle, infringement proceedings may be brought;
 - B. whereas in accordance with Article 12(1) of Directive 2004/23/EC, Member States shall submit reports on the practice of voluntary and unpaid donation to the Commission every three years;
 - C. whereas 27 of the 29 reporting countries have some form of provisions governing the principle of voluntary and unpaid donation of tissues and cells (binding or non-binding);
 - D. whereas 13 countries have guiding principles regarding the possibility of giving forms of compensation or incentives to donors of tissues and cells;
 - E. whereas 19 countries report providing some form of compensation or incentives for living donors of tissues and cells (excluding reproductive cells);
 - F. whereas 14 countries give some form of compensation or incentives for the donation of reproductive cells;
 - G. whereas four countries provide forms of compensation or incentives to relatives of deceased donors;
 - H. whereas targeted public awareness-raising and the dissemination of clear, fair, scientifically based and conclusive medical information at national and European level, particularly among the patient's immediate circle, play a very important role in gaining public support and increasing tissue and cell donation rates;
 - I. whereas advertising the need for, or availability of, human tissues and cells with a view to offering or seeking financial gain or comparable advantage, should be prohibited;
 - J. whereas, while 11 countries have official policies in place to endeavour to promote self-

¹ OJ C 320 E, 15.12.2005, p. 251.

sufficiency of tissues and cells, 17 other countries have bilateral agreements with the same aim of ensuring national supplies of human tissues and cells;

- K. whereas it is also of the utmost ethical importance to ensure, in so far as possible, an adequate supply of tissues and cells needed for medical purposes; whereas that supply must be managed in the interest of citizens and should therefore be supervised by public bodies;
- L. whereas the majority of the reporting countries have public collectors/suppliers of tissues and cells or a dual system of private and public collectors/suppliers;
- M. whereas the procurement of human tissues and cells shall be carried out by persons who have successfully completed a training programme specified by a clinical team specialising in the tissues and cells to be procured or a tissue establishment authorised for procurement;
- N. whereas the removal of tissues and cells for the benefit of recipients may only be carried out under two conditions: it must be done with a medical or scientific and therapeutic aim, and all the elements removed must be donated without any payment being made;
- O. whereas 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;
- P. whereas tissues and cells may only be removed if the donor has given prior free and informed consent to it in writing; whereas this consent may be withdrawn at any time, and with no particular requirement as to format;
- Q. whereas the use of tissues and cells for application in the human body carries a risk of transmission of disease to recipients; whereas that risk can be reduced by careful donor selection, an evaluation of potential donors prior to procurement based on a risk/benefit analysis, testing and monitoring of each donation and the application of procedures to procure tissues and cells in accordance with rules and processes established and updated according to the best available scientific advice;
- R. whereas the donation of some tissues and cells creates a severe risk for the donor; and whereas this risk is particularly high in egg cell donation because of the hormone treatment which is necessary to prepare for the donation;
- S. whereas the EU Charter of Fundamental Rights, which is the EU's leading principle and has been legally binding since the entry into force of the Lisbon Treaty, prohibits making the human body and its parts as such a source of financial gain;
- T. whereas it would be desirable for all Member States to have binding rules to enforce that ethical principle, including by means of criminal law;
- U. whereas, however, doubts remain concerning the compatibility with this ethical principle of certain kinds of compensation provided in connection with donations, particularly when such compensation is provided to the relatives of deceased donors;
- V. whereas unpaid donation is not only an ethical principle but also necessary to protect the health of the donor and the recipient, as the involvement of large sums of money in the

donation process may encourage the donor to take risks and may hinder the disclosure of risks in his/her medical history;

- W. whereas there is ample evidence to show that allogeneic cord blood transplantation is already successful for many patients, and whereas there are also credible reports that in some cases autologous treatment with these kinds of cells can be successful;
 - X. whereas reports from reputable media sources suggest that in the area of tissues and cells the principle of unpaid donation is being violated time and again;
 - Y. whereas the capacity to trace cells and tissues from the donor to recipients and vice versa and long-term follow-up of living donors and recipients of cells and tissues are central elements of safety and quality management;
1. Welcomes the presentation of the Second Report on Voluntary and Unpaid Donation of Tissues and Cells, which shows that much is being done in the Member States to implement the principle of unpaid donation, but also that there is a lot still to do;
 2. 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;

Non-remuneration, consent and safeguarding health

3. Stresses 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 which respect the integrity of the person;
4. 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;
5. Asks the Commission to 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;
6. Believes that it is vital for all Member States 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;
7. Calls on the Commission to report on current national practices and criteria for compensation of living donors, especially as regards egg cell donation;
8. Calls on the Member States to ensure that any compensation provided to donors is compatible with ethical principles; 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;

