Standards of quality and safety of human organs intended for transplantation

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The Committee on the Environment, Public Health and Food Safety adopted the report drawn up by Miroslav MIKOLASIK on the proposal for a regulation of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation. It recommended that the European Parliament's position at first reading under the ordinary legislative procedure (formerly known as the codecision procedure) should be to amend the Commission proposal as follows:

Scope: Members add that the Directive shall not prevent Member States from maintaining or introducing more stringent protective measures, provided that they comply with the provisions of the Treaty.

Definitions: the report amends certain definitions, including "donor", "authorisation", "procurement organisation", "serious adverse event" and "serious adverse reaction." It 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 national quality and safety programmes: the report adds that the national quality programmes shall provide for the adoption and implementation of, inter alia, standard operating procedures for the identification and referral of potential donors. Members feel that identification of potential donors in intensive care units and their referral is the indispensable prerequisite for all organ donation activities. Numerous studies show that there is potentially between 40 to 50 donors per million people in every Member State. This means that every Member State can increase its organ donation rate through systematic analysis of the existing donor potential.

The report also wants national quality programmes to provide for the adoption and implementation of the following :

- procedures to ensure traceability, guaranteeing compliance with the legal requirements on the protection of personal data and confidentiality. Such procedures shall include the responsibilities of procurement organisations and transplantation centres with regard to traceability;
- procedures for the accurate, rapid and verifiable reporting of serious adverse events and, including the responsibilities of procurement organisations and transplantation centres with regard to such reporting;
- procedures for the management of serious adverse events and reactions, including the responsibilities of procurement organisations and transplantation centres with regard to such management.
- standard operating procedures for tracing and limiting the risks of unethical or illegal activities, particularly concerning decisions for organ procurement and transplantation.

Furthermore, the framework for the quality and safety of organs shall ensure that the healthcare personnel involved at all stages of the chain from donation to transplantation or disposal are suitably qualified and competent, and shall develop specific training programmes for such personnel, and shall establish standard operating procedures for matters referred to in the text

Members state that national quality programmes shall also authorise, in life-threatening emergencies, transplant operations using an organ which is not optimal, after consultation between the healthcare personnel and the patient, or the patient's family where the patient is unable to state his or her choice.

Lastly, the programmes should determine the status of transplant coordinators from the stage of organ donation to that of monitoring of the recipient. Members note that Parliament has previously stressed the central role played by transplant coordinators with a view to identifying potential donors. It is therefore essential that the national quality programmes should provide for the establishment of a status of transplant coordinator.

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

Transport of organs: Member States must ensure that the organisation involved in the transportation of organs ensures that the organ is transported with due care.

Traceability: Member States must ensure that access to systems permitting the identification of a donor or recipient is as restricted as possible. They must lay down penalties on (a) any unauthorised accessing of data or systems that makes identification of donors or recipients possible; (b) any use which is made of systems or data that makes the identification of donors or recipients possible with a view to tracing donors or recipients other than for necessary medical purposes.

Third parties: a new article stipulates that procurement organisations and transplantation centres may conclude written agreements with third parties for the carrying out of their functions.. Where they enter into written agreements, they must:

- evaluate and select third parties on the basis of their ability to meet the standards laid down in the Directive;
- keep a complete list of the agreements that they have concluded with third parties;
- specify the responsibilities of the third parties and detailed procedures;
- provide copies of agreements with third parties at the request of the Competent Authority.

The committee refers to Directive 2004/23/EC on tissues and cells.

Principles governing organ donation: the report 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.

It is added that:

- the Commission, in close cooperation with Member States, the European Parliament and relevant stakeholders, shall examine the possibility of developing a system whereby the wishes expressed by citizens consenting to the donation of organs after they are deceased are taken into account in as many Member States as possible;
- Member States shall ensure that systems and registers are in place which are easily accessible for the purposes of recording the wishes of future donors, and that the competent authorities give priority to the wishes expressed by a donor over any possible contrary wishes of a spouse, first-degree relative or other person;

- they shall ensure that organs are allocated to recipients according to transparent, non-discriminatory and scientific criteria;
- organs must not be removed from a deceased person unless that person has been certified dead in accordance with national law;
- Member States shall intensify their cooperation within Interpol and Europol in order to address the problem of trafficking in organs more effectively;
- in order to minimise the risk of organ trafficking in the Union, Member States must reduce demand, promote organ donation more effectively, maintain strict legislation with regard to live unrelated donors, guarantee transparency of national registers and waiting lists, establish the legal responsibility of the medical professional for tracking irregularities, and share information.

In order to meet the quality and safety requirements laid down in this Directive, Member States shall endeavour to obtain all necessary information from living donors and to provide them with the information they need to understand the consequences of donation. In the case of deceased donation, Member States shall endeavour to obtain such information from relatives or other persons authorising donation. Member States shall make all parties, from whom information is requested, aware of the importance of swiftly transmitting such information.

Protection of the living donor: Members state that living donation should be seen as complementary to post-mortem donation and may be carried out where there is no suitable organ available from a deceased person. Living donations are predominantly carried out among family members and close relatives and /or for the benefit of a recipient with whom the donor has a close personal relationship, or where it can be proven that the donor is not acting for the purpose of financial gain in order to prevent commercialisation. Particularly, in the absence of such a close relationship, adequate provisions in national law of the Member States shall be made, thus assuring the highest possible protection of living donors.

The committee adds the following:

- Member States shall also ensure that living donors are legally insured;
- no organ removal may be carried out on a person who under national law does not have the capacity to consent to it;
- follow-up must be ensured in relation to living donors 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: Member States shall take the necessary measures to ensure that donors and recipients whose data are being processed under the Directive are identifiable only by persons who can demonstrate a need to know their identities. They must ensure the confidentiality, integrity, accountability and availability of the personal data of donors and recipients.

The committee deleted the clause on anonymisation of donors and recipients.

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. They must ensure that procurement organisations and transplantations centres are subject to public controls. In addition, the competent authority shall:

- ensure that special protocols are created governing procedures for operative and post-operative stages under the responsibility of the respective operating teams, specialist pathologists and specialists in other necessary fields;

- collect relevant post-transplantation outcome data in order to allow comparable assessment of quality and safety of organ transplantation, which will serve to further improve the transplantation process at European level.

Exchange of organs with third countries: the competent authority shall consult the national Data Protection Authority in respect of developing a framework for the transfer to and from third countries of data concerning the exchange of organs. The specific regime for the transfer of personal data to third countries as laid down in Directive 95/46/EC shall apply. Members add that responsibility for authorising organ exchanges with third countries may be delegated by the Member States to European organ exchange organisations.

Delegated acts: the committee inserts new provisions on delegated acts, and exercise and revocation of the delegation, as well as objections to delegated acts.