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L.N. 368 of 2016

HUMAN BLOOD AND TRANSPLANTS ACT (CAP. 483)

Equivalent Standards of Quality and Safety of Imported Tissues and Cells Regulations, 2016

IN exercise of the powers conferred by article 16 of the Human Blood and Transplants Act, the Minister for Health, after consultation with the Licensing Authority, has made the following regulations:-

Citation and scope.

1. (1) The title of these regulations is the Equivalent Standards of Quality and Safety of Imported Tissues and Cells Regulations, 2016.

(2) The scope of these regulations is to transpose Commission Directive 2015/566/EU of 8 April 2015 implementing Directive 2004/23/EC as regards the procedure for verifying the equivalent standards of quality and safety of imported tissues and cells.

(3) These regulations apply to the importation of human tissues and cells for human application and manufactured products derived from human tissues and cells intended for human application:

Provided that these regulations shall not apply to:

(a) the import of tissues and cells provided for under regulation 16 of the Tissues and Cells (Quality and Safety) Regulations; S.L. 483.01

(b) the import of tissues and cells which are directly authorised in case of emergencies;

(c) blood and blood components as defined under the Blood (Quality and Safety) Regulations; and S.L. 483.02

(d) organs and parts of organs as defined under the Tissues and Cells (Quality and Safety) Regulations. S.L. 483.01

Definitions.

2. In these regulations unless the context otherwise requires:

"the Authority" means the Licensing Authority;

"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 Malta for immediate application to a known

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recipient or known recipients whose health would be seriously endangered without such an import;

"importing tissue establishment" means a tissue bank or a unit of a hospital or another body established in Malta which is a party to a contractual agreement with a third country supplier for the import into Malta of tissues and cells coming from a third country intended for human application;

"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 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";

"third country supplier" means a tissue establishment or another body, established in a third country, which is responsible for the export to Malta 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 Malta, of donation, procurement, testing, processing, preservation, storage or distribution of tissue and cells imported into Malta.

Accreditation, designation authorisation or licensing by the Authority.

3. (1) The Authority shall, without prejudice to the provisions of article 1(3), ensure that all imports of tissues and cells from third countries are undertaken by importing tissue establishments accredited, designated, authorised or licensed by it for the purposes of those activities.

(2) The Authority, after having obtained the information set out in Schedule I and after having verified that the importing tissue establishment complies with the relevant legislation, shall:

(a) accredit, designate, authorise or licence the importing tissue establishment to import tissues and cells;

(b) indicate any conditions which apply on the importing tissue establishment such as restrictions on the types of tissues and cells to be imported or the third country supplier to be used; and

(c) issue the importing tissue establishment with the certificate set out in Schedule II.

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Inspections and other control measures of importing tissue establishments.

4. (1) The Authority shall every two years organise inspections and other control measures of importing tissue establishments and, where appropriate, their third country suppliers and ensure that the importing tissue establishment carries out appropriate controls to ensure quality and safety standards of the imported tissues and cells.

Furthermore, the Authority may suspend or revoke the accreditation, designation, authorisation or licence, in whole or in part, of an importing tissue establishment if the inspections or other control measures demonstrate that such importing tissue establishment no longer meets the requirements set out in these regulations.

(2) All inspections and other control measures shall be carried out by an official, duly authorised in writing, who shall have the authority to:

(a) inspect the importing tissue establishment and, where necessary, the activity of any third country supplier;

(b) evaluate and verify the procedure and activities carried out by the importing tissue establishment and the facilities of the third country supplier that are relevant to ensure the quality and safety standards of the tissues and cells to be imported; and

(c) examine any documents or other records that are relevant for the evaluation and verification.

(3) The Authority shall, upon a justified request from another competent authority of another Member State, or from the Commission, provide information on the results of inspection and other control measures relating to importing tissue establishments and third country suppliers. The appropriate measures to be taken shall be decided by the Authority after consulting with the requesting competent authority.

(4) Where an on-site inspection takes place following a request, the Authority shall agree with the requesting competent authority on whether and how such authority shall participate in the inspection. The final decision shall be taken by the Authority upon a reasoned explanation to the requesting competent authority.

Requisites to act as an importing tissue establishment.

5. Before carrying out any activity, importing tissue establishments shall apply for accreditation, designation, authorisation or licence by:

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(a) providing to the Authority the required information and documentation as set out in Schedule I; and

(b) make available and, when requested by the Authority, provide the documentation listed in Schedule III.

