

# EUROPEAN PARLIAMENT

2004



2009

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*Session document*

**A6-0090/2008**

1.4.2008

## **REPORT**

on organ donation and transplantation: Policy actions at EU level  
(2007/2210(INI))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Adamos Adamou

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## MOTION FOR A EUROPEAN PARLIAMENT RESOLUTION

### on organ donation and transplantation: Policy actions at EU level (2007/2210(INI))

*The European Parliament,*

- having regard to Article 152(4)(a) of the EC Treaty,
- having regard to the Commission Communication on Organ Donation and Transplantation: Policy Actions at EU level (COM (2007)0275) and the Commission Staff Working Document accompanying the Communication: Impact Assessment (SEC(2007)0705),
- 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 Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data<sup>2</sup>,
- having regard to Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector<sup>3</sup>,
- having regard to Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use<sup>4</sup>,
- having regard to the World Health Organisation'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 Council of Europe report "Meeting the organ shortage. Current status and strategies for improvement of organ donation" (1999),
- having regard to the Council of Europe report "Guide to the safety and quality assurance

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

<sup>2</sup> OJ L 281, 23.11.1995, p. 31.

<sup>3</sup> OJ L 201, 31.7.2002, p. 37.

<sup>4</sup> OJ L 121, 1.5.2001, p. 34.

for organs, tissues and cells"<sup>1</sup>,

- having regard to a document from the first national expert meeting on organ donation and transplantation at Community Level, SANCO C6 EFZ/gsc D (2007) 360346, 13 September 2007,
  - having regard to Rule 45 of its Rules of Procedure,
  - having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinions of the Committee on Legal Affairs and the Committee on Civil Liberties, Justice and Home Affairs (A6-0090/2008),
- A. whereas the need for organ transplantation in Europe has increased steadily and more rapidly than the number of organs donated, whereas there are more than 60 000 patients in need of transplants on waiting lists across Europe and whereas a significant number of patients die as a result of the chronic shortage of organs, whereas the increase in the number of donors does not lead to a reduction of the waiting lists,
- B. whereas organ trafficking, commercialism and transplant tourism are rapidly developing, which is inconsistent with respect for human dignity; whereas there is a link between organ shortage and organ trafficking, whereas more data on organ trafficking are needed,
- C. whereas safety issues are often ignored when illegal commercial organ transplantation is practised, which may put the life of the donor and the recipient at risk,
- D. whereas four Member States have still not ratified the United Nations Convention against Transnational Organized Crime, five Member States have not ratified its supplementary Protocol to Prevent, Suppress and Punish Trafficking in Persons, Especially Women and Children ("the Palermo Protocol") and nine Member States have not ratified the UN Optional Protocol to the Convention on the Rights of the Child on the sale of children, child prostitution and child pornography,
- E. whereas although current estimates put organ trafficking at a relatively low level among all forms of trafficking, trafficking in organs and tissues is becoming an increasing global problem which occurs within and across national borders and is demand-driven (estimation of 150-250 cases/year in Europe),
- F. whereas trafficking in organs and tissues is a form of trafficking in human beings, which entails serious violations of fundamental human rights, and in particular of human dignity and physical integrity and can undermine citizens' confidence in the legitimate transplantation system, which may lead to further shortage of supply of voluntarily donated organs and tissues,
- G. whereas quality, safety, efficacy and transparency are essential if society is to reap the benefits transplantation can offer as a therapy,
- H. whereas organ transplantation is the only available treatment for end-stage failure of

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<sup>1</sup>Second edition, 2004.

organs such as the liver, lung and heart and the most cost-effective treatment for end-stage kidney failure; whereas organ transplantation provides the possibility of saving lives and of offering a better quality of life,

- I. whereas there are important differences between and within Member States with respect to rates of transplant, to the source (living or deceased donor) of organs, and even discrepancies in quality and minimum safety requirements for organ donation and transplantation, while the organisational approach to transplantation varies from country to country leading to uneven standards across the EU,
- J. whereas Member States have different legal frameworks (opt-in, opt-out) and experiences in different Member States show that the impact of the legal system on the number of donors is rather limited,
- K. whereas the alternative to transplantation is often intensive care, which is unpleasant for the patient and places a burden on healthcare systems and the family and carers of patients,
- L. whereas organ donation and transplantation are sensitive and complex issues that encompass not only medical but also legal and ethical aspects, which require the full participation of civil society for their development,
- M. whereas the use of organs in therapy contains a risk of transmission of infectious and other diseases,
- N. whereas a number of organs are already exchanged between Member States and different European organ exchange organisations (e.g. Scandiatransplant, Eurotransplant) already exist,
- O. whereas existing experience (e.g. Spanish model, Belgian GIFT project, DOPKI, Alliance-O) shows positive results and should be taken into account,
- P. whereas public awareness, concrete and positive information and the advanced training and communication skills of professionals have an important role to play in increasing the willingness to donate organs,
- 1. Welcomes the Commission Communication "Organ Donation and Transplantation: Policy Actions at EU level" which proposes a very much appreciated integrated three-pillar approach;

## ***LEGAL INSTRUMENT***

- 2. Looks forward to the Commission proposal for a Directive setting quality and safety requirements for organ donation, procurement, testing, preservation, transport and allocation across the EU and the resources needed to meet these requirements; stresses, nonetheless, that the forthcoming legislative framework should not create an additional administrative burden for Member States or service providers, nor should it jeopardize the use of existing good practices or those practices adapted to the prevailing conditions and circumstances in individual Member States, or contain requirements which would

lead to a decrease in the number of potential and actual donors;

