

**"Action plan on organ donation and transplantation (2009-2015)"**

**European Parliament resolution of 19 May 2010 on the Commission Communication: Action plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States (2009/2104(INI))**

*The European Parliament,*

- having regard to Article 184 of the Treaty on the Functioning of the European Union,
  - having regard to the Charter on Fundamental Rights of the European Union,
  - having regard to the Proposal for a Directive of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation (COM(2008)0818),
  - having regard to the Commission Communication entitled ‘Action plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States’ (COM(2008)0819),
  - 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 cells<sup>1</sup>,
  - having regard to the World Health Organization's Guiding Principles on Human 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,
  - having regard to the Conference on Safety and Quality in Organ Donation and Transplantation in the European Union held in Venice on 17-18 September 2003,
  - 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 (A7-0103/2010),
- A. whereas there are currently 56 000 patients waiting for a suitable organ donor in the EU, and it is estimated that every day 12 people die while waiting for a solid organ transplant,
- B. whereas the needs of patients for transplantation in Europe are not being met owing to the limited number of organs available from both deceased and altruistic living donors,
- C. whereas there are wide variations between Member States in deceased organ donation rates, ranging from 34.2 donors per million population (pmp) in Spain to 1.1 pmp in Bulgaria, and the shortage of organs is a major factor affecting transplantation programmes,

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<sup>1</sup> OJ L 102, 7.4.2004, p. 48.

- D. whereas national policies and the regulatory framework for donations and transplantation vary substantially between Member States according to different legal, cultural, administrative and organisational factors,
- E. whereas organ donation and transplantation are sensitive and complex issues, with an important ethical dimension, which require the full participation of society for their development and the involvement of all relevant stakeholders,
- F. whereas organ transplantation provides the possibility of saving lives, offers a better quality of life and (in the case of kidney transplantation) has the best cost/benefit ratio when compared with other replacement therapies as well as increasing the possibilities for patients to participate in social and working life,
- G. whereas the exchange of organs between Member States is already common practice, although there are wide differences in the number of organs exchanged across borders between Member States; and whereas the exchange of organs between Member States has been facilitated by international exchange organisations such as Eurotransplant and Scandiatransplant,
- H. whereas at present there is neither a database covering the whole of the European Union which contains information about organs intended for donation and transplantation or on living or deceased donors, nor, moreover, a pan-European certification system which provides proof that human organs and tissues have been legally obtained,
- I. whereas only Spain and few other Member States have succeeded in increasing significantly the number of deceased donations, and it has been proven that such increases are linked to the introduction of certain organisational practices that allow the systems to identify potential donors and maximise the number of deceased persons becoming actual donors,
- J. whereas Directive 2004/23/EC will provide a clear legal framework for organ donation and transplantation in the European Union, with the result that in every Member State a national competent authority will be created or designated to ensure compliance with EU quality and safety standards,
- K. whereas the trafficking of organs and of human beings for the purpose of removing organs constitutes a severe violation of human rights,
- L. whereas there is a strong link between illegal organ trafficking and the trafficking of persons for the purpose of removing organs on the one hand and the legal system of organ donation on the other because, firstly, the non-availability of organs in the legal system acts as an incentive for illegal activities, and, secondly, illegal activities severely undermine the credibility of the legal system of organ donation,
- M. whereas rates of refusal of organ donation vary widely within Europe, and such variability could be explained by the level of training and expertise of professionals in terms of communication and family care, the different legislative approaches to consent to organ donation and their practical implementation, and other important cultural, economic or social factors that influence society's perception of the benefits of donation and transplantation,
- N. whereas living donation can be a helpful additional measure for patients who cannot get the

organ they need via post-mortem transplantation, but whereas it needs to be emphasised that living donation can only be considered if any illegal activity and payment for the donation has been ruled out,

