

Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells

## CHAPTER II

### OBLIGATIONS ON MEMBER STATES' AUTHORITIES

#### *Article 7*

#### **Inspections and control measures**

1 Member States shall ensure that the competent authority or authorities organise inspections and that tissue establishments carry out appropriate control measures in order to ensure compliance with the requirements of this Directive.

2 Member States shall also ensure that appropriate control measures are in place for the procurement of human tissues and cells.

3 Inspections shall be organised and control measures shall be carried out by the competent authority or authorities on a regular basis. The interval between two inspections shall not exceed two years.

4 Such inspections and control measures shall be carried out by officials representing the competent authority, who shall be empowered to:

- a inspect tissue establishments and the facilities of any third parties as specified in Article 24;
- b evaluate and verify the procedures and the activities carried out in tissue establishments and the facilities of third parties that are relevant to the requirements of this Directive;
- c examine any documents or other records relating to the requirements of this Directive.

5 Guidelines concerning the conditions of the inspections and control measures, and on the training and qualification of the officials involved in order to reach a consistent level of competence and performance, shall be established in accordance with the procedure referred to in Article 29(2).

6 The competent authority or authorities shall organise inspections and carry out control measures as appropriate whenever there is any serious adverse reaction or serious adverse event. In addition, such an inspection shall be organised and control measures shall be carried out at the duly justified request of the competent authority or authorities in another Member State in any such case.

7 Member States shall, upon the request of another Member State or the Commission, provide information on the results of inspections and control measures carried out in relation to the requirements of this Directive.