3. Points out that the new legislative document should complement and reinforce efforts made by Member States to achieve an active and efficient method of coordination without preventing the introduction or maintenance of more stringent measures;
4. Underlines that the Directive should accommodate the progress made by medical science;

### ***COOPERATION BETWEEN MEMBER STATES***

5. Expresses its concern over the insufficiency of available organs for transplantation to meet patient needs; considers reducing the organ (and donor) shortage as the main challenge that EU Member States face with regard to organ transplantation; recalls that currently many thousands of patients in Europe are registered on waiting lists, which have a significant mortality rate;
6. Notes that the allocation of organs should be based on the medical capacity of the patient to accept an organ; is of the opinion that discrimination on the basis of disabilities which have no bearing on the patient's chances of accepting an organ should not be tolerated;
7. Points out that organ donation is a gift; therefore stresses that, while finding an answer to the severe organ shortage in Europe is extremely important, the free choice to donate or not to donate an organ needs to be respected and protected as well;
8. Takes note of the important differences with respect to the source of organs (deceased or living donors) within the EU, the large differences between Member States' success in increasing their donor pool, the discrepancies between Member States when it comes to quality and safety requirements, the different organisational approaches to organ donation and transplantation and the differences in education and training of medical and paramedical professionals; considers that discrepancies can be partly explained by a combination of economic, structural, administrative, cultural, ethical, religious, historical, social and legal factors, although the critical factor seems to be how the whole process leading to donation and transplantation is organised;
9. Strongly believes, therefore, that there is significant potential for sharing expertise between EU Member States which can increase donor rates and equalise access to transplantation across the EU; hence, looks forward to the Commission's Action Plan for strengthened cooperation between Member States in order to:
  - increase organ availability,
  - enhance the efficiency and accessibility of transplantation systems,
  - increase public awareness,
  - guarantee quality and safety;
10. Consequently, stresses that the establishment of well-structured operational systems and the promotion of successful models in and between Member States, and where appropriate at international level, are of the utmost importance; suggests that operational systems should comprise an adequate legal framework, technical and logistic infrastructure, psychological and organisational support and an appropriate organisational structure, at hospital and supra-hospital level, equipped with highly qualified staff,

coupled with clear provisions on traceability and a fair, effective and equitable allocation and access to transplantation system;

### ***INCREASING ORGAN AVAILABILITY***

11. Points out that Member States are responsible for their own legal model; notes that in the EU two models exist, each with different variants; considers it unnecessary to adapt or harmonise legal systems; invites Member States to introduce into their legislation the possibility to appoint a legal representative who can decide on donation after one's death;
12. Calls on Member States to achieve the full potential of post mortem donations; therefore urges Member States to invest to the full in improving their organisational system by:
  - sensitizing, educating and training medical and paramedical staff,
  - supporting hospitals financially to appoint "in-house transplant coordinators" (doctors working inside the intensive care units who are supported by a medical team); their task would be to actively identify potential donors and approach their families,
  - implementing quality improvement programmes in every hospital or cluster of hospitals across Europe where there is proven evidence of potential for organ donation;
13. Asks Member States, with a view to increasing organ availability, to evaluate the use of "expanded" donors (older donors, donors with certain diseases) taking into account quality and safety aspects;
14. Considers that transplants can be carried out using a sub-optimal organ; it would then be for the transplant team, acting in consultation with the patient and/or his or her family, to make decisions about the use of organs for individual patients on the basis of a risk-benefit analysis;
15. Also notes that, in order to ensure swift identification of organs, it is important to encourage those who are not suitable donors to carry a card to that effect;
16. Asks Member States allowing living donation to take into account quality and safety aspects; stresses, however, that living donation should be seen as complementary to post mortem donation;
17. Recognises that when the donor pool is expanded, doctors may be concerned about the increased likelihood of rejection of the organs and gradual decline of the function of the grafted organ, and therefore asks the Commission and Member States to support methods to prevent and treat organ rejection so that the "expanded" organ pool can be used with confidence by doctors;
18. Recognises that biotechnology is already offering solutions to the risk of rejection of transplanted organs, for example through treatments that reduce rates of rejection, which will in turn support the availability of more organs, by allowing doctors to treat or even prevent rejection; argues that this would help support the "expanded" donor pool, by reducing the risk associated with expanded organ programmes;
19. Asks Member States to remove, before January 2010, legislation that reserves donor organs for use solely within that country;

