Commission Directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells (Text with EEA relevance)

Article 1

Definitions

For the purposes of this Directive, the following definitions apply:

(a) ‘reproductive cells’ means all tissues and cells intended to be used for the purpose of assisted reproduction;

(b) ‘partner donation’ means the donation of reproductive cells between a man and a woman who declare that they have an intimate physical relationship;

(c) ‘direct use’ means any procedure where cells are donated and used without any banking;

(d) ‘quality system’ means the organisational structure, defined responsibilities, procedures, processes, and resources for implementing quality management and includes all activities which contribute to quality, directly or indirectly;

(e) ‘standard operating procedures’ (SOPs) means written instructions describing the steps in a specific process, including the materials and methods to be used and the expected end product;

(f) ‘validation’ (or ‘qualification’ in the case of equipment or environments) means establishing documented evidence that provides a high degree of assurance that a specific process, SOP, piece of equipment or environment will consistently produce a product meeting its predetermined specifications and quality attributes; a process is validated to evaluate the performance of a system with regard to its effectiveness based on intended use;

(g) ‘traceability’ means the ability to locate and identify the tissue/cell during any step from procurement, through processing, testing and storage, to distribution to the recipient or disposal, which also implies the ability to identify the donor and the tissue establishment or the manufacturing facility receiving, processing or storing the tissue/cells, and the ability to identify the recipient(s) at the medical facility/facilities applying the tissue/cells to the recipient(s); traceability also covers the ability to locate and identify all relevant data relating to products and materials coming into contact with those tissues/cells;

(h) ‘procurement organisation’ means a health care establishment or a unit of a hospital or another body that undertakes the procurement of human tissues and cells and that may not be accredited, designated, authorised or licensed as a tissue establishment.

Article 2

Requirements for the procurement of human tissues and cells

1 With the exception of partner donation of reproductive cells for direct use, Member States shall ensure that the procurement of human tissues and cells is accredited, designated, authorised or licensed only when the requirements in paragraphs 2 to 12 are met.

2 Procurement of human tissues and cells shall be carried out by persons who have successfully completed a training programme specified by a clinical team specialising in the tissues and cells to be procured or a tissue establishment authorised for procurement.

3 The tissue establishment or procurement organisation shall have written agreements with the staff or clinical teams responsible for donor selection, unless they are employed by the same organisation or establishment, specifying the procedures to be followed to assure compliance with the selection criteria for donors set out in Annex I.

4 The tissue establishment or procurement organisation shall have written agreements with the staff or clinical teams responsible for tissue/cell procurement, unless they are employed by the same establishment or organisation, specifying the type(s) of tissues and/or cells and/or test samples to be procured and the protocols to be followed.

5 There shall be standard operating procedures (SOPs) for the verification of:

a donor identity;

b the details of donor or donor family consent or authorisation;

c the assessment of the selection criteria for donors as detailed in Article 3;

d the assessment of the laboratory tests required for donors as detailed in Article 4.

There shall also be SOPs describing the procedures for procurement, packaging, labelling and transportation of the tissues and cells to the point of arrival at the tissue establishment or, in the case of direct distribution of tissues and cells, to the clinical team responsible for their application or, in the case of tissue/cell samples, to the laboratory for testing, in accordance with Article 5 of this Directive.

6 Procurement shall take place in appropriate facilities, following procedures that minimise bacterial or other contamination of procured tissues and cells, in accordance with Article 5.

7 Procurement materials and equipment shall be managed in accordance with the standards and specifications laid down in Annex IV, section 1.3, and with due regard to relevant national and international regulation, standards and guidelines covering the sterilisation of medicines and medical devices. Qualified, sterile instruments and procurement devices shall be used for tissue and cell procurement.

8 Procurement of tissues and cells from living donors shall take place in an environment that ensures their health, safety and privacy.

9 Where appropriate, the staff and equipment necessary for body reconstruction of deceased donors shall be provided. Such reconstruction shall be completed effectively.

10 The procedures for the procurement of tissues and cells shall be carried out in accordance with the requirements specified in Article 5.

11 A unique identifying code shall be allocated to the donor and the donated tissues and cells, during procurement or at the tissue establishment, to ensure proper identification of the donor and the traceability of all donated material. The coded data shall be entered in a register maintained for the purpose.

12 Donor documentation shall be maintained in accordance with section 1.4 of Annex IV.

Article 3

Selection criteria for donors of tissues and cells

The competent authority or authorities shall ensure that donors comply with the selection criteria set out in:

(a) Annex I for donors of tissues and cells, except donors of reproductive cells;

(b) Annex III for donors of reproductive cells.

Article 4

Laboratory tests required for donors

1 The competent authority or authorities shall ensure that:

a donors of tissues and cells, except donors of reproductive cells, undergo the biological tests set out in point 1 of Annex II;

b the tests referred to in point (a) are carried out in compliance with the general requirements set out in point 2 of Annex II.

2 The competent authority or authorities shall ensure that:

a donors of reproductive cells undergo the biological tests set out in points 1, 2 and 3 of Annex III;

b the tests referred to in point (a) above are carried out in compliance with the general requirements set out in point 4 of Annex III.

Article 5

Tissue and/or cell donation and procurement procedures and reception at the tissue establishment

The competent authority or authorities shall ensure that the tissue and/or cell donation and procurement procedures and the reception of tissues and/or cells at the tissue establishment comply with the requirements set out in Annex IV.

Article 6

Requirements for direct distribution to the recipient of specific tissues and cells

The competent authority or authorities may authorise the direct distribution of specific tissues and cells from where the procurement is carried out to a health care establishment for immediate transplantation.

Article 7

Transposition

1 Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 1 November 2006, at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2 Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 8

Entry into force

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

Article 9

Addressees

This Directive is addressed to the Member States.