Standards of quality and safety of human organs intended for transplantation

2008/0238(COD) - 07/07/2010 - Final act

PURPOSE: to establish rules on the donation, testing, characterisation, procurement, preservation, transport and transplantation of organs intended for transplantation.

LEGISLATIVE ACT: Directive 2010/45/EU of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation.

CONTENT: the Council adopted this Directive, following a first-reading agreement with the European Parliament. The Directive lays down rules to ensure standards of quality and safety for human organs intended for transplantation to the human body, in order to ensure a high level of human health protection. Where such organs are used for research purposes, the Directive only applies where they are intended for transplantation into the human body. It aims to minimise the risk for the organ transplant recipients and to facilitate the exchange of human organs between Member States. It indirectly also seeks to contribute to combating organ trafficking and increasing organ availability. In order to ensure a high level of protection for patients receiving a new organ, the Directive obliges Member States to:

- create or designate a competent national authority which has to ensure compliance with the requirements of the Directive;
- establish 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 EU, accessible to the public and professionals alike;
- introduce frameworks of quality and safety to ensure continuous monitoring of performance;
- put in place an organ traceability system while ensuring the anonymity of both the donor and the recipient;
- take measures to gather serious adverse events related to the procurement, testing and transport of organs, as well as any serious adverse reactions observed during or after transplantation;
- ensure that any organ donation is unpaid and voluntary.

With a view to facilitating cooperation between Member States and to improving the prospects of receiving an organ, in particular of recipients in need of a rare match, the Directive provides for:

- the introduction of quality and safety conditions;
- the standardised collection of the organ's characteristics needed to make a proper risk assessment;
- the establishment of a mechanism for the transmission of the information;
- the setting up of a mechanism for cross-border exchanges of organs to ensure traceability of the organ and reporting of serious adverse events.

Although the number of organ donations and transplantations has grown steadily across the EU, saving thousands of lives each year, nearly 56000 patients are currently on a waiting list for a new organ. Almost 12 people die every day in the EU while waiting for a new heart, liver, lung or another organ.

Reports concerning the Directive: Member States shall report to the Commission before 27 August 2013 and every three years thereafter on the activities undertaken in relation to the Directive, and on the experience gained in implementing it. The Commission shall report before 27 August 2014 and every three years thereafter on the implementation of the Directive.

ENTRY INTO FORCE: 26 August 2010.

TRANSPOSITION: 27 August 2012.