20. Asks Member States to take the necessary measures in the areas of education and training, teamwork and remuneration of transplantation surgeons;
21. Stresses the importance of financing organ procurement and transplantation under a dedicated budget line, so as not to make transplantation a disincentive for hospitals;
22. Underlines the need to ensure that organ donations stay strictly non-commercial;
23. Endorses measures which aim at protecting living donors, from a medical as well as a psychological and social point of view, and ensuring that organ donation is made altruistically and voluntarily, ruling out payments between donors and recipients, any payment being confined solely to compensation which is strictly limited to making good the expense and inconvenience related to the donation; asks Member States to ensure that the anonymity of deceased donors and living donors not genetically or emotionally linked to recipients, where national legislation permits such donations, is preserved; urges Member States to define the conditions under which compensation can be granted;
24. Urges the Member States to adopt or maintain strict legal provisions in connection with transplantation from unrelated living donors, in order to make the system transparent and exclude the possibility of illicit organ selling or coercion of donors; thus, donations by unrelated living donors could only be made under the conditions defined in national law and following authorisation by a suitable independent body;
25. Urges the Member States to ensure that living donors will not be discriminated against, in particular by insurance systems;
26. Urges Member States to ensure the reimbursement of the social security costs of living donors;
27. Considers that, in the future, provided that traceability is guaranteed, biotechnology may offer the possibility for researchers to grow organs from existing tissues and cells, either from the patients themselves or from other tissue donors; asks the Commission to promote such research, which is often carried out by Europe's emerging SME biotech companies within the cultural and ethical frameworks laid down in the Member States and in the Charter on Fundamental Rights and the Convention on biomedicine of the Council of Europe;

#### ***EFFICIENCY AND ACCESSIBILITY OF TRANSPLANTATION SYSTEMS***

28. Takes note that, although several Member States have introduced compulsory registration of transplant activities and some voluntary registers also exist, no comprehensive system exists to collect data on the different types of transplantation and their outcomes; strongly recommends the creation of national follow-up registers of living donors, transplanted patients and transplant procedures; points out that the registers must be regularly updated; stresses that the comparability of the data between EU Member States is important;
29. Asks the Commission to recommend to the Member States certain guidelines as far as registration is concerned to ensure that the registered person submits certain information about his medical history and to ensure the quality and safety of the donor's organs, since



registration is not only the simple act of registering by name but implies consequences for both the donor and the recipient;

30. Invites the Commission to facilitate the development of a core of technical and ethical standards for the management of the safety, quality and efficacy of organ donation in the context of donation and transplantation that can serve as a model for Member States; asks the Commission to establish an EU mechanism which would promote coordination activities between Member States in relation to organ donation and transplantation;
31. Considers that an additional benefit of collaboration between EU Member States which is insufficiently emphasised in the Commission's Communication is the potential value of organ sharing between EU Member States in terms of medical and technical opportunities, always taking account of the geographical limitations to such exchanges and the potential effects on organ viability; underlines in this respect the good results of international systems; believes that organ sharing can be very helpful particularly as far as difficult transplant procedures are concerned (e.g. highly sensitised or urgent patients and patients with special conditions, for whom it is difficult to find a suitable donor);
32. Invites the Commission together with the Member States to conduct a study on all matters concerning organ transplantation for non-EU residents in Member States and to develop a code of conduct containing rules and conditions under which organs donated by deceased EU donors may be allocated to non-EU residents;
33. Emphasises that good co-operation between health professionals and responsible authorities is necessary and provides added value; asks the Commission to facilitate alliances between national transplantation organisations in Member States involving cooperation at legal, ethical and technical level; recognises that there are situations in transplant medicine that cannot be adequately addressed in Member States with a limited donor pool; believes that small Member States, in particular, could clearly benefit from European co-operation;
34. Calls for a European donor card, complementary to existing national systems;
35. Considers that international co-operation to promote availability and safety of organs is desirable; points out, in this regard, that general rules governing best medical practice, diagnostic techniques and conservation would be useful; asks Member States to actively promote such cooperation and to apply this system of general rules;

### ***INCREASING PUBLIC AWARENESS***

36. Underlines the importance of increasing public awareness on organ donation and transplantation since it can facilitate the identification of organ donors and thus increase organ availability; hence, calls on the Commission, Member States and civil society to structurally enhance the promotion of organ donation, inter alia among youngsters in schools; in this regard, suggests using well known personalities (e.g. sportsmen and sportswomen) and educational packs;
37. Points out that information on organ donation and transplantation should be provided in a transparent, unbiased and non-directive manner, addressing the scope of organ donations,

- i.e. that donation might include multiple-organ donations as well as tissue donations;
38. Underlines that the free choice to donate or not to donate an organ needs to be respected and that organ donation must be considered as a gift from one human being to another; points out that this needs to be reflected in the language used, avoiding economic terminology which suggests that organs may be treated as a commodity of the internal market;
  39. Calls on the Commission to take into consideration the further development and expansion of the existing European web page on organ donation [www.eurodonor.org](http://www.eurodonor.org) (and/or [www.eurocet.org](http://www.eurocet.org)), as well as that of the WHO ([www.transplant-observatory.org](http://www.transplant-observatory.org)), to cover all EU Member States, in all official EU languages, with the aim of providing all relevant information and data on organ donation and transplantation;
  40. Calls on the Commission and Member States to promote the World Donor Day and recommends actions that underline the good results and importance of transplantation;
  41. Is convinced that a very effective way of increasing organ availability is to provide more information to the public also at the local and regional level; calls on the Commission, the Member States and the organisations of civil society, churches, religious and humanist communities to take part in this effort to raise public awareness of the possibility of organ donation whilst taking into account the cultural particularities in each Member State; underlines the important role played by registered donors in promoting organ donation among family members and friends and encouraging them to become donors themselves;
  42. Acknowledges that it is important to improve the communication skills of health professionals by, for instance, developing information guidelines; stresses the need for a professional attitude towards communication, as well as support from experts in that field; special attention should be paid to both the content of the message and the best means of dealing with the most controversial topics; stresses the importance of regular meetings with media representatives to promote the good results and importance of transplantation;
  43. Favours the establishment of a transplant "hotline" with a single telephone number which is managed by a national transplantation organisation, where such an organisation exists, and manned 24 hours/day by appropriately trained and experienced professionals who can provide relevant and accurate information rapidly (medical, legal) to all actors concerned;
  44. Asks the Commission to support research into organ donation and transplantation across national boundaries to address the impact of ethnicity, country of origin, religion, level of education and socio-economic class on the decision to offer organs for donation; asks the Commission and Member States to disseminate rapidly the outcomes of research with a view to informing the public and altering misperceptions;

