Commission Directive (EU) 2015/565 of 8 April 2015 amending Directive 2006/86/EC as regards certain technical requirements for the coding 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[(1)] on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, and in particular Article 28 thereof,

Whereas:

(1) Directive 2004/23/EC requires that Member States ensure the traceability of human tissues and cells from the donor to the recipient and vice versa.

(2) In order to facilitate traceability it is necessary to establish a unique identifier applied to tissues and cells distributed in the Union (Single European Code) providing information on the main characteristics and properties of those tissues and cells.

(3) In order to ensure a uniform implementation of the Single European Code throughout the Union, obligations of the Member States competent authorities and of the tissue establishments for the application of the Single European Code should be set out. Only this approach will guarantee a consistent and coherent application of the code in the Union.

(4) Traceability from donor to recipient and vice versa should be ensured through coding of tissues and cells and through accompanying documentation. At the recipient end, the Single European Code provides information on the donation and on the tissue establishment responsible for the procurement of tissues and cells. At the donor end, the tissue establishment responsible for the procurement of tissues and cells may track the tissues and cells distributed for human application by requesting the next operators in the chain to provide data related to the use of the tissues and cells based on the donation identification elements of the Single European Code as contained in the accompanying documentation.

(5) The format of the Single European Code should be harmonised in order to facilitate its application by small and large establishments, whilst allowing some flexibility for establishments to continue using existing codes.

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(6) A Single European Code allowing for donation and product identification should be allocated to all tissues and cells distributed for human application, including those imported from third countries. Member States may allow certain exemptions from the application of the code.

(7) Where tissues and cells are excluded or exempted from the application of the Single European Code, the Member States should ensure that appropriate traceability of these tissues and cells is guaranteed throughout the entire chain from donation and procurement to human application.

(8) In situations where tissues and cells are released for circulation, other than for distribution (such as transfer to another operator for further processing with or without return), as a minimum the donation identification sequence should be applied at least in the accompanying documentation. Where tissues and cells are transferred from a tissue establishment to another operator just for storage and/or for further distribution, the tissue establishment may already apply the Single European Code on their final label in addition to the donation identification sequence which should be applied at least in the accompanying documentation.

(9) In the case of tissues and cells retrieved from a deceased donor by procurement teams operating for two or more tissue establishments, Member States shall ensure an appropriate traceability system across procurements. This may be ensured by developing a central system for the allocation of the unique donation numbers for each donation event recorded at national level, or by requiring all tissue establishments to ensure robust traceability links between the donation identification numbers allocated by each tissue establishment procuring or receiving tissue and cells originating from the same deceased donor.

(10) The Commission should ensure the implementation of the Single European Code by providing the appropriate tools to the Member States competent authorities and tissue establishments. The Member States competent authorities should update the register for tissue establishments, reflecting any changes in tissue establishment accreditations, designations, authorisations, or licences and the Commission should ensure the update of the register of the tissues and cells whenever new products need to be included. For this the Commission should consult a group of experts, in particular experts nominated by the Member States competent authorities.

(11) For the donation identification sequence in the Single European Code, the importing tissue establishment should use the tissue establishment code allocated to it in the EU Tissue Establishment Compendium and should allocate a unique donation number if the donation number on the imported product is not globally unique.

(12) Pooling of tissues or cells is allowed in some Member States. Therefore, the application of the Single European Code in case of pooling is also addressed by this Directive.

(13) A transitional regime for tissues and cells already in storage at the end of the transposition period should be introduced.

(14) This Directive does not prevent Member States from maintaining or introducing more stringent measures relating to coding of tissues and cells, provided that the provisions of the Treaty are met.

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

HAS ADOPTED THIS DIRECTIVE:

Article 1

Commission Directive 2006/86/EC[(2)] is hereby amended as follows:

(1) In Article 2, the following points (k) to (y) are added:

(k) "Single European Code" or "SEC" means the unique identifier applied to tissues and cells distributed in the Union. The Single European Code consists of a donation identification sequence and a product identification sequence, as further specified in Annex VII to this Directive;

(l) "donation identification sequence" means the first part of the Single European Code consisting of the EU tissue establishment code and the unique donation number;

(m) "EU tissue establishment code" means the unique identifier for accredited, designated, authorised, or licensed tissue establishments in the Union. The tissue establishment code consists of an ISO country code and the tissue establishment number set out in the EU Tissue Establishment Compendium, as further specified in Annex VII to this Directive;

