Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells (Text with EEA relevance)

Article 1

Scope

1 This Directive shall apply to the coding, processing, preservation, storage and distribution of:

a human tissues and cells intended for human applications; and

b manufactured products derived from human tissues and cells intended for human applications, where those products are not covered by other directives.

2 The provisions of Articles 5 to 9 of this Directive, concerning traceability and the reporting of serious adverse reactions and events shall also apply to the donation, procurement and testing of human tissues and cells.

Article 2

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) '*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;

(d) '*quality management*' means the coordinated activities to direct and control an organisation with regard to quality;

(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, 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) '*critical*' means potentially having an effect on the quality and/or safety of or having contact with the cells and tissues;

(i) '*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;

(j) '*organisations responsible for human application*' means a health care establishment or a unit of a hospital or another body which carries out human application of human tissues and cells.

Article 3

Requirements for the accreditation, designation, authorisation or licensing of tissue establishments

A tissue establishment must comply with the requirements set out in Annex I.

Article 4

Requirements for the accreditation, designation, authorisation, licensing of tissue and cell preparation processes

Preparation processes at the tissue establishments must comply with the requirements set out in Annex II.

Article 5

Notification of serious adverse reactions

1 Member States shall ensure that:

a procurement organisations have procedures in place to retain the records of tissues and cells procured and to notify tissue establishments without delay of any serious adverse reactions in the living donor which may influence the quality and safety of tissues and cells;

b organisations responsible for human application of tissues and cells have procedures in place to retain the records of tissues and cells applied and to notify tissue establishments without delay of any serious adverse reactions observed during and after clinical application which may be linked to the quality and safety of tissues and cells;

c tissue establishments that distribute tissue and cells for human application provide information to the organisation responsible for human application of tissues and cells about how that organisation should report serious adverse reactions as referred to in (b).

2 Member States shall ensure that tissue establishments:

a have procedures in place to communicate to the competent authority without delay all relevant available information about suspected serious adverse reactions as referred to in paragraph 1(a) and (b);

b have procedures in place to communicate to the competent authority without delay the conclusion of the investigation to analyse the cause and the ensuing outcome.

3 Member States shall ensure that:

a the responsible person referred to in Article 17 of Directive 2004/23/EC notifies the competent authority of the information included in the notification set out in Part A of Annex III;

b tissue establishments notify the competent authority of the actions taken with respect to other implicated tissues and cells that have been distributed for human applications;

c tissue establishments notify the competent authority of the conclusion of the investigation, supplying at least the information set out in Part B of Annex III.

Article 6

Notification of serious adverse events

1 Member States shall ensure that:

a procurement organisations and tissue establishments have procedures in place to retain the records and to notify tissue establishments without delay of any serious adverse events that occur during procurement which may influence the quality and/or safety of human tissues and cells;

b organisations responsible for human application of tissues and cells have procedures in place to notify tissue establishments without delay of any serious adverse events that may influence the quality and safety of the tissues and cells;

c tissue establishments provide to the organisation responsible for human application information about how that organisation should report serious adverse events to them that may influence the quality and safety of the tissues and cells.

2 In the case of assisted reproduction, any type of gamete or embryo misidentification or mix-up shall be considered to be a serious adverse event. All persons or procurement organisations or organisations responsible for human application performing assisted reproduction shall report such events to the supplying tissue establishments for investigation and notification to the competent authority.

3 Member States shall ensure that tissue establishments:

a have procedures in place to communicate to the competent authority without delay all relevant available information about suspected serious adverse events as referred to in paragraph 1(a) and (b);

b have procedures in place to communicate to the competent authority without delay the conclusion of the investigation to analyse the cause and the ensuing outcome.

4 Member States shall ensure that:

a the responsible person referred to in Article 17 of Directive 2004/23/EC notifies the competent authority of the information included in the notification set out in Part A of Annex IV;

b tissue establishments evaluate serious adverse events to identify preventable causes within the process;

c tissue establishments notify the competent authority of the conclusion of the investigation, supplying at least the information set out in Part B of Annex IV.

Article 7

Annual reports

1 Member States shall submit to the Commission an annual report, by 30 June of the following year, on the notification of serious adverse reactions and events received by the competent authority. The Commission shall submit to the competent authorities of Member States a summary of the reports received. The competent authority shall make this report available to tissue establishments.

2 Data transmission shall comply with the data exchange format specifications as set out in Annex V, part A and B, and shall provide all the information necessary to identify the sender and maintain its reference data.

Article 8

Communication of information between competent authorities and to the Commission

Member States shall ensure that their competent authorities communicate to each other and to the Commission such information as is appropriate with regard to serious adverse reactions and events, in order to guarantee that adequate actions are taken.

Article 9

Traceability

1 Tissue establishments shall have effective and accurate systems to uniquely identify and label cells/tissues received and distributed.

2 Tissue establishments and organisations responsible for human application shall retain the data set out in Annex VI for at least 30 years, in an appropriate and readable storage medium.

Article 10

European coding system

1 A single European identifying code shall be allocated to all donated material at the tissue establishment, to ensure proper identification of the donor and the traceability of all donated material and to provide information on the main characteristics and properties of tissues and cells. The code shall incorporate at least the information set out in Annex VII.

2 Paragraph 1 shall not apply to partner donation of reproductive cells.

Article 11

Transposition

1 Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 1 September 2007, 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.

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with Article 10 of this Directive, by 1 September 2008.

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 12

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 13

Addressees

This Directive is addressed to the Member States.

Done at Brussels, 24 October 2006.

For the Commission

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Member of the Commission