### ***IMPROVING QUALITY AND SAFETY***

45. Recognises that it is vitally important to ensure 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 develop their capacity in creating and developing national regulations and a regulatory framework to enhance quality and safety, without this having a negative impact on the availability of transplant organs;

46. Acknowledges that post-transplant and post-donation results should be monitored and evaluated; stresses that a common methodology of data analysis should be promoted, on the basis of the best practices currently employed by Member States, in order to allow optimal comparability of results across countries;
47. Asks Member States to increase the monitoring times for transplant patients (currently between nine and twelve months) to several years and preferably for as long as the patient lives and/or the graft still functions;
48. Calls on the Commission to allocate funds within the Seventh Framework programme to promote research on better and more sensitive diagnostic techniques which will enable early and effective detection of harmful conditions such as HIV/AIDS, hepatitis and others, since an important aspect of organ transplantation is to secure safety from various detrimental factors and agents existing in the organs of the donor;

### ***ORGAN TRAFFICKING***

49. Points out that there is a link between organ shortage and organ trafficking, in that organ trafficking undermines the credibility of the system for potential voluntary and unpaid donors; emphasises that any commercial exploitation of organs is unethical and inconsistent with the most basic human values; stresses that organ donation out of financial motivation degrades the gift of an organ to a mere commodity which constitutes a violation of human dignity and contravenes Article 21 of the Convention on Human Rights and Biomedicine and is prohibited according to Article 3(2) of the EU Charter on Fundamental Rights;
50. Asks the Commission, in relation to third countries, to fight against the practice of organ and tissue trafficking, which should be universally banned, including the transplantation of organs and tissues from minors, from the mentally disabled or from executed prisoners; calls on the Commission and the Member States to raise the awareness of the international community on this issue;
51. Considers that, in order to fight against organ trafficking in the poorer parts of the world, a long-term strategy must be adopted so as to abolish the social inequalities lying at the root of such practices; stresses that, in order to combat the practice of organ selling for money (especially in countries of the developing world), mechanisms of traceability should be put in place so as to prevent these organs entering the European Union;
52. Calls on the Commission and Member States to take measures to prevent 'transplant tourism', by drawing up guidelines to protect the poorest and most vulnerable donors from being victims of organ trafficking, adopting measures that increase the availability of legally procured organs and by exchange of waiting list registrations between existing organ exchange organisations to avoid multiplied listing; asks the Commission to

promote via the Justice, Freedom and Security area a common approach which aims at compiling information on national organ trafficking legislation and to identify the main problems and potential solutions; points out to this effect that a system of traceability and accountability of human material has to be established;

53. Urges the Member States, where necessary, to amend their criminal codes to ensure that those responsible for organ trafficking are adequately prosecuted, including sanctions for medical staff involved in transplantation of organs obtained from trafficking, while making every effort to discourage potential recipients from seeking trafficked organs and tissues; this should include the consideration of criminal liability of European citizens who have purchased organs inside or outside the Union;
54. Calls on the Member States to take the necessary steps to restrain healthcare professionals from facilitating organ and tissue trafficking (i.e. referring a patient to a foreign transplant service, which might be involved in trafficking) as well as health insurance providers from facilitating activities that directly or indirectly promote trafficking in organs, for instance, reimbursing costs incurred in obtaining an illegal organ transplantation;
55. Considers that the Member States should ensure the training of their law enforcement agencies as well as medical staff on trafficking in organs in order to report each known case to the police;
56. Asks Member States to sign, ratify and implement the Council of Europe Convention on Action against Trafficking in Human Beings and the Palermo Protocol if they have not already done so;
57. Asks the Commission and Europol to improve monitoring of cases of organ trafficking;
58. Asks the Commission and the Council to update the Action Plan on Trafficking in human beings and include in it an action plan for the fight against trafficking in organs, in order to enable closer cooperation among the authorities concerned;
59. Calls, in addition, for the action plan to make reference to data which are correct and verified concerning the quantities, types and origin of illegally-trafficked organs;

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60. Instructs its President to forward this resolution to the Council, the Commission, the WHO, the Council of Europe and the Parliaments of Member States.

## **EXPLANATORY STATEMENT**

Organ transplantation means therapeutic use of human organs involving the substitution of a non-functional organ for another one coming from a donor. Successful organ transplants, provided that a proper follow-up procedure is applied, can restore a full and healthy life for many years to people who would otherwise often require intensive care, which is unpleasant for the patients, but also often places a burden not only on the healthcare systems in the Member States but also on the family and carers of the patients.

Although the use of human organs for transplantation has steadily increased during the past decades across the EU, the number of people requiring a transplant is greater than the number of organs available for transplant. Nearly 40.000 patients are now on waiting lists in Western Europe. Mortality rates while waiting for a heart, liver or lung transplant usually range from 15 to 30%.

