Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation

CHAPTER II

THE QUALITY AND SAFETY OF ORGANS

Article 4

Framework for quality and safety

1 Member States shall ensure that a framework for quality and safety is established to cover all stages of the chain from donation to transplantation or disposal, in compliance with the rules laid down in this Directive.

2 The framework for quality and safety shall provide for the adoption and implementation of operating procedures for:

a the verification of donor identity;

b the verification of the details of the donor's or the donor's family's consent, authorisation or absence of any objection, in accordance with the national rules that apply where donation and procurement take place;

c the verification of the completion of the organ and donor characterisation in accordance with Article 7 and the Annex;

d the procurement, preservation, packaging and labelling of organs in accordance with Articles 5, 6 and 8;

e the transportation of organs in accordance with Article 8;

f ensuring traceability, in accordance with Article 10, guaranteeing compliance with the Union and national provisions on the protection of personal data and confidentiality;

g the accurate, rapid and verifiable reporting of serious adverse events and reactions in accordance with Article 11(1);

h the management of serious adverse events and reactions in accordance with Article 11(2).

The operating procedures referred to in points (f), (g) and (h) shall specify, inter alia, the responsibilities of procurement organisations, European organ exchange organisations and transplantation centres.

3 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 are suitably qualified or trained and competent, and shall develop specific training programmes for such personnel.

Article 5

Procurement organisations

1 Member States shall ensure that the procurement takes place in, or is carried out by, procurement organisations that comply with the rules laid down in this Directive.

2 Member States shall, upon the request of the Commission or another Member State, provide information on the national requirements for the authorisation of procurement organisations.

Article 6

Organ procurement

1 Member States shall ensure that medical activities in procurement organisations, such as donor selection and evaluation, are performed under the advice and the guidance of a doctor of medicine as referred to in Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications[(1)].

2 Member States shall ensure that procurement takes place in operating theatres, which are designed, constructed, maintained and operated in accordance with adequate standards and best medical practices so as to ensure the quality and safety of the organs procured.

3 Member States shall ensure that procurement material and equipment are managed in accordance with relevant Union, international and national legislation, standards and guidelines on the sterilisation of medical devices.

Article 7

Organ and donor characterisation

1 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.

The 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 data 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.

2 Notwithstanding paragraph 1, if according to a risk-benefit analysis in a particular case, including in 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.

3 In order to meet the quality and safety requirements laid down in this 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, where possible and appropriate, the medical team shall endeavour to obtain such information from relatives of the deceased donor 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 that information.

4 The tests required for organ and donor characterisation shall be carried out by laboratories with suitably qualified or trained and competent personnel and adequate facilities and equipment.

5 Member States shall ensure that organisations, bodies and laboratories involved in organ and donor characterisation have appropriate operating procedures in place to ensure that

the information on organ and donor characterisation reaches the transplantation centre in due time.

6 Where organs are exchanged between Member States, those Member States shall ensure that the information on organ and donor characterisation, as specified 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 pursuant to Article 29.

Article 8

Transport of organs

1 Member States shall ensure that the following requirements are met:

a the organisations, bodies or companies involved in the transportation of organs have appropriate operating procedures in place to ensure the integrity of the organs during transport and a suitable transport time;

b the shipping containers used for transporting organs are labelled with the following information:

(i) identification of the procurement organisation and the establishment where the procurement took place, including their addresses and telephone numbers;

(ii) identification of the transplantation centre of destination, including its address and telephone number;

(iii) a statement that the package contains an organ, specifying the type of organ and, where applicable, its left or right location and marked ‘HANDLE WITH CARE’;

(iv) recommended transport conditions, including instructions for keeping the container at an appropriate temperature and position;

c the organs transported are accompanied by a report on the organ and donor characterisation.

2 The requirements laid down in paragraph 1(b) need not be met where the transportation is carried out within the same establishment.

Article 9

Transplantation centres

1 Member States shall ensure that transplantation takes place in, or is carried out by, transplantation centres that comply with the rules laid down in this Directive.

2 The competent authority shall indicate in the authorisation which activities the transplantation centre concerned may undertake.

3 The transplantation centre shall verify before proceeding to transplantation that:

a the organ and donor characterisation are completed and recorded in accordance with Article 7 and the Annex;

b the conditions of preservation and transport of shipped organs have been maintained.

4 Member States shall, upon the request of the Commission or another Member State, provide information on the national requirements for the authorisation of transplantation centres.

Article 10

Traceability

1 Member States shall ensure that all organs procured, allocated and transplanted on their territory can be traced from the donor to the recipient and vice versa in order to safeguard the health of donors and recipients.

2 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 a system, Member States shall ensure that confidentiality and data security measures are in place in compliance with Union and national provisions, as referred to in Article 16.

3 Member States shall ensure that:

a the competent authority or other bodies involved in the chain from donation to transplantation or disposal keep the data needed to ensure traceability at all stages of the chain from donation to transplantation or disposal and the information on organ and donor characterisation as specified in the Annex, in accordance with the framework for quality and safety;

b data required for full traceability is kept for a minimum of 30 years after donation. Such data may be stored in electronic form.

4 Where organs are exchanged between Member States, those Member States shall transmit the necessary information to ensure the traceability of organs, in conformity with the procedures established by the Commission pursuant to Article 29.

Article 11

Reporting system and management concerning serious adverse events and reactions

1 Member States shall ensure that there is a reporting system in place to report, investigate, register and transmit relevant and necessary information concerning serious adverse events that may influence the quality and safety of organs and that may be attributed to the testing, characterisation, procurement, preservation and transport of organs, as well as any serious adverse reaction observed during or after transplantation which may be connected to those activities.

2 Member States shall ensure that an operating procedure is in place for the management of serious adverse events and reactions as provided for in the framework for quality and safety.

3 In particular, and with regard to paragraphs 1 and 2, Member States shall ensure that operating procedures are in place for the notification, in due time, of:

a any serious adverse event and reaction to the competent authority and to the concerned procurement organisation or transplantation centre;

b the management measures with regard to serious adverse events and reactions to the competent authority.

4 Where organs are exchanged between Member States, those Member States shall ensure the reporting of serious adverse events and reactions in conformity with the procedures established by the Commission pursuant to Article 29.

5 Member States shall ensure the interconnection between the reporting system referred to in paragraph 1 of this Article and the notification system established in accordance with Article 11(1) of Directive 2004/23/EC.

Article 12

Healthcare personnel

Member States shall ensure that healthcare personnel directly involved in the chain from donation to the transplantation or disposal of organs are suitably qualified or trained and competent to perform their tasks and are provided with the relevant training, as referred to in Article 4(3).

(**1**) OJ L 255, 30.9.2005, p. 22.