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)

COMMISSION DIRECTIVE 2006/17/EC

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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)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community, and in particular Article 152(4)(a) thereof,

Having regard to 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[(1)], and in particular points (b), (d), (e), (f), and (i) of Article 28 thereof,

Whereas:

(1) Directive 2004/23/EC lays down standards of quality and safety for the donation, procurement and testing of all human tissues and cells intended for human applications, and of manufactured products derived from human tissues and cells intended for human applications, so as to ensure a high level of human health protection.

(2) In order to prevent the transmission of diseases by human tissues and cells for human applications and to ensure an equivalent level of quality and safety, Directive 2004/23/EC calls for the establishment of specific technical requirements for each one of the steps in the human tissue and cell application process.

(3) The use of tissues and cells for application in the human body carries a risk of disease transmission and other potential adverse effects in recipients. That risk can be reduced by careful donor selection, testing of each donation and the application of procedures to procure tissues and cells in accordance with rules and processes established and updated according to the best available scientific advice. Therefore, all tissues and cells, including those used as starting material for the manufacture of medicinal products, to be used in the Community should meet the quality and safety requirements laid down in this Directive.

(4) Reproductive cells have, due to the specific nature of their application, specific quality and safety characteristics that are taken into account in this Directive.

(5) 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 this case the risk for the recipient is considered less than for donation from third parties. In order to minimise the risk of cross-contamination, biological testing of the donor will be necessary only when the donated cells will be processed, cultured or stored.

(6) This Directive is based on international experience drawn upon through an extensive consultation, the Council of Europe's Guide to safety and quality assurance for organs, tissues and cells, the European Convention on Human Rights, the Council of Europe's Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (Oviedo, 4.IV.1997), with its additional protocols, and recommendations from the World Health Organisation. In particular, with regard to further additional biological testing for donors originating from high-incidence areas of specific diseases or whose sexual partners or parents originate from high-incidence areas, Member States will refer to existing international scientific evidence. The Directive is consistent with the fundamental principles set out in the European Charter of Fundamental Rights.

(7) The measures provided for in this Directive are in accordance with the opinion of the Committee set up by Directive 2004/23/EC,

HAS ADOPTED THIS DIRECTIVE:

(**1**) OJ L 102, 7.4.2004, p. 48.