### **Quality and safety**

The use of organs in therapy poses a risk of diseases being transmitted to the recipient. Risks include not only the transmission of communicable diseases (viral, bacterial, and fungal infections, human, immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV)) but also the transmission of malignant diseases, such as the transmission of different types of cancers.

Donor testing is important in minimising the risks to the recipient; it is essential to screen donors and establish the presence or absence of risk of disease transmission. In order to establish the standard level of donor safety, a minimum set of examinations should be performed. However, there is no consensus today between Member States on these tests.

Pre-transplant evaluation of potential donors is a vital part of solid organ transplantation. In other words, donor suitability is an essential prerequisite for donation. The main goals include: identifying conditions which disqualify donors; identifying possible pre-transplant infections and defining the level of risk in order to determine strategies for preventing post-transplant effects. The differences on screening between the living donor and the deceased donor are largely based on the different time at which this screening takes place. For the living donor it is possible to treat active infection and to defer transplant until such infection resolves. By contrast the timeframe for deceased donor evaluation is typically hours. Donor suitability criteria should be established according to existing accepted medical standards. Long-term follow-up and monitoring of patients following transplants are also needed to evaluate the best treatment outcomes for patients. The monitoring and evaluation of post-transplant results is crucial and should therefore be carried out on the basis of a common methodology, which ensures the maximum health and safety standards in all Member States.

Currently, organ transplants are only followed up for around 9 months to 12 months following the transplant. Evaluation of transplant outcomes should be extended to several years, to give the best evaluation of outcomes, both clinically and in economic terms.

## **Organ Shortage**

The severe shortage of organ donors remains the main challenge that Member States face with regard to organ transplantation. Growing waiting lists are a serious problem. More than 40,000 patients are currently waiting for a kidney in Western Europe. Waiting lists have become longer in all EU countries as well as in the rest of the world. Even in cases of sustained increases in the number of donors, waiting lists and waiting times are very difficult to shorten.

The establishment of an efficient system for identifying persons that could become organ donors upon their death, once all mandatory consent requirements in Member States have been met, is a key element in fighting organ shortage. The process of evaluation of organ suitability is a multiphase event, focused on a) the definition of acceptable-unacceptable risk of transmission of infectious or neoplastic diseases and b) the establishment of practical steps for the risk evaluation process, considering in the single case the transmittable disease, the specific conditions of the recipient with respect to the transmittable disease, the available means of prevention and the treatment of the disease.

Another important option in expanding the donor pool is considering the promotion of altruistic donations from living donors. The morbidity and mortality of patients waiting for transplantation require careful consideration of those potential donors who would normally not be considered as ideal candidates; these are called expanded donors (i.e. allowing transplants from HIV positive patients to other HIV positive patients.) When the donor pool is expanded in this way, doctors are concerned with increased likelihood of rejection of the organs and gradual decline of the function of the grafted organ. It is vital to support methods to prevent and treat organ rejection so that the expanded pool can be used with confidence by doctors. The training and employment of health professionals responsible for identifying potential donors has also proven to be useful and must be encouraged wherever resources allow it. Biotechnology is already offering solutions e.g., treatments that reduce rates of rejection, which will, in turn, support the availability of more organs, by allowing doctors to treat or even prevent rejection. This, therefore, helps support the expanded donor pool, by reducing the risk associated with expanded organ programmes. It is worth mentioning that in the future, biotechnology may offer the possibility for researchers to grow organs from existing tissues, either from the patient themselves (autologous) or from other tissue donors (allogeneic). Work to promote such research, which is often carried out by Europe's emerging SME biotech companies, should be stimulated wherever possible, within the cultural and ethical frameworks laid down in the Member States.

## **Organisational aspects**

Organisational systems not only have an impact on quality and safety of organs but also on their availability. There are severe discrepancies in organ donation and transplantation activity within and between Member States. The different organisational systems in Europe are the result of their origin and history. Comparison between countries shows that final national donation rates do not always correlate with the percentage of people who have previously declared themselves ready to donate in these countries. This clearly indicates the importance of having an efficient transplant system in place ensuring that the organs of people willing to donate become available.

A prerequisite for any action in this area is the establishment of an adequate transplant system at national level. Such a system requires an appropriate legal framework, which is not market-oriented, and a good technical approach as well as organisational support. The role of competent authorities is crucial in the organisational system. These authorities must ensure compliance with basic standards and organise the donation and transplantation activities. The most efficient organisational systems should be used and promoted.

As mentioned above, organ transplants are subject to time pressure. The process from procurement to transplantation should be completed in a few hours (in order to preserve organ viability). In addition, for organs to be transplanted the donor has to match with the recipient. This makes the organisational structure a key element of organ donation/transplantation systems. As part of this organisation, an effective allocation system is essential, which takes into account the short time organs can be maintained and the need to ensure that the organ is assigned to the most suitable recipient, according to predefined criteria.

### **Public awareness**

Public awareness and public opinion also have an important role to play in increasing organ donation. Organ donation and transplantation are medical treatments that require the full participation of society for their development. Many complex and sensitive ethical issues are linked to this area, and it has become clear that several of these aspects are dealt with differently in different countries depending on the prevailing values and beliefs. These different values and concerns should remain and should be dealt with at a national level. Increasing public willingness to donate can be supported by improving the knowledge of health professionals and the media about transplantation issues. Continued education should form an important element in any communication strategy. People should be encouraged to speak about organ donation and to communicate their wishes to their relatives. There is a strong positive correlation between having discussed it within the family and the willingness to donate organs.