Measures to be taken by importing tissue establishments.

6. Importing tissue establishments shall take all measures in order to ensure that any imports of tissues and cells meet the standards and quality and that the imported tissues and cells can be traced from the donor to the recipient and vice versa.

Duties of importing tissue establishments.

7. (1) The importing tissue establishments shall not undertake any substantial changes, such as changes to the types of imported tissues and cells and activities undertaken in third countries which may have an influence on the quality and safety of imported tissues and cells or the third party suppliers, without the prior written approval of the Authority.

(2) When 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 and cells from another country supplier or suppliers.

(3) The importing tissue establishment shall inform the Authority in the case it ceases its import activities in full or in part.

(4) The importing tissue establishment shall notify without delay the Authority of any suspected or actual serious adverse event or reactions reported to them by third country suppliers which may influence the quality and safety of the tissues and cells they import. Such notification shall also include the information set out in Schedules III and IV of the Human Tissues and Cells (Coding, Processing, Preservation, Storage and Distribution) Regulations. S.L. 483.04

(5) The importing tissue establishment shall, without delay, notify the competent authority of:

(a) any revocation or suspension, in whole or in part, of a third country supplier authorisation to export tissues and cells; and

(b) any other decision taken for reasons of non-compliance by the competent authority of the country in which the third country supplier is based and which may be relevant to the quality and safety of the imported tissues and cells.

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Written agreements with third country suppliers.

8. (1) The importing tissue establishment shall enter into written agreement with the third country supplier where any of the activities of donation, procurement, testing, processing, preservation, storage or export to Malta of tissues and cells to be imported into Malta are carried out outside of the Union:

Provided that, where the importing tissue establishment decides not to enter into a written agreement with the third country supplier in the case of one-off imports, the said importing tissue establishment shall ensure that suitable national measures are in place to regulate such imports and that such national measures ensure:

(a) traceability from donor to recipient and vice versa; and

(b) imported tissues and cells are not applied to anyone other than their intended recipients.

(2) The written agreement referred to in sub-article (1) shall specify:

(a) the quality and safety requirements to be met to ensure the quality and safety standards of the tissues and cells to be imported;

(b) the contents listed in Schedule IV; and

(c) the right of the Authority to inspect the activities including the facilities of any third country supplier during the duration of the written agreement and for a period of two years following its termination.

(3) The importing tissue establishment shall provide copies of such written agreement to the Authority, together with the application for accreditation, designation, authorisation or licence provided for under regulation 5.

Register of importing tissue establishments.

S.L. 483.01

9. (1) The importing tissue establishments shall keep a record of their activities, including, but not limited to, the types and quantities of tissues and cells imported, and on their origin and destination. This record shall also include the same information for any one-off imports carried out. The annual report shall include the information provided for under regulation 7 of the Tissues and Cells (Quality and Safety) Regulations.

(2) The Authority shall include the importing tissue establishment in the publicly accessible register of tissue establishments laid down in Article 10(2) of Directive 2004/23/EC.

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(3) Information on the accreditations, designations, authorisations or licence of importing tissue establishment shall also be made available through the network of the registers referred to in Article 10(3) of Directive 2004/23/EC.

SCHEDULE I

Minimum requirements concerning the information and documentation to be provided by importing tissue establishment applicants when applying to be accredited, designated, authorised or licensed for the purpose of import activities

When applying for an accreditation, designation, authorisation or licence for the purpose of import activities, the importing tissue establishment applicant shall, unless already provided as part of previous applications for accreditation, designation, authorisation or licensing as a tissue establishment or importing tissue establishment, provide the most up-to-date information and, for Part F, documentation on the following:

A. General Information on the Importing Tissue Establishment (ITE)

1. Name of the ITE (Company name).

2. Visiting address of the ITE.

3. Postal address of the ITE (*if different*).

4. Status of the applicant ITE: It should be indicated if this is the first application for accreditation, designation, authorisation or licensing as an ITE or, where applicable, whether this is a renewal application. Where the applicant is already accredited, designated, authorised or licensed as a tissue establishment, the TE compendium code should be provided.

5. Name of the applying unit (*if different from the company name*).

6. Visiting address of the applying unit.

7. Postal address of the applying unit (*if different*).

8. Name of the site of reception of imports (*if different from the company name and applying unit*).

9. Visiting address of the site of reception.

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10. Postal address of the site of reception (*if different*).

