



# Procedure file

Basic information		
INI - Own-initiative procedure	<a href="#">2007/2210(INI)</a>	Procedure completed
Organ donation and transplantation: policy actions at EU level		
Subject 4.20.05 Health legislation and policy		

Key players			
European Parliament	Committee responsible	Rapporteur	Appointed
	<b>ENVI</b> Environment, Public Health and Food Safety		
	Committee for opinion	Rapporteur for opinion	Appointed
	<b>AFET</b> Foreign Affairs	The committee decided not to give an opinion.	
	<b>LIBE</b> Civil Liberties, Justice and Home Affairs		03/10/2007
		PPE-DE <a href="#">BAUER Edit</a>	
	<b>JURI</b> Legal Affairs		19/11/2007
		PPE-DE <a href="#">GARGANI Giuseppe</a>	
European Commission	Commission DG <a href="#">Health and Food Safety</a>	Commissioner KYPRIANOU Markos	

Key events			
29/05/2007	Non-legislative basic document published	<a href="#">COM(2007)0275</a>	Summary
27/09/2007	Committee referral announced in Parliament		
26/03/2008	Vote in committee		Summary
01/04/2008	Committee report tabled for plenary	<a href="#">A6-0090/2008</a>	
21/04/2008	Debate in Parliament		
22/04/2008	Results of vote in Parliament		
22/04/2008	Decision by Parliament	<a href="#">T6-0130/2008</a>	Summary
22/04/2008	End of procedure in Parliament		

Technical information	
Procedure reference	2007/2210(INI)
Procedure type	INI - Own-initiative procedure
Procedure subtype	Strategic initiative
Legal basis	Rules of Procedure EP 54
Stage reached in procedure	Procedure completed

## Documentation gateway

Non-legislative basic document		<a href="#">COM(2007)0275</a>	30/05/2007	EC	Summary
Document attached to the procedure		<a href="#">SEC(2007)0704</a>	30/05/2007	EC	
Document attached to the procedure		<a href="#">SEC(2007)0705</a>	30/05/2007	EC	
Committee draft report		<a href="#">PE398.666</a>	15/01/2008	EP	
Amendments tabled in committee		<a href="#">PE400.651</a>	11/02/2008	EP	
Committee opinion	LIBE	<a href="#">PE398.622</a>	27/02/2008	EP	
Committee opinion	JURI	<a href="#">PE400.324</a>	28/02/2008	EP	
Committee report tabled for plenary, single reading		<a href="#">A6-0090/2008</a>	01/04/2008	EP	
Text adopted by Parliament, single reading		<a href="#">T6-0130/2008</a>	22/04/2008	EP	Summary
Commission response to text adopted in plenary		<a href="#">SP(2008)3169</a>	28/05/2008	EC	
Commission response to text adopted in plenary		<a href="#">SP(2008)3407</a>	25/06/2008	EC	

## Organ donation and transplantation: policy actions at EU level

**PURPOSE** : to propose a set of EU policy actions on organ donation and transplantation.

**CONTENT** : organ donation and transplantation is a complex and sensitive issue, with an important ethical dimension. Policies on organ donation vary across the Member States depending on cultural, legal, administrative and organisational issues.

The excellent results of transplants, in terms of life years gained and in terms of improved quality of life have multiplied the indications of these therapies. There are, however, risks associated with organ donation particularly the risk of disease transmission. On the other hand, the shortage of donors affects transplantation programmes. Nearly 40 000 patients are now on waiting lists in Europe. Mortality rates while waiting for a heart, liver or lung transplant range from 15-30%. There are large differences in the deceased and living organ donor rate within the EU. These differences cannot be easily explained. Even among EU countries with well-developed services, there are considerable differences in organ donation and transplantation activity and it would appear that some organisational models are performing better than others. A further concern associated with organ donation is the trafficking of human organs by criminal gangs, who track down and remove organs in developing countries and hand them on to recipients within the European Union.

In short, therefore, the challenges facing organ donation are:

- Transplant risks: the risk of diseases being transmitted to the recipients such as HIV, hepatitis B and C, bacteria, fungi, parasites and different types of cancers.
- Organ shortages: The severe shortage of organ donors remains the main challenge facing EU Member States. Every day nearly ten patients die waiting for an organ in European societies.
- Organ trafficking: While current estimations indicate that organ trafficking remains relatively modest in Europe, the issue is nevertheless of serious political and ethical concern.

In recent years, the Commission has put considerable effort into supporting organ transplantation under various Community programmes. A large number of projects have been funded, the result of which have generated a considerable amount of information. In June 2006 the Commission launched an open consultation on organ donation and transplantation. Based on the outcome of this consultation, the Commission now proposes that new initiatives be taken, at a Community level, that seek to alleviate the challenges identified. In summary, the new initiatives are as follows:

**Improving safety and quality:** The Commission will define the precise, balanced scope of the EU legal framework on quality and safety for human organs taking account of Member State consultations. The framework must be backed-up by inter-Member State co-operation.

**Increasing organ availability:** The Commission will seek to boost Member State co-operation to allow for the exchange of experience and best practices with a view to establishing the most efficient systems.

**Making transplantation systems more efficient and accessible:** Initiatives in this area will focus on identifying the most efficient systems, sharing experience and promoting best practices in accordance with local needs. Member States, whose transplant systems have yet to reach their full potential, could be supported and guided in their efforts to improve patient care.

**Action plan on strengthened co-operation between the Member States:** Analysis of organ transplantation in the EU reveals large differences in the organ donor rate within the EU. Differences in transplantation activity have also been identified. These differences can not be easily

explained and it is clear that some models are performing better than others. The Commission, will therefore, identify which models work the best and support its application throughout the EU, while respecting cultural and organisation diversity.

EU legal instruments on quality and safety of organ donation and transplantation: The Community has already adopted a Directive on the quality and safety standards for blood, tissues and cells. A possible European Directive setting quality standards for organs could also be envisioned that addresses similar topics ? but which takes account of issues uniquely linked to organ donation. Such a legislative act would be based on a separate impact assessment. A future legislative act could include the following elements:

- Establishing national oversight authorities responsible for implementing the Directive.
- Setting common quality and safety standards.
- Authorising programmes on organ donation and procurement.
- Setting provisions on the effective preservation and transportation of organs.
- Setting provisions on traceability.
- Establishing a procedure for reporting serious adverse events and reactions.
- Establishing control measure and inspection procedures.
- Ensuring a complete characterisation of the organ to allow transplant team to undertake risk assessments.

## Organ donation and transplantation: policy actions at EU level

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The Committee on the Environment, Public Health and Food Safety adopted the own-initiative report by Adamos ADAMOY (GUE/NGL, CY), welcoming the Commission's communication ?Organ Donation and Transplantation: Policy Actions at EU level?, which proposes an integrated approach, based on three pillars.

Concerned with guaranteeing the quality and safety of organ donation and transplantation, MEPs await a proposal for a Directive from the Commission establishing the quality and safety requirements for the donation, procurement, verification, preservation, transport and distribution of organs in the European Union and anticipating the resources to fulfil these requirements. However, they emphasise that the future legal framework must not: place additional administrative responsibility on Member States or on service providers; challenge the use of existing good practice, or include requirements which would lead to a lower number of potential and actual donors.

Expressing their concern regarding the scarcity of human organs available for transplantation compared to the needs of patients, MEPs await an action plan from the Commission aiming to strengthen cooperation between Member States in order to: (i) increase the availability of organs; (ii) strengthen the efficiency and accessibility of transplantation systems; (iii) increase public awareness; and (iv) guarantee quality and security.

The report underlines that the establishment of well-structured operational systems and the promotion of tested models, in the Member States or between them, or failing that, at international level, are extremely important. In order to increase the availability of organs, MEPs call on Member States to fully invest in the improvement of their organisational system:

- by increasing awareness among medical staff and paramedics and by ensuring their education and training;
- by financially assisting hospitals to hire ?internal transplantation coordinators? responsible for actively identifying potential donors and making contact with their family;
- by introducing quality improvement programmes in each hospital or group of hospitals in Europe.

In addition, the parliamentary committee insists that organ donations remain strictly without commercial gain. It endorses measures which aim to protect donors and to ensure that organ donation is chosen selflessly and on a voluntary basis, preventing any payment between donor and recipient, other than a compensation payment, which is strictly limited to reimbursing any expenses or inconvenience due to the operation.

Member States are called to adopt strict legislative provisions concerning transplantations to ensure the transparency of the system and that all possibility of selling organs illegally or coercive action towards donors is avoided. Moreover, the Commission is called upon to promote research in the field of biotechnology, which could provide researchers with a means of reconstituting organs from tissues or cells of the patients themselves.

In order to improve the efficiency and accessibility of transplantation systems, the report strongly argues for the creation of national registers to monitor living donors, patients with a transplant and transplant procedures. In this context, the Commission is called to:

- facilitate the development of a set of technical and ethical standards relating to the management of security, quality and the efficiency of organ donation, in the case of a donation followed by a transplant, this set of standards could be used by Member States as a model;
- create a European mechanism to promote coordination activities between Member States regarding organ donation and transplantation;
- enable closer association between national transplant organisations of Member States, which necessitates cooperation at legal, ethic, and technical levels.

MEPs call for the creation of a European organ donor card to be added to current national systems. They also note that to ensure the rapid identification of organs, it is vital to encourage those who are not suitable donors to be in possession of a card signalling this. Furthermore, MEPs call on Member States to anticipate, in their legislation, the possibility of appointing a legal representative authorised to make a decision in terms of donation after death.

