

NEW EU DIRECTIVE PROPOSED FOR QUALITY AND SAFETY OF ORGAN TRANSPLANTATION

A. MAHALATCHIMY* and A. CAMBON-THOMSEN*

*Joint research unit INSERM and University of Toulouse, UMR 558, Epidemiology and public health analyses ,
Faculty of Medicine, 37 allées Jules Guesde, 31073 Toulouse, France

Background

During the past decades, organ transplantation has constantly developed. This led to a lack of available organs and enhanced the exchange of organs across borders, notably between Member States (MS) within the European Union (EU). Consequently, new quality and safety challenges appear concerning risks, characteristics of transplanted organs and conditions of donation. In the legal system at EU level, Directives exist for tissues and cells since 2004 and for blood since 2003, but not for organs.

Thus, the EU developed policy actions for organs:

2003: A survey on legal requirements related to transplantation in the EU showed important differences in quality and safety requirements between Member States.

2007: The European Commission (EC) adopted a Communication on organ donation and transplantation.

2008: Adoption of a proposal of a Directive on standards of quality and safety of human organs intended for transplantation [COM(2008) 818 final] and of an Action plan on Organ Donation and Transplantation where the challenges addressed are: improving quality and safety of organs across Europe, increasing organ availability and making transplant systems more efficient and accessible.

Scope

It aims:

- to ensure quality and safety of human organs that are used for transplantation, hence a high level of protection.

It covers:

- human organs that are used for transplantation, during all the phases of the process: donation, procurement, testing, preservation, transport and use
- “where such organs are used for research purposes, this Directive only applies where they are intended for transplantation into the human body”.

It excludes:

- blood and blood components (already covered by Directives 2002/98/CE, 2004/33/CE, 2005/61/CE and 2005/62/CE)
- human tissues and cells (already covered by Directives 2004/23/CE, 2006/17/CE and 2006/86/CE)
- organs or tissues and cells of animal origin.

In this context, the proposal of Directive sets up specific measures related to:

Quality & Safety for patients

- System for the authorisation of programmes of organ procurement and transplantation & designation of a competent national authority in each Member State (MS)
- Common quality and safety standards for the processes of evaluating donors and human organs
- Introduction of national quality programmes
- Traceability system from donors to recipients and vice versa
- Measures to capture serious adverse events

Basic quality and safety requirements
needed
in each transplantation system

Protection of donors & recipients

- Voluntary and unpaid donations of human organs, altruism of the donor and solidarity between donor and recipient
- Consent and authorisation requirements prior to procurement (MS' competence)
- Protection of the living donor (correct evaluation of his/her health & comprehensive information)
- Protection of personal data, confidentiality and security of processing
- Anonymisation of donors and recipients

Use of human organs under conditions
protecting the rights and health of
donors & recipients

Cooperation between Member States & cross-borders exchanges

- Registers and reports concerning procurement organisations and transplantation centres with a public annual report
- Exchange of information: setting up a network of the competent authorities
- Exchange of organs with third countries and agreements with European organ exchange organisations

High level of quality and safety
throughout the “organ transplantation
chain” in all Member States

Combating organ trafficking

By securing quality and safety of human organs, this future directive “will indirectly contribute to combating organ trafficking through the establishment of competent authorities, the authorisation of transplantation centres, the establishment of conditions of procurement and systems of traceability”.