In other words, public awareness must be enhanced to the as much as possible, both through provision of adequate information upon request, and its extensive dissemination to local, regional and central communities in Member States, including, but not limited to, schools, clinics, social and community centres and churches. Additionally, in the light of the evidence that people are more willing to donate organs if they have discussed the matter first with their family, comprehensive information should be provided to the family of the donor or potential donor.

### **Other Issues**

#### *\* Co-ordination and other activities*

Bearing in mind that there is no pan-European coordination of organ exchange, it is crucial that the existing arrangements for organ exchange between Member States are reinforced and coordinated in a more specific way in order to cover national needs and increase the efficiency of such exchanges. The existing practices should not be jeopardised nor should the administrative burden be increased.

*\* Altruism*

Altruism must constitute the main element of organ donation and transplantation. The economic terminology used in the Commission's Communication is therefore not adequate, in particular in view of the principle of non-commercialisation of the human body. Therefore, the language used must not suggest, under any circumstances, that organs may be treated as a commodity of the Internal Market.

This principle of non-commercialisation of the human body and its parts is expressly stated in Article 3 (2) of the EU Charter on Fundamental Rights. The Commission Communication mentions this principle only in relation to organ trafficking. Thus, we find it crucial to stress that this fundamental principle also applies to the donation of one's own organs.

In general, ethical aspects relating to organ donations should remain within the competence of Member States in accordance with the principle of subsidiarity.

*\* Trafficking*

In the face of available data on the trafficking of human organs and evidence for rapidly developing commercialism and transplant tourism, it is pertinent not to underestimate organ trafficking as a secondary area of concern. It must be recognised that organ trafficking is caused by a combination of poverty and hopelessness, the desire to make a living, as well as corruption and unscrupulousness of criminals, globalisation of the economy and the exploitation of human beings. Unfortunately, in many cases, people in the East become the spare parts inventory for the sick in the West.

Cooperation with international organisations (such as EUROPOL and INTERPOL) must be pursued to combat organ trafficking both in the EU and outside its borders. Policy changes should not create further obstacles to cross-EU cooperation and cooperation with other international and European organisations, where desired.



28.2.2008

## **OPINION OF THE COMMITTEE ON LEGAL AFFAIRS**

for the Committee on the Environment, Public Health and Food Safety

on organ donation and transplantation: policy actions at EU level  
(2007/2210(INI))

Draftsman: Giuseppe Gargani

### **SUGGESTIONS**

The Committee on Legal Affairs calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to incorporate the following suggestions in its motion for a resolution:

- A. whereas organ donation and transplantation are complex and particularly sensitive issues, especially because of their important ethical dimension,
- B. whereas national policies and the regulatory framework for donations and transplantation vary substantially between Member States in accordance with different legal, cultural, administrative and organisational factors,
- C. whereas Article 152(4) of the EC Treaty enables Community measures to be adopted with a view to ensuring that transplantation systems are more efficient and accessible whilst fully respecting the principle of subsidiarity and, accordingly, the national provisions on donation or medical use of organs of each Member State;
  - 1. Believes that consideration should be given to the need for a legislative measure to ensure quality and safety standards at Community level on organ donation and transplantation alongside close cooperation between Member States taking into account the regulatory framework which already exists in the various EU Member States and the activities of other international organisations;
  - 2. Supports an appropriate Community legal instrument on organ donation and transplantation, following cost benefit analysis and comprehensive impact assessment, while taking into consideration the specificities of organ transplantation and the work carried out by the Council of Europe alongside strengthened cooperation between Member

States by respecting their existing national provisions; stresses that any legislation should not add administrative burdens which divert resources from care and, given the shortage of organs for donation, must allow clinicians to continue to take a risk-based approach to assessing potential organ donors;

3. Stresses that the aim of making transplantation systems more efficient and accessible by improving their safety and quality and ensuring greater organ availability, by respecting the principle of self-determination of the potential donor, cannot be pursued at the expense of the complex ethical issues relating to organ transplantation;
4. Stresses that closer cooperation between Member States is vital; suggests that exchange of best practice in the field of donation and transplantation should be stepped up and calls for the setting up of a data bank at Community level for the purposes of donation and transplantation; asks Member States to consider removing restrictions on transportation of organs across borders, particularly in cases where the biological indicators of the organ in one country are in accordance with the required conditions of the organ in another country; considers that a flexible system between Member States for organ transplantation, organ exchange, organ importation and exportation could save many lives by allowing more people to find suitable donors;
5. Considers it would be advisable to provide for high standards in order to prevent any medical, surgical, psychological, social or ethical problems which might be encountered by live donors following the necessary tests to ascertain whether they are suitable donors and the medical treatment and surgical operations geared to donation, in order to minimise the risk to the donor;
6. Considers it necessary to ensure that deceased donors are suitably managed, by ensuring appropriate safety and quality standards for donated organs, for which purpose a system should be adopted whereby consent for removal is always assumed except in the case of express refusal on the part of the donor; considers that no-one may contradict the wishes of a donor expressed in this way, not even a spouse or first-degree relative;
7. Asks Member States to analyse the benefits of implementing a donation system of 'presumed consent' as a means to achieve greater numbers of organ transplantations. Considers that this system fully preserves donor's consent as citizens can consider whether to remain within the system or opt out;
8. Believes it is necessary to ensure that a suitable balance is struck between the protection of the donor in respect of anonymity, confidentiality and the traceability of organ donations, in order to prevent remuneration, trade and trafficking in organs.

