Commission Directive (EU) 2015/566 of 8 April 2015 implementing Directive 2004/23/EC as regards the procedures for verifying the equivalent standards of quality and safety of imported tissues and cells (Text with EEA relevance)

COMMISSION DIRECTIVE (EU) 2015/566

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implementing Directive 2004/23/EC as regards the procedures for verifying the equivalent standards of quality and safety of imported tissues and cells

(Text with EEA relevance)

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 Article 9(4) thereof,

Whereas:

(1) Directive 2004/23/EC lays down standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of all human tissues and cells intended for human application, and for the donation, procurement, and testing of human tissues and cells contained in manufactured products intended for human application where those products are covered by other Union legislation, so as to ensure a high level of human health protection in the Union.

(2) Exchanges of tissues and cells increasingly take place on a worldwide basis and Directive 2004/23/EC therefore requires that imports of tissues and cells are undertaken by tissue establishments accredited, designated, authorised or licensed by Member States for that purpose. Exceptions to that requirement are laid down in Article 9(3) of Directive 2004/23/EC allowing competent authorities to directly authorise the import of specific tissues and cells under the conditions laid down in Article 6 of Commission Directive 2006/17/EC[(2)] or in case of emergency. These exceptions are regularly used, but not limited to, allowing the import of haematopoietic stem cells from bone marrow, peripheral blood or cord blood which is used in the treatment of a number of life-threatening conditions.

(3) Directive 2004/23/EC, furthermore, requires Member States and importing tissue establishments to ensure that imports of tissue and cells meet standards of quality and safety equivalent to the ones laid down in Directive 2004/23/EC and calls for the establishment of procedures to verify the equivalency of the quality and safety standards of imports of tissues and cells. Those procedures should be laid down in this Directive without prejudice to the Union legislation on customs.

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(4) In particular, it is appropriate to establish authorisation and inspection schemes mirroring the verification process in place for activities related to tissues and cells carried out within the Union. It is also appropriate to lay down the procedures to be followed by importing tissue establishments in their relations with their third country suppliers.

(5) With the exception of imports directly authorised by competent authorities pursuant to Article 9(3) of Directive 2004/23/EC, all imports of tissues and cells from third countries must be undertaken by importing tissue establishments. Where competent authorities do directly authorise imports pursuant to Article 9(3) of Directive 2004/23/EC, the responsibility to ensure that such imports meet quality and safety standards equivalent to those laid down in that Directive falls upon the competent authorities.

(6) Tissues and cells should normally be imported by tissue banks or units of hospitals which are accredited, designated, authorised or licensed as importing tissue establishments for the purpose of their import activities. Tissue banks or units of hospitals should be considered to be importing tissue establishments where they are a party to a contractual agreement with a third country supplier for the import of tissues and cells. Where an organisation offering brokerage services is a party to a contractual agreement with a third country supplier to facilitate the import of tissues and cells but not for the import itself, it should not be considered to be an importing tissue establishment. Member States may choose to regulate such services outside the scope of this Directive.

(7) Where other bodies such as organisations responsible for human application, manufacturers of advanced therapy medicinal products, clinical practitioners or individuals are a party to a contractual agreement with a third country supplier for the import of tissues and cells, they should be considered to be an importing tissue establishment. They must comply with the requirements of this Directive as well as with all relevant provisions of Directive 2004/23/EC and be accredited, designated, authorised or licensed as importing tissue establishments for the purpose of their import activities by their relevant competent authorities. Where, subsequent to the import, they also undertake testing, processing, preservation, storage or distribution of the imported tissues and cells they must also be accredited, designated, authorised or licensed by their relevant competent authorities for the purpose of those activities and comply with the requirements of Directive 2004/23/EC. Alternatively they may obtain tissues and cells originating from third countries from tissue banks or units of hospitals located within the Union which are accredited, designated, authorised or licensed as importing tissue establishments by their relevant competent authorities.

(8) Where importing tissue establishments are also accredited, designated, authorised or licensed as tissue establishments for the activities they carry out within the Union, Member States may align their authorisation, inspection and reporting procedures provided the procedures laid down in this Directive are followed.

(9) In order to facilitate the distribution within the Union of imported tissues and cells including where such distribution is cross-border in nature, the competent authority

or authorities should issue the certificate attesting the accreditation, designation, authorisation, or licence of the importing tissue establishment.

(10) Inspection measures play an important role in the verification of the equivalency of imported tissues and cells with the quality and safety standards laid down in Directive 2004/23/EC. Member States are therefore encouraged, where appropriate to also inspect third country suppliers and cooperate with other Member States into which imported tissues and cells are likely to be distributed. Member States in which the importing tissue establishments are located retain the responsibility for deciding on the most appropriate measures to be undertaken and for decisions on whether on-site inspections of third country suppliers are needed.

(11) The Operational Manual for Competent Authorities on inspections has been updated to take into account inspections of importing tissue establishments and their third country suppliers and is available to Member States as a guidance document when undertaking such inspection measures.

(12) Importing tissue establishments should verify that the standards of quality and safety of the tissues and cells they import into the Union are equivalent to the standards of quality and safety laid down in Directive 2004/23/EC. Written agreements with third country suppliers and the documentation to be provided and made available to competent authorities are key elements in ensuring such verification takes place and in particular providing traceability back to the donor and ensuring that the principle of voluntary and unpaid donation is adhered to in line with Directive 2004/23/EC. Importing tissue establishments are also encouraged to audit their third country suppliers as part of this verification process.