- O. whereas a healthcare intervention may only be carried out after the person concerned has given free and informed consent to it; whereas that person should be given appropriate information beforehand as to the purpose and nature of the intervention as well as on its consequences and risks; and whereas the person concerned may freely withdraw consent at any time,
  - P. whereas Member States must ensure that organs intended for transplantation are not removed from a deceased person unless that person has been certified dead in accordance with national law,
  - Q. whereas living donation should be complementary to deceased donation,
  - R. whereas the use of organs in therapy entails a risk of transmission of infectious and other diseases,
  - S. whereas the fact that people are living longer is serving to reduce the quality of available organs, which in turn is leading in many cases to a reduction in the number of transplants, including in those Member States where the number of donors is increasing,
  - T. whereas public awareness and opinion play a very important role in increasing organ donation rates,
  - U. whereas work carried out by charities and other voluntary organisations in Member States increases awareness of organ donation, and whereas their efforts ultimately contribute to an increase in the numbers of people on organ donor registers,
1. Welcomes the Action Plan on Organ Donation and Transplantation (2009-2015) adopted by the Commission in December 2008, which sets out a cooperative approach between Member States in the form of a set of priority actions based on the identification and development of common objectives and the evaluation of donation and transplantation activities through agreed indicators that might help to identify benchmarks and best practices;
  2. Expresses its concern over the insufficiency of available human organs for transplantation to meet patients' needs; acknowledges that the severe shortage of organ donors remains a major obstacle preventing the full development of transplant services and the main challenge that the Member States face with regard to organ transplantation;
  3. Notes the success of schemes whereby citizens are given the option of directly joining an organ-donor register when completing certain administrative procedures, such as applying for a passport or driving licence; urges the Member States to look into adopting such schemes with a view to increasing the numbers of people on donor registers;
  4. Considers that, to ensure that organs available for therapy are not wasted, it is important that there is a clearly defined legal framework regarding their use and that society trusts the donation and transplantation system;

5. Notes the importance of organisational aspects of organ procurement and stresses that the exchanging of information and best practice among Member States will help countries with low organ availability to improve their donation rates, as demonstrated, for example, by the implementation of elements of the Spanish Model in different countries both within and outside the EU which have succeeded in increasing organ donation rates;
6. Stresses the importance of donor coordinators, and the importance to appoint donor coordinators at hospital level. The role of the donor coordinator should be recognised as a key figure for improving, not only the effectiveness of the process of donation and transplantation, but also the quality and safety of the organs to be transplanted;
7. Emphasises that changes to the organisation of organ donation and procurement can substantially increase and sustain organ donation rates;
8. Emphasises that the identification of potential donors has been considered one of the key steps in the process of deceased donation; stresses that the appointment of a key donation person at hospital level (transplant donor coordinator), whose main responsibility is to develop a proactive donor detection programme and optimise the entire process of organ donation, is the most important step towards improving donor detection and organ donation rates;
9. Takes note of the importance of the cross-border exchange of organs, given the need to match donors with recipients and the consequent importance of a large donor pool to cover the needs of all the patients on the waiting lists; considers that if there is no exchange of organs between Member States, then recipients that need a rare match will have very low chances of receiving an organ, while at the same time specific donors will not be considered because there is not a suitable recipient on the waiting lists;
10. Welcomes the activities of Eurotransplant and Scanditransplant, but notes that exchanges of organs outside these systems and between these systems can be significantly improved, especially for the benefit of patients in small countries;
11. Stresses that the establishment of common binding standards of quality and safety will be the only mechanism that can ensure a high level of health protection throughout the EU;
12. Stresses that donation should be voluntary and unpaid, and take place in clearly defined legal and ethical contexts;
13. Calls on Member States to ensure that organs are allocated to recipients according to transparent, non-discriminatory and scientific criteria;
14. Calls on Member States to ensure that a legal basis for ensuring valid consent or objection to organ donation by a deceased person or his/her relatives is clearly defined and to ensure that organs are not removed from a deceased person unless that person has been certified dead in accordance with national law;
15. Endorses measures which aim at protecting living donors and ensuring that organ donation is made altruistically and voluntarily, without any payment other than compensation which is strictly limited to making good the expenses incurred in donating an organ, such as travel expenses, childminding costs, loss of earnings or recovery costs, prohibiting any financial incentives or disadvantages for a potential donor; urges Member States to define the

conditions under which compensation may be granted;