## RESULT OF FINAL VOTE IN COMMITTEE

<b>Date adopted</b>	26.2.2008
<b>Result of final vote</b>	+: 22 -: 0 0: 0
<b>Members present for the final vote</b>	Titus Corlăţean, Monica Frassoni, Giuseppe Gargani, Lidia Joanna Geringer de Oedenberg, Neena Gill, Piia-Noora Kauppi, Klaus-Heiner Lehne, Katalin Lévai, Antonio López-Istúriz White, Hans-Peter Mayer, Manuel Medina Ortega, Hartmut Nassauer, Aloyzas Sakalas, Francesco Enrico Speroni, Diana Wallis, Rainer Wieland
<b>Substitute(s) present for the final vote</b>	Vicente Miguel Garcés Ramón, Sajjad Karim, Georgios Papastamkos, Gabriele Stauner, József Szájer, Jacques Toubon

28.2.2008

## **OPINION OF THE COMMITTEE ON CIVIL LIBERTIES, JUSTICE AND HOME AFFAIRS**

for the Committee on the Environment, Public Health and Food Safety

on Organ donation and transplantation: Policy actions at EU level  
(2007/2210(INI))

Draftswoman: Edit Bauer

### **SUGGESTIONS**

The Committee on Civil Liberties, Justice and Home Affairs calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to incorporate the following suggestions in its motion for a resolution:

- A. whereas there are more than 60 000 patients in need of transplants on waiting lists across Europe, and whereas a significant number of patients die as a result of the chronic shortage of organs;
- B. whereas there is currently no comprehensive European Union database collecting all necessary data on organs earmarked for donations and transplants or on living and deceased donors from the national databases/registries and international organisations of Member States;
- C. whereas four Member States have still not ratified the United Nations Convention against Transnational Organized Crime, five Member States have not ratified its supplementary Protocol to Prevent, Suppress and Punish Trafficking in Persons, Especially Women and Children ("the Palermo Protocol"), and nine Member States have not ratified the UN Optional Protocol to the Convention on the Rights of the Child on the sale of children, child prostitution and child pornography;
- D. whereas although current estimates put organ trafficking at a relatively low level among all forms of trafficking, trafficking in organs and tissues is becoming an increasing global problem which occurs within and across national borders and is demand-driven (estimation of 150-250 cases/year in Europe);

- E. whereas trafficking in organs and tissues is a form of trafficking in human beings, which entails serious violations of fundamental human rights, and in particular of human dignity and physical integrity, and can undermine citizens' confidence in the legitimate transplantation system, which may lead to further shortage of supply of voluntarily donated organs and tissues;
- F. whereas experience shows that the legal systems requiring consent "opt-in" or "opt-out" do not produce profoundly different results in organ procurement and transplantation;
1. Welcomes the Commission's initiative to prepare a legal framework on safety and quality for donation and transplantation, and calls for minimum standards of requirements to be defined in a flexible manner, bearing in mind that transplantation could be a life-saving treatment for the patient, in which case a risk level even higher than that for tissues and cells can be accepted;
  2. Asks Member States to sign, ratify and implement the Council of Europe Convention on Action against Trafficking in Human Beings and the Palermo Protocol if they have not already done so;
  3. Asks the Commission and the Council to update the Action Plan on Trafficking in human beings and include in it an action plan for the fight against trafficking in organs, in order to enable closer cooperation among the authorities concerned;
  4. Calls, in addition, for the action plan to make reference to data which are correct and verified concerning the quantities, types and origin of illegally-trafficked organs;
  5. Calls on the Member States to exchange best practices and information regarding organ donation and transplantation, highlighting in particular the positive experiences and results of organ procurement and transplantation in Spain;
  6. Urges the Member States to maintain and strengthen the transparency and safety management of waiting lists, imposing a clear requirement for tracking irregularities and maintaining the traceability of organs, while ensuring anonymity for both donors and recipients;
  7. Urges the Member States to give general practitioners a proactive role in talking to their patients in order to enable them to make an informed choice concerning donor registration, and to allay unjustified fears and thereby increase the number of donors;
  8. Urges the Member States to adopt or maintain strict legal provisions in connection with transplantation from unrelated living donors, in order to make the system transparent and exclude the possibility of illicit organ selling or coercion of donors; thus, donations by unrelated living donors could only be made under the conditions defined in national law and following authorisation by a suitable independent body;
  9. Asks the Commission, in relation to third countries, to fight against the practice of organ and tissue trafficking, which should be universally banned, including the transplantation of organs and tissues from minors, from the mentally disabled or from executed

prisoners; calls on the Commission and the Member States to raise the awareness of the international community on this issue;