(13) Importing tissue establishments should ensure that the Single European Code is applied to imported tissues and cells in line with Commission Directive 2006/86/EC[(3)], either by carrying out this task themselves or delegating it to third country suppliers as part of the terms of their written agreements with such suppliers.

(14) Member States should be allowed to exempt one-off imports from the requirements laid down in this Directive in respect of documentation and written agreements. Such one-off imports should, however, be carried out by accredited, designated, authorised or licensed importing tissue establishments and as a general rule should not take place on a regular or repeated basis from the same third country supplier. The use of such exemptions should be limited to situations where a person or persons has or have had tissues and cells stored in a third country for their future use, in particular in cases of partner donations of reproductive cells, of autologous donations, or donations directed to close relatives, and subsequently, wishes to have such tissues or cells imported into the Union on their behalf. Such an import of any specific type of tissue or cell should normally not occur more than once for any given recipient and should not include tissues or cells for third parties.

(15) This Directive does not prevent Member States from maintaining or introducing more stringent measures relating to imports of tissues and cells, in particular in order to ensure the principle of voluntary and unpaid donation is respected, provided that the provisions of the Treaty are met.

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(16) The measures provided for in this Directive are in accordance with the opinion of the Tissues and Cells Regulatory Committee established by Article 29(3) of Directive 2004/23/EC,

HAS ADOPTED THIS DIRECTIVE:

CHAPTER I

GENERAL PROVISIONS

Article 1

Scope

1 This Directive shall apply to the import into the Union of:

a human tissues and cells intended for human application; and

b manufactured products derived from human tissues and cells intended for human applications, where those products are not covered by other Union legislation.

2 Where the human tissues and cells to be imported are intended to be used exclusively in manufactured products which are covered by other Union legislation, this Directive shall only apply to the donation, procurement and testing which takes place outside of the Union as well as to contributing to ensuring traceability from donor to recipient and vice versa.

3 This Directive shall not apply to:

a the import of tissues and cells referred to in Article 9(3)(a) of Directive 2004/23/EC which are directly authorised by the competent authority or authorities;

b the import of tissues and cells referred to in Article 9(3)(b) of Directive 2004/23/EC which are directly authorised in case of emergencies;

c blood and blood components as defined by Directive 2002/98/EC;

d organs or parts of organs, as defined in Directive 2004/23/EC.

Article 2

Definitions

For the purposes of this Directive, the following definitions apply:

(a) ‘emergency’ means any unforeseen situation in which there is no practical alternative other than to urgently import tissues and cells from a third country into the Union for immediate application to a known recipient or known recipients whose health would be seriously endangered without such an import;

(b) ‘importing tissue establishment’ means a tissue bank or a unit of a hospital or another body established within the Union which is a party to a contractual agreement with a third country supplier for the import into the Union of tissues and cells coming from a third country intended for human application;

(c) ‘one-off import’ means the import of any specific type of tissue or cell which is for the personal use of an intended recipient or recipients known to the importing tissue establishment and the third country supplier before the importation occurs. Such an

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import of any specific type of tissue or cell shall normally not occur more than once for any given recipient. Imports from the same third country supplier taking place on a regular or repeated basis shall not be considered to be 'one-off imports';

(d) 'third country supplier' means a tissue establishment or another body, established in a third country, which is responsible for the export to the Union of tissues and cells it supplies to an importing tissue establishment. A third country supplier may also carry out one or more of the activities, which take place outside of the Union, of donation, procurement, testing, processing, preservation, storage or distribution of tissues and cells imported into the Union.

CHAPTER II

OBLIGATIONS ON MEMBER STATES' AUTHORITIES

Article 3

Accreditation, designation, authorisation or licensing of importing tissue establishments

1 Without prejudice to Article 1(3), Member States shall ensure that all imports of tissues and cells from third countries are undertaken by importing tissue establishments accredited, designated, authorised or licensed by a competent authority or authorities for the purposes of these activities.

2 The competent authority or authorities, having obtained the information set out in Annex I to this Directive and, having verified that the importing tissue establishment complies with the requirements of this Directive, shall accredit, designate, authorise or license the importing tissue establishment to import tissues and cells and indicate any conditions which apply such as any restrictions of the types of tissues and cells to be imported or the third country suppliers to be used. The competent authority or authorities shall issue the accredited, designated, authorised or licensed importing tissue establishment with the certificate set out in Annex II to this Directive.

3 The importing tissue establishment shall not undertake any substantial changes to its import activities without the prior written approval of the competent authority or authorities. In particular, any changes to the type of tissues and cells imported, the activities undertaken in third countries which may have an influence on the quality and safety of imported tissues and cells or the third country suppliers used shall be considered as substantial changes. Where an importing tissue establishment undertakes a one-off import of tissues or cells originating from a third country supplier not covered by its existing accreditation, designation, authorisation or licence, such an import shall not be considered as a substantial change if the importing tissue establishment is authorised to import the same type of tissues or cells from another third country supplier or suppliers.

4 The competent authority or authorities may suspend or revoke the accreditation, designation, authorisation, or licence, in part or in full, of an importing tissue establishment if, in particular, inspections or other control measures demonstrate that such an establishment no longer meets the requirements of this Directive.