16. Calls on the Commission to evaluate the possibility to ensure that living donors are legally insured in all Member States; calls on the Commission to analyse the different health care coverage of living donors in all Member States in order to identify best practices across the EU;
17. Stresses that Member States shall ensure that living donors are selected on the basis of their health and medical history, including a psychological evaluation if deemed necessary, by qualified or trained and competent professionals;
18. Stresses that the establishment of well-structured operational systems and the promotion of successful models at a national level are of the utmost importance; suggests that operational systems should comprise an adequate legal framework, technical and logistic infrastructure, and organisational support coupled with an effective allocation system;
19. Calls on Member States to promote the development of quality improvement programmes for organ donation in every hospital where there is potential for organ donation, as a first step, on the basis of a self-evaluation of the entire process of organ donation by specialists in intensive care and the transplant coordinator of every hospital, but seeking complementarity with external audits to the centres, if necessary and feasible;
20. Stresses that continuous education should form an essential part of all Member States' communication strategies on the issue; in particular, suggests that people should be better informed and encouraged to speak about organ donation and to communicate their wishes about donation to their relatives; notes that only 41% of European citizens seem to have discussed organ donation within their families;
21. Encourages the Member States to make it easier for living persons to make explicit statements of willingness to donate organs by offering on-line enrolment in a national and/or European donors' register with a view to speeding up procedures for verifying consent to donate organs;
22. Calls on the Commission, in close cooperation with Member States, the European Parliament and relevant stakeholders, shall examine the possibility of developing a system whereby the wishes expressed by citizens consenting to the donation of organs after they are deceased are taken into account in as many Member States as possible;
23. Calls on Member States to ensure the accomplishment of systems and related registers which are easily accessible for the purposes of recording the wishes of future donors;
24. Calls, further, on the Member States to take steps to facilitate the inclusion, on national identity cards or driving licences, of references or symbols which identify the holder as an organ donor;
25. Calls, consequently, on Member States to improve the knowledge and communication skills of health professionals and patient support groups on organ transplantation; calls on the Commission, the Member States and civil society organisations to take part in this effort to raise public awareness of the possibility of organ donation whilst taking into account the cultural particularities of each Member State;

26. Calls on Member States to reach the full potential of deceased donation by establishing efficient systems for identifying organ donors and by promoting transplant donor coordinators in hospitals across Europe; asks Member States to evaluate and make more frequent use of organs from 'expanded' criteria donors (i.e. older donors or those who have certain diseases), maintaining the highest quality and safety standards by exploiting, in particular, recent biotechnological advances which limit the risk of transplanted organs being rejected;
27. Believes it is necessary to ensure that a suitable balance is struck between, on the one hand, the protection of the donor in terms of anonymity and confidentiality and, on the other hand, the ability to trace organ donations for medical purposes, in order to prevent the remuneration of organ donation and trading and trafficking in organs;
28. Stresses that living donors should be treated in accordance with the highest medical standards and without any financial burden for themselves when medical problems such as hypertension, renal failure and their consequences occur which are potentially caused by the transplantation process, and any loss of earning as consequence of the transplantation or any medical problem should be avoided; the donors should be protected against discrimination in the social system;
29. Considers that all transplant system rules (allocation, access to transplant services, activity data, etc.) should be made public and be properly controlled, with a view to avoiding any unjustified discrimination in terms of access to transplant waiting lists and/or therapeutic procedures;
30. Notes that, although several Member States have introduced compulsory registration of transplant procedures and some voluntary registries also exist, no comprehensive system exists to collect data on the different types of transplantation and their outcomes;
31. Strongly supports, in consequence, the creation of national and EU-wide registers as well as the establishment of a methodology to compare the results of existing post-transplant follow-up registers of organ recipients in compliance with the existing European legal framework on the protection of personal data;
32. Supports the creation of special EU-wide protocols to provide procedures for operative and post-operative stages under the responsibility of the respective operating teams, specialist pathologists and specialists in other necessary fields;
33. Supports the creation of national and EU-wide registers on the follow-up of living donors, with the purpose of better ensuring their health protection;
34. Emphasises that any commercial exploitation of organs that denies equitable access to transplantation is unethical, is inconsistent with the most basic human values, contravenes Article 21 of the Convention on Human Rights and Biomedicine and is prohibited under Article 3(2) of the EU Charter on Fundamental Rights;
35. Points out that the organ shortage is linked in two ways to organ trafficking and trafficking in persons for the purpose of the removal of organs: firstly, increased organ availability in the Member States would contribute to better monitoring of these practices, by obviating any need for EU citizens to consider seeking an organ outside the EU, and, secondly, illegal activity seriously undermines the credibility of the legal organ donation system;

