Standards of quality and safety of human organs intended for transplantation

2008/0238(COD) - 08/12/2008 - Legislative proposal

PURPOSE: to ensure that human organs used for transplantation in the EU comply with the same quality and safety requirements and to facilitate their exchange between Member States.

PROPOSED ACT: Directive of the European Parliament and of the Council.

BACKGROUND: over the past 50 years organ transplantation has become an established worldwide practice, bringing immense benefits to hundreds of thousands of patients. Organ transplantation is now the most cost-effective treatment for end-stage renal failure, while for end-stage failure of organs such as the liver, lung and heart it is the only available treatment. The shortage of organs is a major factor affecting transplantation programmes. Nearly 56 000 patients are now on waiting lists in the EU. Mortality rates while waiting for a heart, liver or lung transplant usually range from 15 to 30%. Donation rates and availability of organs varies considerably across Europe with achievable good practice delivering far greater benefits in some Member States than in others.

On 31 May 2007, the Commission adopted a Communication on organ donation and transplantation based on that analysis. This Communication proposes what activities the EU should undertake in the field of organ transplantation.

In December 2007, the Council adopted conclusions on organ donation and transplantation which recognised the importance of having high standards with respect to the quality and safety of organs for transplantation, so as to ensure a high level of protection for patients throughout Europe. The Council called on the Commission to consult the Member States, and continue its examination of the need for an EU framework on quality and safety for human organs. The European Parliament resolution adopted on 22 April 2008 recognised that it is vitally important to improve the quality and safety of organ donation and transplantation to reduce transplant risks. It invited the Commission to present a proposal for a directive stipulating requirements to ensure the quality and safety of organ donation across the EU.

CONTENT: this proposal for a Directive covers human organs, that are used for transplantation, during all the phases of the process – donation, procurement, testing, preservation, transport and use – and aims to ensure their quality and safety and hence a high level of health protection. Organs that are transplanted into the human body in clinical trials should comply with the quality and safety standards laid down in this Directive.

The added value of the Directive:

Ensuring quality and safety for patients at EU level: this Directive sets out the basic quality and safety requirements needed in every transplant system. More specifically, the proposal:

- provides for the creation or designation of a competent national authority in each Member State which will ensure compliance with the requirements of the Directive;
- establishes a system for the authorisation of programmes of organ procurement and transplantation based on common quality and safety criteria. This system would provide a complete list of authorised centres throughout the European Union, accessible to the public and professionals alike;
- establishes common quality and safety standards for the processes of evaluating donors and human organs, thus ensuring the health of recipients;
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proposes the introduction of national quality programmes to ensure continuous monitoring of performance and improvement and learning;

- ensures that Member States put in place organ traceability systems. The Commission will adopt procedures for guaranteeing full traceability of organs exchanged between Member States;
- includes measures to capture serious adverse events related to the procurement, testing and transport of organs, as well as any serious adverse reactions observed during or after transplantation which may be connected to the procurement, testing and transport of the organ in the European Union. The Commission will adopt procedures for ensuring interoperability between the reporting systems on adverse events and reactions.

Ensuring the protection of donors: the proposed Directive contains a number of measures to protect living donors. These include correct evaluation of the health of the donor and comprehensive information about the risks prior to donation, the introduction of registers for living donors to follow up their health and measures to ensure the altruistic and voluntary donation of organs by living donors.

Facilitating cooperation between Member States and cross-border exchanges: the Directive will: i) put in place the quality and safety conditions needed to facilitate cross-border exchanges; ii) standardise the collection of the relevant information on the characteristics of the organ needed to make a proper risk assessment; iii) establish a mechanism for transmission of the information; iv) provide for the necessary mechanisms to be put in place for cross-border exchanges of organs to ensure traceability of the organ and pre-empt serious adverse reporting.