Standards of quality and safety of human organs intended for transplantation

2008/0238(COD) - 19/05/2010 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 643 votes to 16 with 8 abstentions a resolution setting out its position at first reading under the ordinary legislative procedure (formerly known as the codecision procedure) with a view to the adoption of on the proposal for a directive of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation. Following agreement with the Council, it made some amendments:

Scope: this Directive shall also apply to the procurement of organs of human origin intended for transplantation.

Definitions: Parliament amends certain definitions, including “donor” and inserts others, including “competent authority””. It also states that the definition of an “organ” includes a part of an organ if its function is to be used for the same purpose as the entire organ in the human body, maintaining the requirements of structure and vascularisation.

Framework for quality and safety: the resolution states that the framework for quality and safety shall provide for the adoption and implementation of:

- procedures for the verification of donor identity;
- procedures for the verification of the details of the consent, authorisation or absence of any objection of the donor or donor family;
- procedures for the verification of the completion of the organ and donor characterisation;
- procedures for the procurement, preservation packaging and labelling of organs;

- procedures needed to ensure traceability, guaranteeing compliance with the legal requirements on the protection of personal data and confidentiality;
- procedures for the accurate, rapid and verifiable reporting of serious adverse events and reactions;
- procedures for the management of serious adverse events and reaction.

These procedures shall specify, inter alia the responsibilities of procurement organizations, European organ exchange organisations and transplantation centres in this respect. In addition, the framework for quality and safety shall ensure that the healthcare personnel involved at all stages of the chain from donation to transplantation or disposal is suitably qualified or trained and competent, and shall develop specific training programmes for such personnel.

Procurement organisations: Members deleted certain clauses on organisational structure and operational procedures of procurement organisation, stating that such detailed provisions did not belong in the body of the text. They deleted certain provisions on normal standards for operation theatres for the same reasons.

Organ and donor characterisation: the text states that Member States shall ensure that all procured organs and donors thereof are characterised before transplantation through the collection of the information set out in the Annex. Information specified in Part A of the Annex contains a set of minimum data which has to be collected for each donation. Information specified in Part B of the Annex contains a set of complementary information to be collected in addition, based on the decision of the medical team, taking into account the availability of such information and the particular circumstances of the case.

If according to a risk-benefit analysis in a particular case, including life-threatening emergencies, the expected benefits for the recipient outweigh the risks posed by incomplete data, an organ may be considered for transplantation even where not all of the minimum data specified in Part A of the Annex are available.

In order to meet the quality and safety requirements laid down in the Directive, the medical team shall endeavour to obtain all necessary information from living donors and for that purpose shall provide them with the information they need to understand the consequences of donation. In the case of deceased donation, whenever possible and appropriate, the medical team shall endeavour to obtain such information from relatives or other persons. The medical team shall also endeavour to make all parties from whom information is requested aware of the importance of the swift transmission of this information.

Where organs are exchanged between Member States, they shall ensure that the information on organ and donor characterisation, as detailed in the Annex, is transmitted to the other Member State with which the organ is exchanged in conformity with the procedures established by the Commission.

New recitals note that the shortage of organs available for transplantation and the time constraints in the process of organ donation and transplantation makes it necessary to take into account those situations in which the transplantation team lacks some of the information required for donor and organ characterisation as set out in Part A of the Annex, which specifies a minimum mandatory data set of information. In those particular cases, the medical team shall assess the particular risk posed to the potential recipient by the lack of information and by not proceeding with transplantation of the organ in question. Therefore, if a complete characterisation of an organ, according to Part A of the Annex, is not possible in time or due to particular circumstances, such organ may be considered for transplantation where the non-transplantation may pose a greater risk to the potential recipient. Part B of the Annex, referring to a complementary data set of information, will allow performing a more detailed organ and donor characterisation.

Transport of organs: Parliament added to the requirements that the organs transported must be accompanied by the report on the donor and organ characterization.

Traceability: Member States shall ensure the implementation of a donor and recipient identification system that can identify each donation and each of the organs and recipients associated with it. With regard to such system, Member States shall ensure that confidentiality and data security measures are in place in compliance with Union and national rules,

Furthermore, where organs are exchanged between Member States, they shall transmit the necessary information to ensure the traceability of organs, in conformity with the procedures established by the Commission in accordance with Article 29.

Reporting systems and management for serious adverse events and reactions: the text specifies that Member States shall ensure that procedures are in place for: (i) the notification of any serious adverse event and reaction to the competent authority and to the concerned procurement or transplantation organisation in due time; (ii)the notification of the management measures with regards to serious adverse events and reactions to the competent authority in due time.

Principles governing organ donation: the text specifies that the principle of non-payment shall not prevent living donors from receiving compensation, provided it is strictly limited to making good the expenses and inconveniences related to the donation. For such cases, Member State shall define the conditions under which compensation may be granted, while avoiding any financial incentives or benefit for a potential donor.

Protection of the living donor: Member States shall take all necessary measures to ensure the highest possible protection of living donors in order to fully guarantee the quality and safety of organs for transplantation. They shall endeavour to carry out the follow-up of living donors and shall have a system in place in accordance with national provisions, in order to identify, report, and manage any event potentially relating to the quality and safety of the donated organ, and hence of the safety of the recipient, as well as any serious adverse reaction in the living donor that may result from the donation.

Data protection and confidentiality: the fundamental right to protection of personal data must be fully and effectively protected in all organ donation and transplantation activities, in conformity with Union provisions on the protection of personal data, such as Directive 95/46/EC. Member States must ensure that the data processed are kept confidential and secure and that donors and recipients whose data are being processed within the scope of the Directive are not identifiable, except as permitted by Directive 95/46/EC, and national provisions implementing that Directive. Any use of systems or data that makes the identifications of donors or recipients possible with a view to tracing donors or recipients other than the purposes permitted by Directive 95/46/EC, including medical purposes, and national provisions implementing that Directive should be penalized according to this Directive

Designation and tasks of competent authorities: Member States may delegate, or may allow a Competent Authority to delegate, part or all of the tasks assigned to it under this Directive to another body which is deemed suitable under national provisions. Such a body may also assist a Competent Authority in carrying out its functions.

Exchange of organs with third countries: exchanges from or to third countries must be supervised by the competent authority. For this purpose, the competent authority and European organ exchange organisations may establish agreements with counterparts in third countries. The supervision of organ exchanges with third countries may be delegated by the Member States to European organ exchange organisations.

Delegated acts: there are new provisions on delegated acts, and exercise and revocation of the delegation, as well as objections to delegated acts, in accordance with the new Treaty.