Human tissues and cells: quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution

2002/0128(COD) - 24/10/2006 - Implementing legislative act

LEGISLATIVE ACT: Commission Directive 2006/86/EC 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.

CONTENT: this Directive implements Directive 2004/23/EC, which calls for the establishment of specific technical requirements for each one of the steps in the human tissues and cells application process, including standards and specifications with regard to a quality system for tissue establishments. It establishes technical requirements for an accreditation, designation, authorisation or licensing system for tissue establishments and for the preparation processes at the tissue establishments in Member States.

The Directive applies to the coding, processing, preservation, storage and distribution of:

- human tissues and cells intended for human applications; and

- manufactured products derived from human tissues and cells intended for human applications, where those products are not covered by other directives. However, it does not extend to the human application of these tissues and cells (such as implantation surgery, perfusion, insemination or transfer of embryos).

The main points are as follows:

- requirements for the accreditation, designation, authorisation or licensing of tissue establishments are set out in Annex I. They coverthe organisation and management, personnel, equipment and materials, facilities /premises, documentation and records and quality review;

- requirements for the accreditation, designation, authorisation, licensing of tissue and cell preparation processes are set out in Annex II, and include the air quality standard during the processing of tissues and cells;

- since the use of tissues and cells for human application carries a risk of disease transmission and other potential adverse effects in recipients, specific requirements for traceability and a Community procedure for notifying serious adverse reactions and events are set out;

- to facilitate traceability and information on the main characteristics and properties of tissues and cells, the Directive lays down the basic data to be included in a single European code.

Lastly, provisions of the Directive concerning traceability and the reporting of serious adverse reactions and events also apply to the donation, procurement and testing of human tissues and cells.

ENTRY INTO FORCE: 14/11/2006.

TRANSPOSITION: 01/09/2007. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with Article 10 of the Directive (European coding system) by 1 September 2008.