Commission Directive 2012/39/EU of 26 November 2012 amending Directive 2006/17/EC as regards certain technical requirements for the testing of human tissues and cells (Text with EEA relevance)

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

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 point (e) of the Article 28 thereof,

Whereas:

(1) 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[(2)] requires that HTLV-I antibody testing must be performed for donors living in, or originating from, high-incidence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas. This testing is required both for donors of reproductive cells, in accordance with Annex III to Directive 2006/17/EC, and for other donors, in accordance with Annex II thereof.

(2) Recent scientific evidence provided by the European Centre for Disease Prevention and Control (ECDC) and field practice experience showed that it is very difficult, in the current state of scientific knowledge, to determine what is an HTLV-I high-incidence area. This testing requirement is thus not implemented in a uniform manner.

(3) 'Incidence' measures the rate of occurrence of new cases of a disease or condition, while 'prevalence' is the proportion of a population that is affected by a particular disease at a specific time. In practice, data for prevalence are more available than data on incidence. In addition, prevalence is a more relevant measure than incidence when assessing the impact of a chronic disease within a community and to assess the subsequent needs. It is therefore appropriate to replace references to high-incidence by references to high-prevalence in order to ensure a more consistent implementation of the HTLV-I testing requirements across the Member States.

(4) Point 4.2 of Annex III to Directive 2006/17/EC requires that blood samples must be obtained at the time of each donation both, for partner donation (not for direct use) and for non-partner donation of reproductive cells.

(5) As far as partner donation of reproductive cells is concerned, recent scientific evidence has demonstrated that requiring testing at fixed time intervals up to a maximum of 24 months would not diminish the level of safety of the cells concerned as long as appropriate safety and quality systems are in place in tissue establishments using Assisted Reproductive Technology, in accordance with Article 16 of Directive 2004/23/EC. During these time intervals, the results of the previous test carried out on the same donor can be relied upon.

(6) Whereas testing at the time of each donation does not improve the safety of reproductive cells donated between partners, field practice experience shows that this requirement is costly and cumbersome for both, patients and healthcare systems. In order to act in a more proportionate manner to the safety objective pursued, it is therefore appropriate to allow the Member States to require testing at fixed time intervals which they may determine up to a maximum of 24 months instead of at the time of each donation.

(7) The measures provided for in this Directive are in accordance with the opinion of the Committee set up by Article 29 of Directive 2004/23/EC,

HAS ADOPTED THIS DIRECTIVE:

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

(**2**) OJ L 38, 9.2.2006, p. 40.