

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 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.