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

2002/0128(COD) - 08/02/2006 - Implementing legislative act

ACT: Commission Directive 2006/17/EC 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.

CONTENT: this Commission Directive relates to the establishment of specific technical requirements for each step in human tissue and cell application processes and implements Directive 2004/23. This is being done in order to avoid and minimise any adverse risks to human health. Risks can be reduced by careful donor selection, testing of each donation and the application of procedures to procure tissue and cells in accordance with rules and processes established and update according to best available scientific advice. Under the terms of the Directive, all tissues and cells, including those used as starting material for the manufacture of medicinal products to be used in the Community, must meet the safety requirements set out in this Directive.

There are special procedures governing reproductive cells, which due to their specific nature require certain unique requirements. For example, for the donation of reproductive cells between partners that have an intimate physical relationship, it is justified to require less stringent biological testing – given that in such a case the risk for the recipients is less than for donation from a third party. In order to minimise the risk of cross-contamination, biological testing of the donor will only become necessary in cases where the donated cells are processed, cultured or stored.

The Directive defines a number of related terms including, *inter alia*, reproductive cells, partner donation, direct use, quality system, standard operating procedures, validation or qualification, traceability and procurement organisation. The Directive states that, with the exception of partner donation of reproductive cells for direct use, Member States are obliged to ensure that the procurement of human tissues and cells is accredited, designated, authorised and licensed under certain strict criteria, the conditions of which are set out in the Directive. The provisions governing laboratory tests required of donors as well as the selection criteria of donor’s tissues and cells are set out in Annexes attached to the Directive. In additions Member State authorities are obliged to follow procurement procedures relating to tissue and/or cell donation that are compatible with requirements set out in Annex to the Directive. The 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.

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