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 5

Supervision of human tissue and cell procurement

1 Member States shall ensure that tissue and cell procurement and testing are carried out by persons with appropriate training and experience and that they take place in conditions accredited, designated, authorised or licensed for that purpose by the competent authority or authorities.

2 The competent authority or authorities shall take all necessary measures to ensure that tissue and cell procurement complies with the requirements referred to in Article 28(b), (e) and (f). The tests required for donors shall be carried out by a qualified laboratory accredited, designated, authorised or licensed by the competent authority or authorities.

Article 6

Accreditation, designation, authorisation or licensing of tissue establishments and tissue and cell preparation processes

1 Member States shall ensure that all tissue establishments where activities of testing, processing, preservation, storage or distribution of human tissues and cells intended for human applications are undertaken have been accredited, designated, authorised or licensed by a competent authority for the purpose of those activities.

2 The competent authority or authorities, having verified that the tissue establishment complies with the requirements referred to in Article 28(a), shall accredit, designate, authorise or license the tissue establishment and indicate which activities it may undertake and which conditions apply. It or they shall authorise the tissue and cell preparation processes which the tissue establishment may carry out in accordance with the requirements referred to in Article 28(g). Agreements between tissue establishments and third parties, as referred to in Article 24, shall be examined within the framework of this procedure.

3 The tissue establishment shall not undertake any substantial changes to its activities without the prior written approval of the competent authority or authorities.

4 The competent authority or authorities may suspend or revoke the accreditation, designation, authorisation or licensing of a tissue establishment or of a tissue or cell preparation process if inspections or control measures demonstrate that such an establishment or process does not comply with the requirements of this Directive.

5 Some specified tissues and cells, which will be determined in accordance with the requirements referred to in Article 28(i), may, with the agreement of the competent authority or

authorities, be distributed directly for immediate transplantation to the recipient as long as the supplier is provided with an accreditation, designation, authorisation or licence for this activity.

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.

Article 8

Traceability

1 Member States shall ensure that all tissues and cells procured, processed, stored or distributed on their territory can be traced from the donor to the recipient and vice versa. This traceability shall also apply to all relevant data relating to products and materials coming into contact with these tissues and cells.

2 Member States shall ensure the implementation of a donor identification system which assigns a unique code to each donation and to each of the products associated with it.

3 All tissues and cells must be identified with a label that contains the information or references allowing a link to the information referred to in Article 28(f) and (h).

4 Tissue establishments shall keep the data necessary to ensure traceability at all stages. Data required for full traceability shall be kept for a minimum of 30 years after clinical use. Data storage may also be in electronic form.

[[F1]5 The traceability requirements for tissues and cells, as well as for products and materials coming into contact with those tissues and cells and having an effect on their quality and safety, shall be adopted by the Commission. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 29(3).**]**

[[F1]6 The procedures for ensuring traceability at Community level shall be established by the Commission. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 29(3).**]**

Textual Amendments

F1 Substituted by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Four.

Article 9

Import/export of human tissues and cells

1 Member States shall take all necessary measures to ensure that all imports of tissues and cells from third countries are undertaken by tissue establishments accredited, designated, authorised or licensed for the purpose of those activities, and that imported tissues and cells can be traced from the donor to the recipient and vice versa in accordance with the procedures referred to in Article 8. Member States and tissue establishments that receive such imports from third countries shall ensure that they meet standards of quality and safety equivalent to the ones laid down in this Directive.

2 Member States shall take all necessary measures to ensure that all exports of tissues and cells to third countries are undertaken by tissue establishments accredited, designated, authorised or licensed for the purpose of those activities. Those Member States that send such exports to third countries shall ensure that the exports comply with the requirements of this Directive.

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a The import or export of tissues and cells referred to in Article 6(5) may be authorised directly by the competent authority or authorities.

b In case of emergency, the import or export of certain tissues and cells may be authorised directly by the competent authority or authorities.

c The competent authority or authorities shall take all necessary measures to ensure that imports and exports of tissues and cells referred to in subparagraphs (a) and (b) meet quality and safety standards equivalent to those laid down in this Directive.

[F1 4 The procedures for verifying the equivalent standards of quality and safety in accordance with paragraph 1 shall be established by the Commission Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 29(3).**]**

Textual Amendments

F1 Substituted by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Four.

Article 10

Register of tissue establishments and reporting obligations

1 Tissue establishments shall keep a record of their activities, including the types and quantities of tissues and/or cells procured, tested, preserved, processed, stored and distributed, or otherwise disposed of, and on the origin and destination of the tissues and cells intended for human applications, in accordance with the requirements referred to in Article 28(f). They shall submit to the competent authority or authorities an annual report on these activities. This report shall be publicly accessible.

2 The competent authority or authorities shall establish and maintain a publicly accessible register of tissue establishments specifying the activities for which they have been accredited, designated, authorised or licensed.

3 Member States and the Commission shall establish a network linking the national tissue establishment registers.

Article 11

Notification of serious adverse events and reactions

1 Member States shall ensure that there is a system in place to report, investigate, register and transmit information about serious adverse events and reactions which may influence the quality and safety of tissues and cells and which may be attributed to the procurement, testing, processing, storage and distribution of tissues and cells, as well as any serious adverse reaction observed during or after clinical application which may be linked to the quality and safety of tissues and cells.

2 All persons or establishments using human tissues and cells regulated by this Directive shall report any relevant information to establishments engaged in the donation, procurement, testing, processing, storage and distribution of human tissues and cells in order to facilitate traceability and ensure quality and safety control.

3 The responsible person referred to in Article 17 shall ensure that the competent authority or authorities is or are notified of any serious adverse events and reactions referred to in paragraph 1 and is or are provided with a report analysing the cause and the ensuing outcome.

4 The procedure for notifying serious adverse events and reactions shall be established by the Commission, in accordance with the procedure referred to in Article 29(2).

5 Each tissue establishment shall ensure that an accurate, rapid and verifiable procedure is in place which will enable it to recall from distribution any product which may be related to an adverse event or reaction.