36. Repeats the recommendations on the fight against the organ trade made in the Adamou report on organ donation and transplantation<sup>1</sup> and takes the view that these should be taken fully into account by the Commission when drafting the action plan; insists that awareness of the problem within the Commission and Europol needs to be increased;
37. Emphasises the importance of the World Health Assembly to be held in May 2010 and urges the Commission and the Council to fight strongly at WHO level for the principle of voluntary and unpaid donation;
38. Welcomes the joint Council of Europe/United Nations study on trafficking in organs, tissues and cells and trafficking in human beings for the purpose of the removal of organs;
39. Notes the report of David Matas and David Kilgour about the killing of members of Falun Gong for their organs, and asks the Commission to present a report on these allegations, along with other such cases, to the European Parliament and to the Council;
40. Urges Member States to establish mechanisms to avoid a situation where healthcare professionals, institutions or insurance companies encourage citizens of the Union to acquire an organ in third countries through practices involving trafficking in organs or in persons for the purpose of the removal of organs; urges Member States to monitor cases of this nature occurring within their territories; urges Member States to evaluate the introduction of legislative measures, including sanctions, applicable to persons promoting and / or participating in such activities;
41. Strongly rejects the behaviour of some health insurance organisations in encouraging patients to participate in transplant tourism and asks the Member States to monitor strictly and punish such behaviour;
42. Emphasises that patients who have received an organ under illegal circumstances cannot be excluded from healthcare in the European Union; points out that as in any other case a distinction should be drawn between the punishment for illegal activity and the need for treatment;
43. Stresses that the Member States should intensify their cooperation under the auspices of Interpol and Europol in order to address the problem of trafficking in organs more effectively;
44. Recognises that it is vitally important to improve the quality and safety of organ donation and transplantation; points out that this will have an impact on reducing transplant risks and will consequently reduce adverse effects; acknowledges that actions on quality and safety could have an effect on organ availability and vice versa; asks the Commission to help Member States to develop their capacity in creating and developing regulatory frameworks to enhance quality and safety;
45. Emphasises that good cooperation between health professionals and national authorities or other legitimised organisations is necessary and provides added value;
46. Recognises the important role of post-transplantation care, including the appropriate use of

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<sup>1</sup> European Parliament resolution of 22 April 2008 on organ donation and transplantation: Policy actions at EU level (Texts adopted, P6\_TA(2008)0130).

anti-rejection therapies, in the success of transplants; acknowledges that optimum use of anti-rejection therapies can lead to improved long-term health for patients, graft survival and, hence, wider availability of organs owing to the reduced need for retransplantation, and asserts that Member States should ensure that patients have access to the best available therapies;

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