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 IV

OBLIGATIONS OF COMPETENT AUTHORITIES AND EXCHANGE OF INFORMATION

Article 17

Designation and tasks of competent authorities

1 Member States shall designate one or more 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 the competent authority in carrying out its functions.

2 The competent authority shall, in particular, take the following measures:

a establish and keep updated a framework for quality and safety in accordance with Article 4;

b ensure that procurement organisations and transplantations centres are controlled or audited on a regular basis to ascertain compliance with the requirements of this Directive;

c grant, suspend, or withdraw, as appropriate, the authorisations of procurement organisations or transplantation centres or prohibit procurement organisations or transplantation centres from carrying out their activities where control measures demonstrate that such organisations or centres are not complying with the requirements of this Directive;

d put in place a reporting system and management procedure for serious adverse events and reactions as provided for in Article 11(1) and (2);

e issue appropriate guidance to healthcare establishments, professionals and other parties involved in all stages of the chain from donation to transplantation or disposal, which may include guidance for the collection of relevant post-transplantation information to evaluate the quality and safety of the organs transplanted;

f participate, whenever possible, in the network of competent authorities referred to in Article 19 and coordinate at national level input to the activities of that network;

g supervise organ exchange with other Member States and with third countries as provided for in Article 20(1);

h ensure that the fundamental right to protection of personal data is fully and effectively protected in all organ transplantation activities, in conformity with Union provisions on the protection of personal data, in particular Directive 95/46/EC.

Article 18

Records and reports concerning procurement organisations and transplantation centres

1 Member States shall ensure that the competent authority:

a keeps a record of the activities of procurement organisations and transplantation centres, including aggregated numbers of living and deceased donors, and the types and quantities of organs procured and transplanted, or otherwise disposed of in accordance with Union and national provisions on the protection of personal data and statistical confidentiality;

b draws up and makes publicly accessible an annual report on activities referred to in point (a);

c establishes and maintains an updated record of procurement organisations and transplantation centres.

2 Member States shall, upon the request of the Commission or another Member State, provide information on the record of procurement organisations and transplantation centres.

Article 19

Exchange of information

1 The Commission shall set up a network of the competent authorities with a view to exchanging information on the experience acquired with regard to the implementation of this Directive.

2 Where appropriate, experts on organ transplantation, representatives from European organ exchange organisations, as well as data protection supervisory authorities and other relevant parties may be associated with this network.