



**COUNCIL OF  
THE EUROPEAN UNION**

**Brussels, 29 November 2012**

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**SAN 291**

**NOTE**

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from: Permanent Representatives Committee (Part I)  
to: Council  
Subject: **Employment, Social Policy, Health** and Consumer Affairs Council meeting  
on 6 and 7 December 2012

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**Draft Council Conclusions on Organ Donation and Transplantation**

*- Adoption of Council conclusions*

(Public debate in accordance with Article 8(2) CRP [proposed by the Presidency])

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1. At its meeting on 28 November 2012 the Committee of Permanent Representatives examined the above-mentioned text as prepared by the Working Party on Public Health and agreed to transmit the draft Council conclusions as set out in the Annex to the Council for adoption.
2. The Council is invited to adopt the proposed draft conclusions, which will then be published in the Official Journal of the European Union.

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**Draft Council conclusions on organ donation and transplantation**

The Council of the European Union

**RECALLS**

- The Communication from the Commission "Action Plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States"<sup>1</sup>, which identified ten priority actions to help Member States address the three main challenges in the field of organ donation and transplantation, namely: (1) increasing organ availability, (2) enhancing efficiency and accessibility of transplant systems and (3) improving quality and safety.

**I. Increasing organ availability****1. WELCOMES**

- The development of national programmes to improve performance across the different steps of the deceased donation process (from donor identification and maintenance to procurement and transport).
- The development of a European manual for living donation practices, for kidney and liver transplants.
- The dissemination of best practices, e.g. through the European manual for setting up and maintaining systems for transplant donor coordination for deceased donation.
- The planned development of a comprehensive overview of national donor consent systems, as well as the efforts carried out to integrate the participation of intensive care professionals in the deceased donation process.
- The role of professional societies, such as the European Society for Organ Transplantation (ESOT) and its section, the European Transplant Coordinators Organisation and the European Donation Committee (ETCO-EDC).

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<sup>1</sup> 16545/08 (COM(2008) 819 final).

- The efforts undertaken by the Member States in further development of living donation programmes while ensuring a comprehensive protection of the living donor, as discussed at the informal meeting of Ministers of Health on 10-11 July 2012.
- The organisation of national awareness campaigns and European initiatives, such as the European Organ Donation Days and the Journalists Workshops on Organ Donation and Transplantation organised respectively by the Council of Europe and the European Commission.
- The development of best practices and training programmes at national and European level supported by the EU Programme of action in the field of health.

## 2. RECALLS

- The importance of encouraging people to commit to becoming organ donors after death.
- The importance to prioritise prior donation of organs from deceased donors.
- The improved quality of life for patients and high cost-effectiveness of kidney transplants compared to dialyses treatments for end-stage renal disease, as analysed for example by authorities in the United Kingdom (Department of Health 2009) or in France (Haute Autorité de Santé, 2010).
- The lack of medical alternatives for patients in need of life-saving transplants of other organs.
- That although this is a matter of national competence, there is a need for each Member State to clearly define and organise donor consent systems and to manage waiting lists in a transparent way at national level.
- The requirement on the Member States to protect living donors against potential risks, physical and financial disadvantages related to the donation process, as well as to ensure voluntary and unpaid donation as laid down in Directive 2010/53/EU.
- The importance of transparent and comprehensive communication to strengthen public trust in the value of transplant systems based on deceased organ donation as well as on living donations.

- The need to emphasize the responsibility of intensive care and emergency care professionals and to place donation as part of the decisions to be made in the end of life care.
- That removal of organs from a living person for transplantation purposes must be carefully scrutinized, case by case, taking in account relevant criteria, in particular the principle that the human body should not be used for financial gain.

### 3. INVITES THE MEMBER STATES

1. To continue sharing expertise on all key aspects of organ donation and transplantation programmes in order to allow for mutual learning and an increase in the number of available organs.
2. To provide for continuous training of professionals involved in deceased organ donation and transplantation, including both donor transplant coordinators and staff from intensive and emergency care units.
3. To share information on their national donor consent systems.
4. To set up comprehensive mechanisms to protect living donors, including the creation of follow-up registers or records, in line with the requirements of Directive 2010/53/EU.
5. To create transparent and official mechanisms for reimbursing living donors for the costs incurred and, if applicable, for compensating the loss of income in direct relation to the living donation procedure.

6. To improve awareness amongst patients and their families on the different transplant options, including deceased and living donor transplantation as well as other alternative replacement therapies. To improve information on donation and transplantation in general and to engage healthcare professionals in providing appropriate information on organ donation.
7. To exchange information on their communication strategies, and to proactively communicate to the general public, including the use of social media.
8. To develop and improve, as appropriate, programmes for cooperation with intensive care and emergency care professionals, jointly with national and international professional associations, in order to optimize the identification of potential donors and the realisation of the deceased donation process.

## **II. Enhancing efficiency and accessibility of transplant systems**

### **4. WELCOMES**

- the establishment and implementation of bilateral or multilateral agreements between Member States to exchange organs and patients that respect the principle of self sufficiency in transplantation, as specified in the Madrid Resolution <sup>2</sup>.
- The setting up of cooperation agreements between national transplant organisations such as the South Transplant Alliance.
- The sharing of expertise on transplant systems between Member States' competent authorities and with European organ exchange organisations, in particular Eurotransplant and Scandiatransplant.

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<sup>2</sup> The Madrid Resolution on Organ Donation and Transplantation. National responsibilities in meeting the needs of patients, guided by the WHO principles. Transplantation 2011; 91 (11S): S29- S31.

## 5. RECALLS

- The significant opportunity that exists to treat more patients and to use an increasing number of available organs effectively within the Member States through the conclusion and implementation of bilateral or multilateral agreements between Member States.
- The need for sufficient administrative capacity within the set-up of national authorities in accordance with Directive 2010/53/EU.
- That organ trafficking violates fundamental human rights such as those of human dignity and integrity, and has a negative impact on public trust and potential donors willingness to donate organs.
- That limited knowledge and research of some scientific and organisational aspects of organ transplantation and the lack of the necessary expertise in some areas limit the further development of transplant activities within the EU.

## 6. INVITES THE MEMBER STATES

1. To engage actively in twinning agreements whenever they have less than ten deceased donors per million inhabitants or when there is a lack of specific transplantation programmes within their borders.
2. To use community instruments to build up national transplant capacities, where appropriate.
3. To continue sharing information on the set-up and funding of transplant activities and their oversight.
4. To engage in operational cross-border exchange of organs, including through the participation in a Joint Action dedicated to cross-border exchange agreements starting in 2013.
5. To support national and international collaboration, as appropriate, between transplantation authorities and police and customs services in order to detect and prevent organ trafficking.

7. INVITES THE EUROPEAN COMMISSION

1. To include organ transplantation within the scope of EU initiatives against trafficking of human beings<sup>3</sup> in line with recommendations of the World Health Organisation and the Council of Europe.
2. To address research on technical and organisational aspects of transplantation within the European Research Programme Horizon 2020.

**III. Improving quality and safety**

8. RECALLS

- That Directive 2010/53/EU sets up minimum standards of quality and safety of human organs intended for transplantation.
- The need to improve knowledge on health outcomes in transplanted patients in order to further optimize transplant activities taking into account the scarcity of organs.

9. INVITES THE MEMBER STATES

1. To share Member States' national procedures for authorisation of procurement organisations and transplantation centres.
3. To share expertise on the transplantation of organs from expanded criteria donors (for example older donors) in order to increase the number of available organs, while setting the quality and safety limits of such practice.
4. To engage in collecting and sharing knowledge about quality and safety and in setting up standardised patient follow-up registers or records, based on models commonly developed and agreed upon.

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<sup>3</sup> Directive 2011/36/EU on Preventing and Combating Trafficking in Human Beings and Protecting its Victims (O.J. L101/1 of 15/4/2011).