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 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.