

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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requirements for the testing of human tissues and cells

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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<sup>(1)</sup>, 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<sup>(2)</sup> 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:

*Article 1*

Annexes II and III to Directive 2006/17/EC are amended in accordance with the Annex to this Directive.

*Article 2*

1 Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 17 June 2014 at the latest. They shall forthwith communicate to the Commission the text of those provisions.

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 3*

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

*Article 4*

This Directive is addressed to the Member States.

Done at Brussels, 26 November 2012.

*For the Commission*

*The President*

José Manuel BARROSO

## ANNEX

Annexes II and III to Directive 2006/17/EC are amended as follows:

- (1) in Annex II, point 1.2 is replaced by the following:
  - 1.2. HTLV-I antibody testing must be performed for donors living in, or originating from, high-prevalence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas;
- (2) Annex III is amended as follows:
  - (a) point 2.4 is replaced by the following:
    - 2.4. HTLV-I antibody testing must be performed for donors living in, or originating from, high-prevalence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas;
  - (b) point 3.3 is replaced by the following:
    - 3.3. HTLV-I antibody testing must be performed for donors living in, or originating from, high-prevalence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas;
  - (c) point 4.2 is replaced by the following:
    - 4.2. For donations other than by partners, blood samples must be obtained at the time of each donation.

For donation by partners (not for direct use), blood samples must be obtained within three months before the first donation. For further partner donations by the same donor, further blood samples must be obtained according to national legislation, but no later than 24 months from the previous sampling..

- (1) [OJ L 102, 7.4.2004, p. 48.](#)
- (2) [OJ L 38, 9.2.2006, p. 40.](#)