B. Contact Details for the Application

1. Name of contact person for the application.

2. Telephone number.

3. E-mail address.

4. Name of Responsible Person (*if different from contact person*).

5. Telephone number.

6. E-mail address.

7. URL of ITE website (*if available*).

C. Details of Tissues and Cells to be Imported

1. A list of the types of tissues and cells to be imported, including one-off imports of specific types of tissues or cells.

2. The product name (*where applicable, in accordance with the EU generic list*) of all types of tissues and cells to be imported.

3. The trade name (*if different to the product name*) of all types of tissues and cells to be imported.

4. The name of the third country supplier for each type of tissue and cell to be imported.

D. Location of Activities

1. A list specifying which of the activities of donation, procurement, testing, processing, preservation or storage are carried out prior to import by the third country supplier per type of tissue or cell.

2. A list specifying which of the activities of donation, procurement, testing, processing, preservation or storage are carried out prior to import by sub-contractors of the third country supplier per type of tissue or cell.

3. A list of all activities carried out by the ITE subsequent to import per type of tissue or cell.

4. The names of the third countries in which the activities

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prior to import take place per type of tissue or cell.

E. Details of Third Country Suppliers

1. Name of third country supplier(s) (company name).

2. Name of contact person.

3. Visiting address.

4. Postal address (*if different*).

5. Telephone number including international dialling code.

6. Emergency contact number (*if different*).

7. E-mail address.

F. Documentation to Accompany the Application

1. A copy of the written agreement with the third country supplier(s).

2. A detailed description of the flow of imported tissues and cells from their procurement to their reception at the importing tissue establishment.

3. A copy of the third country supplier’s export authorisation certificate or, where a specific export authorisation certificate is not issued, certification from the relevant third country competent authority or authorities authorising the third country supplier's activities in the tissue and cells sector including exports. This documentation shall also include the contact details of the third country competent authority or authorities. In third countries where such documentation is not available, alternative forms of documentation shall be provided such as reports of audits of the third country supplier.

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SCHEDULE II

Certificate of Accreditation, Designation, Authorisation or Licence to be issued by the competent authority or authorities to importing tissue establishments

Certificate of Accreditation, Designation, Authorisation or Licence of an Importing Tissue Establishment								
1. Importing Tissue Establishment (ITE) Details								
1.1 Name of ITE								
1.2 EU Tissue Establishment Compendium Code								
1.3 ITE Address and postal address *(if different)*								
1.4 Site of reception of imports *(if different from the above address)*								
1.5 Name of accreditation, designation, authorisation or licence holder								
1.6 Address of accreditation, designation, authorisation or licence holder								
1.7 Telephone number of accreditation, designation, authorisation or licence holder *(optional)*								
1.8 E-mail address of accreditation, designation, authorisation or licence holder *(optional)*								
1.9 URL of ITE website								
2. Scope of Activities								
2.1 Type of Tissues and Cells *(list below using categories of tissues and cells listed in the EU Tissue Establishment Compendium adding rows as necessary)*	Activities in third countries						Import Accreditation, Designation, Authorisation or Licence Status	
	Donation	Procurement	Testing	Preservation	Processing	Storage		
	3CS — Third country supplier *SC — Sub-contractor of third country supplier*						*G — Granted* *S — Suspended* *R — Revoked* *C — Cessation*	
2.2 One-off imports							☐	
2.3 Product name(s) of imported tissues and cells								
2.4 Any conditions placed on the import or clarifying remarks								

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2.5 Third country or countries of procurement *(per tissue and cell import)*		
2.6 Third country or countries in which other activities take place *(if different)*		
2.7 Name and country of third country supplier(s) *(per tissue and cell import)*		
2.8 EU Member States in which imported tissues and cells will be distributed *(if known)*		
3. **Competent Authority (CA) Accreditation, Designation, Authorisation or Licence**		
3.1 National accreditation, designation, authorisation or licence number		
3.2 Legal basis of accreditation, designation, authorisation or licence		
3.3 Date of expiry of accreditation, designation, authorisation or licence *(if any)*		
3.4 First accreditation, designation, authorisation or licence as ITE or renewal	First time ☐	Renewal ☐
3.5 Additional remarks		
3.6 Name of CA		
3.7 Name of CA Officer		
3.8 Signature of CA Officer *(electronic or otherwise)*		
3.9 Date of accreditation, designation, authorisation or licence		
3.10 CA Stamp		

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SCHEDULE III

Minimum requirements concerning the documentation to be made available to the competent authority or authorities by tissue establishments intending to import tissues and cells from third countries

With the exception of one-off imports which have been exempted from these documentation requirements, the applicant importing tissue establishment shall make available and, unless already provided as part of previous applications for accreditation, designation, authorisation or licensing as an importing tissue establishment or tissue establishment, shall provide when requested by the competent authority or authorities the most up-to-date version of the following documents regarding the applicant and its third country supplier(s).