(n) "unique donation number" means the unique number attributed to a specific donation of tissues and cells in line with the system in place in each Member State for allocating such numbers, as further specified in Annex VII to this Directive;

(o) "product identification sequence" means the second part of the Single European Code consisting of the product code, the split number and the expiry date;

(p) "product code" means the identifier for the specific type of tissue and cell in question. The product code consists of the product coding system identifier indicating the coding system used by the tissue establishment ("E" for the EUTC, "A" for ISBT128, "B" for Eurocode) and the tissues and cells product number foreseen in the respective coding system for the product type, as further defined in Annex VII to this Directive;

(q) "split number" means the number which distinguishes and uniquely identifies tissues and cells having the same unique donation number and the same product code and originating from the same tissue establishment, as further defined in Annex VII to this Directive;

(r) "expiry date" means the date by which the tissues and cells can be applied, as further defined in Annex VII to this Directive;

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(s) "EU Coding Platform" means the IT platform hosted by the Commission which contains the EU Tissue Establishment Compendium and the EU Tissue and Cell Product Compendium;

(t) "EU Tissue Establishment Compendium" means the register of all tissue establishments which are authorised, licensed, designated or accredited by the Member States' competent authority or authorities and which contains the information about these tissue establishments as set out in Annex VIII to this Directive;

(u) "EU Tissue and Cell Product Compendium" means the register of all types of tissues and cells circulating in the Union and the respective product codes under the three permitted coding systems (EUTC, ISBT128 and Eurocode);

(v) "EUTC" means the product coding system for tissues and cells developed by the Union consisting of a register of all types of tissues and cells circulating in the Union and their corresponding product codes.

(w) "released for circulation" means distribution for human application or transfer to another operator, e.g. for further processing with or without return.

(x) "within the same centre" means that all steps from procurement to human application are carried out under the same responsible person, quality management system and traceability system, within a healthcare centre comprising at least an accredited, designated, authorised, or licensed tissue establishment and an organisation responsible for human application at the same location;

(y) "pooling" means the physical contact or mixing in a single container, of tissues or cells from more than one procurement from the same donor, or from two or more donors.

(2) Article 9 is replaced by the following:

Article 9

Traceability

1 Member States shall ensure that tissues and cells shall be traceable in particular through documentation and the use of the Single European Code from procurement to human application or disposal and vice versa. Tissues and cells used for advanced therapy medicinal products shall be traceable under this Directive at least until transferred to the ATMP manufacturer.

2 Member States shall ensure that tissue establishments and organisations responsible for human application shall retain the data set out in Annex VI for at least 30 years, using an appropriate and readable storage medium.

3 In case of tissues and cells retrieved from a deceased donor by procurement teams operating for two or more tissue establishments, Member States shall ensure an appropriate traceability system across the procurements.

(3) Article 10 is replaced by the following:

Article 10

European coding system

1 Without prejudice to paragraphs 2 or 3 of this Article, a Single European Code shall be applied to all tissues and cells distributed for human application. For the other situations where tissues and cells are released for circulation, as a minimum the donation identification sequence shall be applied at least in the accompanying documentation.

2 Paragraph 1 shall not apply to:

a reproductive cells from partner donation;

b tissues and cells distributed directly for immediate transplantation to the recipient, as referred to in Article 6(5) of Directive 2004/23/EC;

c tissues and cells imported into the Union in case of emergency authorised directly by the competent authority or authorities, as referred to in Article 9(3)b of Directive 2004/23/EC.

3 Member States may also allow exemptions from the requirement provided for in paragraph 1 for:

a tissues and cells other than reproductive cells for partner donation, when these tissues and cells remain within the same centre;

b tissues and cells that are imported into the Union, when these tissues and cells remain within the same centre from importation to application, provided that the centre comprises a tissue establishment authorised, designated, accredited, or licensed to carry out importing activities.

(4) The following Articles are inserted:

Article 10a

Format of the Single European Code

1 The Single European Code referred to in Article 10(1) shall comply with the specifications set out in this Article and in Annex VII.

2 The Single European Code shall be in eye-readable format and shall be preceded by the acronym “SEC”. The parallel use of other labelling and traceability systems is possible.

3 The Single European Code shall be printed with the Donation Identification Sequence and Product Identification Sequence separated by a single space or as two successive lines.

Article 10b

Requirements related to the application of the Single European Code

1 Member States shall ensure that the following minimum requirements are complied with by tissue establishments, including importing tissue establishments as defined by Commission Directive (EU) 2015/566[(3)]: