Basic information

2009/2104(INI) INI - Own-initiative procedure	Procedure completed
Action plan on organ donation and transplantation (2009-2015): strengthened cooperation between Member States **Subject** 4.20.02.06 Clinical practice and experiments 4.20.05 Health legislation and policy	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ENVI Environment, Public Health and Food Safety	PERELLÓ RODRÍGUEZ Andrés (S&D)	13/10/2009

Committee for opinion	Rapporteur for opinion	Appointed
JURI Legal Affairs	LICHTENBERGER Eva (Verts/ALE)	05/10/2009
LIBE Civil Liberties, Justice and Home Affairs	The committee decided not to give an opinion.	

European Commission

Commission DG	Commissioner
Health and Food Safety	DALLI John

Key events

Date	Event	Reference	Summary
08/12/2008	Non-legislative basic document published	COM(2008)0819	Summary
22/10/2009	Committee referral announced in Parliament		
16/03/2010	Vote in committee		Summary
26/03/2010	Committee report tabled for plenary	A7-0103/2010	
18/05/2010	Debate in Parliament		
19/05/2010	Decision by Parliament	T7-0183/2010	Summary

19/05/2010	Results of vote in Parliament		
19/05/2010	End of procedure in Parliament		

Technical information	
Procedure reference	2009/2104(INI)
Procedure type	INI - Own-initiative procedure
Procedure subtype	Strategic initiative
Legal basis	Rules of Procedure EP 55
Other legal basis	Rules of Procedure EP 165
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/7/00827

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE430.960	11/01/2010	
Committee opinion	JURI	PE430.860	29/01/2010	
Amendments tabled in committee		PE439.156	17/02/2010	
Committee report tabled for plenary, single reading		A7-0103/2010	26/03/2010	
Text adopted by Parliament, single reading		T7-0183/2010	19/05/2010	Summary

European Commission

Document type	Reference	Date	Summary
Non-legislative basic document	COM(2008)0819	08/12/2008	Summary
Commission response to text adopted in plenary	SP(2010)4416	16/09/2010	
Commission working document (SWD)	SWD(2014)0147	25/04/2014	Summary

Action plan on organ donation and transplantation (2009-2015): strengthened cooperation between Member States

2009/2104(INI) - 08/12/2008 - Non-legislative basic document

PURPOSE: to present an Action Plan on Organ Donation and Transplantation (2009-2015).

BACKGROUND: currently, the demand for organs exceeds the number of available organs in all Member States and this demand for organs is increasing faster than organ donation rates. There are currently more than 56 000 patients waiting for a suitable donor organ within the European Union. There are large differences in practices and results among Member States.

In the field of organ donation and transplantation in particular, there is huge potential for sharing experience and expertise among EU Member States.

On 31 May 2007, the Commission adopted a Communication on organ donation and transplantation. This Communication and the Impact Assessment accompanying made a number of suggestions for actions at Community and Member State levels designed to help increase the supply of organ donors across the EU and ensure the quality and safety of these procedures.

The Communication proposed a **dual mechanism of action**: an Action Plan enhancing active coordination and cooperation between Member States complemented by a legal instrument containing the basic quality and safety principles (a Directive on the standards and quality of safety of human organs intended for transplantation).

Following the adoption of this first Communication, the Commission started a process of consultation with national experts and key stakeholders with the focus on the quality and safety requirements of human organ donation and transplantation and key priority areas for the proposed action plan. This consultation process enabled the Commission to identify 10 priority actions, which are grouped under three challenges:

- increasing organ availability
- enhancing the efficiency and accessibility of transplantation systems
- improving quality and safety.

CONTENT: this Action Plan aims at **reinforcing the cooperation between Member States**, through the identification and development of common objectives and guidelines, jointly-agreed indicators and benchmarks, regular reporting, and identification and sharing of best practices.

Actions at Community level will complement Member States' efforts to improve the quality and safety of organ donation and transplantation, combat the organ shortage problem and make transplantation systems more efficient. Through the utilization of Community tools, especially the Health Programme 2008-2013, the Commission will provide assistance to the Member States.

This Action Plan sets out 10 priority actions to help Member States address the challenges in the field of organ donation and transplantation. It will promote strengthened cooperation between Member States and exchange of best practices as a key element in the strategy. This cooperation process must be based on the identification and development of common objectives and guidelines, jointly-agreed quantitative and qualitative indicators and benchmarks and identification and sharing of best practices. On the basis of these actions Member States should develop their own sets of **National Priority Actions**. The Action plan will provide the basis for an overall evaluation of the success Member States have in achieving the common objectives. A mid-term review of the actions will be carried out in 2012 to evaluate the efficacy of this action plan.

The 10 priority actions are as follows:

- **Priority action 1**: promote the role of transplant donor coordinators in every hospital where there is potential for organ donation. Member States should aim to incorporate in their Sets of National Priority Actions the objective of gradually appointing **Transplant Donor Coordinators** in all hospitals where there is potential for organ donation. The Commission could have a coordinating and monitoring role in this respect
- **Priority action 2:** promote Quality Improvement Programmes in every hospital where there is potential for organ donation. These programmes are primarily a self evaluation of the whole process of organ donationaccording to the characteristics of the hospital and the health system. These will make it possible to compare results and thus to pinpoint areas for improvement.
- **Priority Action 3:** exchange of best practices on living donation programmes among EU Member States. The Action Plan aims to promote altruistic donation programmes and the development of registration practices regarding living donors in order to guarantee their safety. The Commission will help to develop adequate tools to facilitate the proper collection of information on the medical, psychological, financial and social consequences of a living donation. **Registers of living donors** should be established to facilitate monitoring and follow-up.
- **Priority Action 4:** improve the knowledge and communication skills of health professionals and patient support groups on organ transplantation. Awareness campaigns should include information regarding the rights citizens and patients have concerning organ donation and transplantation in different Member States. The Commission can actively contribute by helping Member States to collect this kind of information.
- **Priority Action 5:** facilitate the identification of organ donors across Europe and cross-border donation in Europe. The Commission will help Member States to develop identification mechanisms.
- **Priority Action 6:** enhancing the organisational models of organ donation and transplantation in the EU Member States. Member States should aim to establish, in close collaboration with the Commission, a common set of indicators to monitor organ policy and a methodology to evaluate the potential in each Member State. The Action Plan further encourages Member States to promote the twinning of projects and peer review programmes.
- **Priority Action 7:** promote EU-wide agreements on aspects of transplantation medicine. A cooperation method is the ideal context in which to discuss issues of mutual concern and come up with common solutions and monitoring mechanisms. For instance, Member States are advised to establish such EU-wide agreements to deal with all aspects concerning transplant medicine for extra-Community patients.
- **Priority Action 8:** facilitate the interchange of organs between national authorities. Particularly for **urgent patients and difficult to treat patients.** An IT tool to support this action could be designed with guidance from the Commission and Community funding. Moreover, the Commission will support the Member States in the development of a structured system for exchanges of surplus organs between them.
- **Priority Action 9:** evaluation of post-transplant results. Evaluating post-transplant results through common definitions of terms and methodology could help to promote EU-wide registers, if necessary, and create a methodology to compare the results of existing post-transplant follow-up registers of organ recipients.
- In an effort to increase the pool of organs available for transplantation, the use of expanded donors (donors that from a medical point of view can only be considered for specific recipients under specific circumstances) should also be considered.
- **Priority Action 10:** promote a common accreditation system for organ donation/procurement and transplantation programmes and support centres of excellence. The Action Plan seeks to develop a methodology that could support the EU legal framework in order for Member States to accredit programmes on organ donation, procurement and transplantation. These objectives and priority actions are set out under the three challenges mentioned above. In turn, the Action Plan divides each priority action into various actions enumerated in Annex. Each Member

State will decide what action and measures need to be taken in order to achieve the objectives. These will be included in their Sets of National Priority Actions, which should serve as a platform for discussion, exchange of expertise, and identification of best practices in the framework of this Action Plan. The Sets of National Priority Actions should be country-specific and tailored to the specific situation of each Member State.

Action plan on organ donation and transplantation (2009-2015): strengthened cooperation between Member States

2009/2104(INI) - 19/05/2010 - Text adopted by Parliament, single reading

The European Parliament adopted a resolution on the Commission Communication: Action Plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States.

Parliament recalls that this Action Plan 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.

According to the Parliament, the following main principles should be respected:

Organ-donor register: Parliament 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. It urges the Member States to look into adopting such schemes and 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. It also calls 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. Plenary calls in particular on the Commission, in close cooperation with Member States, the European Parliament and relevant stakeholders, to 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**.

Parliament 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. It 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. Plenary 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. It calls on the 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.

Transplant donor coordinators: Parliament emphasises that the identification of potential donors has been considered one of the key steps in the process of deceased donation. It 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. Plenary 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.

Exchange of organs between Member States: Parliament 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. It 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. Members welcome the activities of Eurotransplant and Scanditransplant, but note that exchanges of organs outside these systems and between these systems can be significantly improved, especially for the benefit of patients in small countries.

Towards a legal framework and common binding standards: to ensure that organs available for therapy are not wasted, Parliament considers that a clearly defined legal framework regarding their use and that society trusts the donation and transplantation system should be put in place. The exchanging of information and best practice among Member States will at first help countries with low organ availability to improve their donation rates. Parliament stresses however 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. It also stresses that the establishment of well-structured operational systems and the promotion of successful models at a national level are of the utmost importance and suggests that operational systems should comprise an adequate legal framework, technical and logistic infrastructure, and organisational support coupled with an effective allocation system.

Improve the quality and safety of donations: Parliament recognises that it is vitally important to improve the quality and safety of organ donation and transplantation. It points out that this will have an impact on reducing transplant risks and will consequently reduce adverse effects. It asks the Commission to help Member States to develop their capacity in creating and developing regulatory frameworks and to promote the development of **quality improvement programmes for organ donation in every hospital** where there is potential for organ donation

Unpaid and voluntary donation: Parliament emphasises that any commercial exploitation of organs that denies equitable access to transplantation is unethical, therefore, it stresses that donation should be **voluntary and unpaid**, and take place in clearly defined legal and ethical contexts. It 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. Parliament 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. It urges Member States to define the conditions under which compensation may be granted. Plenary calls on Member States to ensure that organs are allocated to recipients according to transparent, non-discriminatory and scientific criteria.

Donations from living donors: Parliament 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. Donors should be protected against discrimination in the social system. The Commission is called upon to evaluate the possibility to ensure that **living donors are legally insured** in all Member States. Parliament also 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. The resolution 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.

Post-transplant and follow-up of patients: Parliament recognises the important role of post-transplantation care, including the appropriate use of anti-rejection therapies, in the success of transplants. It 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.

Educate, raise-awareness and communication: Parliament calls on Member States to improve the knowledge and communication skills of health professionals and patient support groups on organ transplantation. It emphasises that good cooperation between health professionals and national authorities or other legitimised organisations is necessary and provides added value. Parliament 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. It stresses that continuous education should form an essential part of all Member States' communication strategies on the issue. In particular, Members suggest that people should be better informed and encouraged to speak about organ donation and to communicate their wishes about donation to their relatives. They note that only 41% of European citizens seem to have discussed organ donation within their families.

Combat organ trafficking: Parliament underlines that the non-availability of organs is linked to illegal organ trafficking and the trafficking of persons. It repeats the recommendations on the fight against the organ trade made in the Adamou report on organ donation and transplantation and takes the view that these should be taken fully into account by the Commission when drafting the action plan. Member States are urged 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. Parliament 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 intensify their cooperation under the auspices of Interpol and Europol in order to address the problem of trafficking in organs more effectively.

Action plan on organ donation and transplantation (2009-2015): strengthened cooperation between Member States

2009/2104(INI) - 25/04/2014 - Follow-up document

The Commission presented a staff working document on the mid-term review of the Action Plan on Organ Donation and Transplantation (2009-2015).

State of play: more than **60 000 patients** are on a waiting list for an organ transplant in the European Union. Of these over 80% are waiting for a kidney, about 10% for a liver, and several thousands for other organs such as a heart or lungs. In 2012 more than 4 000 patients died in the EU while waiting for an organ.

Accordingly, in December 2008, the European Commission adopted the Action Plan on Organ Donation and Transplantation (2009-2015) which aimed at strengthening cooperation between Member States in this area.

This Action Plan aimed to tackle three main challenges in organ donation and transplantation:

- increasing organ availability,
- enhancing the efficiency and accessibility of transplant systems,
- improving quality and safety.

The Action Plan identified 10 key priority actions and 28 specific actions within a common framework. These actions are supported by EU funded projects under the Health Programme or other Community instruments such as research funding. Some were also taken forward by expert working groups organised by the Commission. **The ultimate responsibility for implementation remains of course with the Member States**.

Progress accomplished: this report on the mid-term review of the Action Plan is a factual progress report taking stock of progress made between 2009 and 2012, both at national and EU level. It also identifies gaps and topics that should be further addressed in the coming years.

This report is therefore not a revision of the Action Plan, but merely seeks to set out, from an EU perspective, where the emphasis of EU activities has lied in the past years and where the emphasis is intended to lie in the remaining period of the Action Plan (2014-15).

Overall, the report highlighted that good progress has been made by the Member States in the first half of the Action Plan. The most important achievements were made relating to the increase and training of transplant donor coordinators (PA1), the introduction or development of living donation programmes in some Member States (PA3) as well as the improvements of the organisational models (PA6).

Concretely:

- more coordinators were appointed and trained (PA1), thus improving deceased donation rates;
- living donation programmes were created or developed, seeking also for a better protection of living donors (PA3);
- organisational models that proved to be efficient in some Member States were introduced in other EU or non EU countries (PA6).

Many projects on these topics and practices received funding under the EU Health programme. For many other actions, national efforts and EU support have already provided Member States with a good knowledge base and tools.

While at some stage further EU funding could be foreseen, the emphasis for 2014-15 will lie on the implementation of these actions (for example on the evaluation of post-transplant results).

Three other Priority Actions:

1. facilitate the identification of organ donors across Europe and cross border donation;
2. the promotion of EU-wide agreements on aspects of transplantation medicine;
3. common accreditation system for organ donation/procurement and transplantation programmes;

are not foreseen for major new initiatives at EU level in 2014-15, because efforts are already undertaken by ongoing EU-funded Research projects and by other actors in the field, such as professional societies, the scientific community and other national and international institutions.