A. Documentation relating to the importing tissue establishment

1. A job description of the Responsible Person and details of his/her relevant qualifications and training record as laid down in Tissues and Cells (Quality and Safety) Regulations;

2. A copy of the primary label, repackage label, external package and transport container;

3. A list of relevant and up-to-date versions of standard operating procedures (SOPs) relating to the establishment's import activities including SOPs on applying the Single European Code, reception and storage of imported tissues and cells at the importing tissue establishment, management of adverse events and reactions, management of recalls and traceability from donor to recipient.

B. Documentation relating to the third country supplier or suppliers

1. A detailed description of the criteria used for donor identification and evaluation, information provided to the donor or donor family, how consent is obtained from the donor or donor family and whether the donation was voluntary and unpaid or not;

2. Detailed information on the testing centre(s) used by third country suppliers and the tests performed by such centres;

3. Detailed information on the methods used during the processing of the tissues and cells including details of the validation for the critical processing procedure;

4. A detailed description of the facilities, critical equipment

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and materials and criteria used for quality control and control of the environment for each activity carried out by the third country supplier;

5. Detailed information on the conditions for release of tissues and cells by the third country supplier or suppliers;

6. Details of any sub-contractors used by the third country suppliers including the name, location and activity undertaken;

7. A summary of the most recent inspection of the third country supplier by the third country competent authority or authorities including the date of the inspection, type of inspection and main conclusions;

8. A summary of the most recent audit of the third country supplier carried out by, or on behalf of, the importing tissue establishment.

9. Any relevant national or international accreditation.

SCHEDULE IV

Minimum requirements concerning the contents of written agreements between importing tissue establishments and their third country suppliers

With the exception of one-off imports which have been exempted from these requirements, the written agreement between the importing tissue establishment and the third country supplier shall contain at least the following provisions.

1. Detailed information on the specifications of the importing tissue establishment aimed at ensuring that the quality and safety standards laid down in Tissues and Cells (Quality and Safety) Regulations are met and the mutually agreed roles and responsibilities of both parties in ensuring that imported tissues and cells are of equivalent standards of quality and safety;

2. A clause ensuring that the third country supplier provides the information set out in section B of Schedule III to the importing tissue establishment;

3. A clause ensuring that the third country supplier informs the importing tissue establishment of any suspected or actual serious adverse events or reactions which may influence the quality and

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safety of tissues and cells imported or to be imported by the importing tissue establishment;

4. A clause ensuring that the third country supplier informs the importing tissue establishment of any substantial changes to its activities, including any revocation or suspension, in part or in full, of its authorisation to export tissue and cells or other such decisions of non-compliance by the third country competent authority or authorities, which may influence the quality and safety of tissues and cells imported or to be imported by the importing tissue establishment;

5. A clause guaranteeing the competent authority or authorities the right to inspect the activities of the third country supplier, including on-site inspections, should it wish to do so as part of its inspection of the importing tissue establishment. The clause should also guarantee the importing tissue establishment the right to regularly audit its third country supplier;

6. The agreed conditions to be met for the transport of tissues and cells between the third country supplier and importing tissue establishment;

7. A clause ensuring that donor records relating to imported tissues and cells are kept by the third country supplier or its sub-contractor, in line with EU data protection rules, for 30 years following procurement and that suitable provision is made for their retention should the third country supplier cease to operate;

8. Provisions for the regular review and, where necessary, revision of the written agreement including in order to reflect any changes in the requirements of the EU quality and safety standards laid out in Tissues and Cells (Quality and Safety) Regulations;

9. A list of all standard operating procedures of the third country supplier relating to the quality and safety of imported tissues and cells and a commitment to provide these on request.

Ippubblikat mid-Dipartiment tal-Informazzjoni (doi.gov.mt) — Valletta — ***Published by the Department of Information (doi.gov.mt) — Valletta***
Mitbugħ fl-Istamperija tal-Gvern fuq karta riċiklata — ***Printed at the Government Printing Press on recycled paper***

Prezz/*Price*
€1.17