



**COUNCIL OF  
THE EUROPEAN UNION**



Luxembourg, 29 June 2010  
10999/10  
PRESSE 172

## **Council improves safety of transplantations and facilitates the exchange of human organs in the EU**

The Council today<sup>1</sup> adopted a directive setting out the basic quality and safety requirements for human organs intended for transplantation ([19/10](#) + [11143/10 ADD 1](#) + [11143/10 ADD 2](#)), following a first-reading agreement with the European Parliament. The directive 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 new directive obliges the member states to:

- create or design 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;

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<sup>1</sup> The decision was taken, without debate, at a session of the Council in charge of Agriculture and Fisheries in Luxembourg.

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- 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 facilitate cooperation between member states and to improve the prospects to receive 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.

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