The report also emphasises the importance of increasing public awareness regarding organ donation and transplantation, and calls on the Commission, Member States and organisations in civil society, churches and religious or humanist communities, to participate in this endeavour. They also are in favour of the creation of a special transplant telephone line, with a single hotline number, which would be managed by the national transplant organisation, when such an organisation exists, and entrusted to a well trained and experienced team of professionals who could provide accurate and specific information (medical and legal) to all those concerned 24 hours a day.

Lastly, MEPs highlight that organ trafficking undermines the credibility of the system for eventual voluntary unpaid donors. The Commission and Member States are called to take measures to prevent ?transplant tourism?, notably by enacting guidelines which aim to protect the poorest and most vulnerable donors from becoming victims of organ trafficking, and by adopting measures to increase the availability of

organs that have been lawfully obtained. Moreover, Member States are called to take all necessary measures to ensure that those responsible for organ trafficking are subject to legal prosecution, and to prevent healthcare services from encouraging those activities that benefit directly or indirectly from organ trafficking, for example by reimbursing costs to obtain an illegal organ transplant.

## Organ donation and transplantation: policy actions at EU level

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The European Parliament adopted, by 653 votes to 14 with 16 abstentions, a resolution on organ donation and transplantation: Policy actions at EU level, in response to the Commission Communication on the subject. The own-initiative report had been tabled for consideration in plenary by Adamos ADAMOY (GUE/NGL, CY), on behalf of the Committee on the Environment, Public Health and Food Safety. Parliament welcomed the Communication which proposes an integrated approach, based on three pillars.

Concerned with guaranteeing the quality and safety of organ donation and transplantation, MEPs await a proposal for a Directive from the Commission establishing the quality and safety requirements for the donation, procurement, verification, preservation, transport and distribution of organs in the European Union and anticipating the resources to fulfil these requirements. However, they emphasise that the future legal framework must not: place additional administrative responsibility on Member States or on service providers; challenge the use of existing good practice, or include requirements which would lead to a lower number of potential and actual donors.

Expressing their concern regarding the scarcity of human organs available for transplantation, MEPs await an action plan from the Commission aiming to strengthen cooperation between Member States in order to: (i) increase organ availability; (ii) strengthen the efficiency and accessibility of transplantation systems; (iii) increase public awareness; and (iv) guarantee quality and safety.

Parliament underlines that the establishment of well-structured operational systems in the Member States or between them is extremely important.

With regard to increasing the availability of organs, Parliament invites Member States to adopt legislation enabling the appointment of a legal representative who can decide on donation after a person's death. It calls on Member States to achieve the full potential of post-mortem donations through a series of measures which Parliament recommends. These include financially supporting hospitals in the appointment of in-house transplant coordinators (doctors working inside the intensive care units who are supported by a medical team), whose task would be actively to identify potential donors and approach their families.

Parliament asks Member States to remove, before January 2010, legislation that reserves donor organs for use solely within that Member State. It stresses the importance of financing organ procurement and transplantation under a dedicated budget line, so as not to make transplantation a disincentive for hospitals. Members go on to underline the need to ensure that organ donations stay strictly non-commercial. Any payments between donors and recipients must be confined solely to compensation strictly limited to making good the expense associated with the donation. Member States must adopt strict legal provisions, in order to exclude the possibility of illicit organ selling or coercion of donors. Parliament also urges Member States to ensure that living donors are not discriminated against, in particular by insurance systems.

With regard to improving the efficiency and accessibility of transplantation systems, Parliament notes that, although several Member States have introduced compulsory registration of transplant activities, there is no comprehensive system for the collection of data on the different types of transplantation and their outcomes. It strongly recommends the creation of national follow-up registers of living donors, transplanted patients and transplant procedures, and stresses the importance of ensuring the comparability of the data between Member States. Parliament makes a series of recommendations for Commission action, including the creation of a European mechanism to promote coordination activities between Member States regarding organ donation and transplantation. It calls for an EU donor card, complementary to existing national systems.

It underlines the importance of increasing public awareness of organ donation and transplantation and calls on the Commission, Member States and civil society to enhance structurally the promotion of organ donation, inter alia among youngsters in schools. Parliament 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 staffed 24 hours per day by appropriately trained professionals.

Lastly, MEPs highlight that organ trafficking undermines the credibility of the system for potential voluntary and unpaid donors. 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 those organs from entering the EU. The Commission and Member States are called to take measures to prevent 'transplant tourism', notably by enacting guidelines which aim to protect the poorest and most vulnerable donors from becoming victims of organ trafficking, and by adopting measures to increase the availability of legally procured organs. Those responsible for organ trafficking must be subject to prosecution, including sanctions for medical staff involved in transplantation of organs obtained from trafficking.