9. Calls on Member States to ensure that living donors are selected on the basis of an evaluation of their health and medical history, including a psychological evaluation if deemed necessary, based on a risk-benefit analysis, by qualified and trained professionals;
10. Calls on Member States to take measures to protect minors and adults under guardianship with regard to the removal of tissues and cells;

Anonymity, traceability, transparency and information

11. Stresses that the principles of transparency and safety are key to achieving a high level of public support for donation; encourages Member States to work towards creating a transparent donation system which is safe for donors and recipients;
12. 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;
13. Calls on Member States to 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; stresses that donors should be fully informed of the procedures used in this process and their moral, psychological, medical and social consequences;
14. Calls on Member States to 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

15. 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;
16. Expects all Member States to establish public tissue and cell banks;
17. Calls for European standards and requirements for private tissue and cell banks;
18. Considers that, in order to pursue the ethical imperative of ensuring adequate supply, the Commission and the 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;
19. Considers that the role of bilateral agreements is extremely important in supporting countries which experience shortages in tissues and cells or have no domestic donor matches and in ensuring that information on tissues and cells flows more freely between states;

20. Particularly applauds, in the European context, 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; calls 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;
21. Calls on Member States to explore all possible opportunities for wider international cooperation in this field, in particular with regard to the potential uses of haematopoietic stem cells;

Cord blood and stem cells

22. Recognises 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;
23. Points out that currently, clinical trials using umbilical cord blood stem cells for treatments linked to non-haematological diseases are mostly taking place outside the EU; calls 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;
24. Regrets that at present, stem cells from umbilical cord blood are only stored at 1% of total births in the EU; underlines, consequently, the importance of mothers donating cord blood and tissue at birth into banks which adhere to common operational and ethical standards in order to help treat illnesses and further research in the field; stresses moreover that traceability must be one of the conditions required for the authorisation of these banks at national or European level; emphasises that the allocation process through such banks must be fair, equitable, non-discriminatory and transparent;
25. Points out that public cell banks must take the necessary steps to protect data confidentiality in order to reconcile the traceability requirement with the need to protect donors' rights, such as medical confidentiality and privacy;
26. 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;
27. Points out that this donation must be subject to consent from the mother that is free, informed and given in writing, and that this consent may be withdrawn at any time prior to the donation, with no particular requirement as to format;
28. Calls on Member States 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;
29. Considers that men and women should be informed about all existing options related to cord blood donation at birth e.g.: public or private storage, donation for autologous or

heterologous purposes or for research; considers that comprehensive, objective and accurate information should be provided about the advantages and disadvantages of cord blood banks;

30. Calls on Member States to improve, at the same time, the protection of parents' rights to informed consent and freedom of choice regarding cord blood stem cell preservation practices;
31. 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;
32. Expects all Member States to establish at least one public stem cell bank;
33. Calls for the opinion issued by the European Group on Ethics in Science and New Technologies in 2004 on "Ethical Aspects of Umbilical Cord Blood Banking" (Opinion No 19) to be updated in the light of developments in cord blood stem cell preservation and ongoing clinical trials on the use of umbilical cord blood stem cells;
34. Calls on Member States to provide a territorial network of maternity centres authorised to carry out this procurement to guarantee cord blood supply in all population centres;
35. Calls for that all banks that respect the EU operational standards for collection and storage of cord blood to be consulted by national authorities when defining and implementing national information campaign strategies for parents;
36. Calls for European standards and requirements for private stem cell banks;
37. Notes that collaboration models and opportunities between public and private sectors already exist in some Member States, and encourages 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; calls on Member States to appropriately regulate both public and private banks to guarantee the fullest transparency and safety of cord blood, underlining that banks need to ensure working practices which are open and robust in their information sharing, in order to provide maximum benefit for the patient;
38. Highlights the development of non-intrusive procedures of harvesting stem cells using peripheral blood stem cell collection (PBSC);
39. Takes the view that Member States ought to consider increasing the number of donors of bone marrow and peripheral blood stem cells, improving their registries of bone marrow donors so that, with the collaboration of other countries' national registries through the BMDW, any patient in need of a stem cell transplant has the best chance of finding a compatible donor;
40. Calls on Member States to develop programmes which encourage minority ethnic backgrounds to donate tissues and cells to public banks in order to address the shortages of successful donor matches in this group;
41. Emphasises that it is for the Member States to decide whether to allow, prohibit or regulate

research with human embryonic stem cells and in vitro fertilisation but that Member States in this respect need to respect the rules set out in Directive 2004/23/EC, including those on quality and safety and those relating to the principle of unpaid donation; points out that the European Union 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 of the European Union;

42. Calls on the Commission to propose, as soon as possible, 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;

43. Also calls on the Commission to 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;

o

o o

44. Instructs its President to forward this resolution to the Council, the Commission and the governments and parliaments of the Member States.