10. Urges the Member States, where necessary, to amend their criminal codes to ensure that those responsible for organ trafficking are adequately prosecuted, including sanctions for medical staff involved in transplantation of organs obtained from trafficking, while making every effort to discourage potential recipients from seeking trafficked organs and tissues; this should include the consideration of criminal liability of European citizens who have purchased organs inside or outside the Union;
11. Encourages the Commission and the Member States to cooperate with "donor" countries with the support of Europol and Interpol to carry out necessary surveys, to detect cases of organ trafficking and to dismantle trafficking networks;
12. Calls on the Member States to take the necessary steps to restrain healthcare professionals from facilitating organ and tissue trafficking (i.e. referring a patient to a foreign transplant service, which might be involved in trafficking) as well as health insurance providers from facilitating - financially or otherwise - activities that directly or indirectly promote trafficking in organs;
13. Calls on the Member States to ensure that all tissue and organ donations by a living person are subject to their express full legal consent;
14. Urges the Member States to ensure that living donors will not be discriminated against, in particular by insurance systems;
15. Urges Member States to ensure the reimbursement of the social security costs of living donors;
16. Stresses the importance of financing organ procurement and transplantation under a dedicated budget line, so as not to make transplantation a disincentive for hospitals;
17. Calls on the Commission and the Member States to encourage and support research in the field of organ and tissue transplantation;
18. Calls on the Commission and the Member States to raise public awareness of the necessity of organ donation via a suitable awareness-raising campaign at European level; welcomes the Commission's initiative to launch the European Donor Card that could also serve as one of the tools for raising public awareness; calls on the Member States to support this initiative;
19. Calls on the Commission to take into consideration the further development and expansion of the existing European web page on organ donation [www.eurodonor.org](http://www.eurodonor.org) (and/or [www.eurocet.org](http://www.eurocet.org)), as well as that of the WHO ([www.transplant-observatory.org](http://www.transplant-observatory.org)), on all EU Member States in all official EU languages, with the aim to provide all relevant information and data on organ donation and transplantation;
20. Calls on the Commission and the Member States to launch a pan-European database and communication network or to support an existing one in order to interconnect the national

databases and provide them with a platform for fast exchanges of comprehensive data on organ donations and transplantations and on living and deceased donors;

21. Considers that the Member States should ensure the training of their law enforcement agencies as well as medical staff on trafficking in organs in order to report each known case to the police.

## RESULT OF FINAL VOTE IN COMMITTEE

<b>Date adopted</b>	27.2.2008
<b>Result of final vote</b>	<div style="display: flex; justify-content: flex-end; align-items: center;"> <div style="text-align: right; padding-right: 10px;"> + :            48  - :            0  0 :            1 </div> </div>
<b>Members present for the final vote</b>	Philip Bradbourn, Mihael Brejc, Kathalijne Maria Buitenweg, Giusto Catania, Jean-Marie Cavada, Carlos Coelho, Esther De Lange, Panayiotis Demetriou, Gérard Deprez, Bárbara Dührkop Dührkop, Claudio Fava, Armando França, Urszula Gacek, Kinga Gál, Roland Gewalt, Lilli Gruber, Jeanine Hennis-Plasschaert, Livia Járóka, Ewa Klamt, Magda Kósáné Kovács, Wolfgang Kreissl-Dörfler, Stavros Lambrinidis, Roselyne Lefrançois, Sarah Ludford, Viktória Mohácsi, Claude Moraes, Javier Moreno Sánchez, Rareş-Lucian Niculescu, Luciana Sbarbati, Inger Segelström, Csaba Sógor, Søren Bo Søndergaard, Vladimir Urutchev, Ioannis Varvitsiotis, Renate Weber, Manfred Weber, Tatjana Ždanoka
<b>Substitute(s) present for the final vote</b>	Edit Bauer, Maria da Assunção Esteves, Anne Ferreira, Genowefa Grabowska, Sophia in 't Veld, Metin Kazak, Marian-Jean Marinescu, Marianne Mikko, Bill Newton Dunn, Hubert Pirker, Nicolae Vlad Popa, Eva-Britt Svensson



## RESULT OF FINAL VOTE IN COMMITTEE

<b>Date adopted</b>	26.3.2008
<b>Result of final vote</b>	+: 60 -: 0 0: 1
<b>Members present for the final vote</b>	Adamos Adamou, Georgs Andrejevs, Kader Arif, Margrete Auken, Liam Aylward, Pilar Ayuso, Irena Belohorská, Johannes Blokland, John Bowis, Frieda Brepoels, Hiltrud Breyer, Martin Callanan, Dorette Corbey, Magor Imre Csibi, Avril Doyle, Mojca Drčar Murko, Edite Estrela, Jill Evans, Anne Ferreira, Karl-Heinz Florenz, Alessandro Foglietta, Matthias Groote, Françoise Grossetête, Satu Hassi, Gyula Hegyi, Marie Anne Isler Béguin, Caroline Jackson, Christa Klauf, Eija-Riitta Korhola, Holger Krahmer, Urszula Krupa, Aldis Kušķis, Peter Liese, Marios Matsakis, Roberto Musacchio, Riitta Myller, Péter Olajos, Miroslav Ouzký, Vladko Todorov Panayotov, Dimitrios Papadimoulis, Dagmar Roth-Behrendt, Guido Sacconi, Karin Scheele, Richard Seeber, Kathy Sinnott, María Sornosa Martínez, Antonios Trakatellis, Evangelia Tzampazi, Marcello Vernola, Anja Weisgerber, Åsa Westlund, Anders Wijkman, Glenis Willmott
<b>Substitute(s) present for the final vote</b>	Iles Braghetto, Bairbre de Brún, Milan Gaľa, Jutta Haug, Erna Hennicot-Schoepges, Justas Vincas Paleckis, Lambert van Nistelrooij
<b>Substitute(s) under Rule 178(2) present for the final vote</b>	Miguel Angel Martínez Martínez