SECOND SUPPLEMENT TO THE GIBRALTAR GAZETTE

No. 4361 of 20 April, 2017

LEGAL NOTICE NO. 81 OF 2017.

INTERPRETATION AND GENERAL CLAUSES ACT

PUBLIC HEALTH (HUMAN TISSUES, CELLS AND ORGANS) ACT 2009 (AMENDMENT) REGULATIONS 2017

In exercise of the powers conferred upon it by section 23(g)(ii) of the Interpretation and General Clauses Act, and for the purposes of transposing into the law of Gibraltar 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, the Government has made the following Regulations–

Title and commencement.

1. These Regulations may be cited as the Public Health (Human Tissues, Cells and Organs) Act 2009 (Amendment) Regulations 2017 and come into operation on 29 April 2017.

Amendment of the Public Health (Human Tissues, Cells and Organs) Act 2009.

2.(1) The Public Health (Human Tissues, Cells and Organs) Act 2009 is amended in accordance with the provisions of this regulation.

(2) Section 2 is amended as follows-

(a) after the definition of "donation" insert-

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

(b) after the definition of "donor" insert-

""EU Coding Platform" means the IT platform hosted by the European Commission which contains the EU Tissue

Establishment Compendium and the EU Tissue and Cell Product Compendium;

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

"EU tissue establishment code" means the unique identifier for accredited, designated, authorised, or licensed tissue establishments in the European 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 Schedule 11;

"EU Tissue Establishment Compendium" means the register of all tissue establishments which are authorised, licensed, designated or accredited by the competent authority and which contains the information about these tissue establishments as set out in Schedule 12;

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

"expiry date" means the date by which the tissues and cells can be applied, as further defined in Schedule 11;";

(c) after the definition of "partner donation" insert-

""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;";

(d) after the definition of "procurement organisation" insert-

""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 Schedule 11;

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

(e) after the definition of "record" insert-

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

(f) after the definition of "serious adverse reaction" insert-

""Single European Code" or "SEC" means the unique identifier applied to tissues and cells distributed in the European Union. The Single European Code consists of a donation identification sequence and a product identification sequence, as further specified in Schedule 11;"

(g) after the definition of "site" insert-

""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 Schedule 11;";

(h) after the definition of "traceability" insert-

""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 Schedule 11;"

(i) in the definition of "validation" for the full-stop at the end substitute a semicolon;

(j) after the definition of "validation" insert-

""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.".

(3) Section 16 is amended as follows-

(a) subsection (1) is deleted;

(b) subsection (3) is deleted;

(c) subsection (4) is deleted;

(d) after subsection (8) insert-

" (9) 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.

(10) Tissues and cells used for advanced therapy medicinal products shall be traceable under this Act at least until transferred to the manufacturer of the advanced therapy medicinal product.

(11) Procurement teams operating for two or more tissue establishments, which are involved in the retrieval of tissues and cells from deceased donors shall ensure that they have an appropriate traceability system across the procurements.

Single European Code.

16A.(1) Subject to subsection (2), and without prejudice to subsection (3), a Single European Code shall be applied to all tissues and cells distributed for human application.

(2) For other situations where tissues and cells are released for circulation, there shall be included as a minimum, the donation identification sequence to be applied at least in the accompanying documentation.

(3) Subsection (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 the principal Directive;

(c) tissues and cells imported into the European Union in case of emergency authorised directly by the competent authority, as referred to in Article 9(3)b of the principal Directive.

(4) The Single European Code shall comply with the specifications set out in this section and in Schedule 11.

(5) The Single European Code shall be in eye-readable format and shall be preceded by the acronym "SEC", although parallel use of other labelling and traceability systems is possible.

(6) 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.

(7) Tissue establishments, including importing tissue establishments as defined in the Safety of Imported Human Tissues and Cells Regulations 2017, shall ensure that they-

(a) allocate a Single European Code to all tissues and cells requiring application of this code at the latest before their distribution for human application;

(b) allocate a donation identification sequence after procuring the tissues and cells, or when receiving them from a procurement organisation, or when importing tissues and cells

from a third country supplier, and the donation identification sequence shall include-

(i) their EU tissue establishment code as assigned in the EU Tissue Establishment Compendium;

(ii) a unique donation number allocated by the tissue establishment, unless such number is allocated centrally at national level or is a globally unique number as used by the ISBT128 coding system. Where allowed, in case of pooling of tissues and cells, a new donation identification number shall be allocated to the final product; traceability with the individual donations shall be ensured by the tissue establishment in which pooling is carried out;

(c) do not alter the donation identification sequence once it is allocated to tissues and cells released for circulation, unless it is necessary to correct an encoding error; any correction requires proper documentation;

(d) use one of the permitted product coding systems and the corresponding tissue and cell product numbers included in the EU Tissue and Cell Product Compendium at the latest before their distribution for human application;

(e) use an appropriate split number and expiry date. For tissues and cells for which no expiry date is defined, the expiry date shall be 00000000 at the latest before their distribution for human application;

(f) apply the Single European Code on the label of the product concerned in an indelible and permanent manner and mention that code in the relevant accompanying documentation at the

latest before its distribution for human application;

(g) notify the competent authority when-

(i) information contained in the EU Tissue Establishment Compendium requires an update or correction;

(ii) the EU Tissue and Cell Product Compendium requires an update;

(iii) the tissue establishment observes a situation of significant non-compliance with the requirements relating to the Single European Code concerning tissues and cells received from other EU tissue establishments;

(h) take the necessary measures in case of incorrect application of the Single European Code on the label.

(8) The tissue establishment may entrust the task in paragraph 16A(7)(f) to a third party, provided the tissue establishment ensures compliance with this Act, in particular in terms of uniqueness of the code.

(9) In regards to paragraph 16A(7)(f), where the label size precludes the application of the Single European Code on the label, the code shall be unambiguously linked to tissues and cells packaged with such a label through the accompanying documentation;

(10) The competent authority shall-

(a) subject to subsections (11) and (12), ensure that a unique tissue establishment number is allocated to all tissue establishments that are authorised, accredited, designated or licensed in Gibraltar;

(b) decide which system or systems shall be used for the allocation of unique donation numbers;

(c) monitor and enforce the full implementation of the Single European Code;

(d) ensure the validation of the data on the tissue establishments contained in the EU Tissue Establishment Compendium and update the Compendium without undue delay in particular in the following situations-

(i) when a new tissue establishment is authorised, designated, accredited, or licensed;

(ii) when tissue establishment information changes or is not correctly recorded in the EU Tissue Establishment Compendium;

(iii) when the accreditation, designation, authorisation or licence details of a tissue establishment, as listed in Schedule 12, change, including-

(A) accreditation, designation, authorisation or licence for a new tissue or cell type;

(B) accreditation, designation, authorisation or licence for a new prescribed activity;

(C) details of any conditions and or exemptions added to an authorisation;

(D) suspension, in part or in full, of a specific accreditation,

designation, authorisation or licence for a particular activity or tissue or cell type;

(E) revocation, in part or in full, of an accreditation, designation, authorisation or licence for a tissue establishment;

(F) situations when a tissue establishment voluntarily ceases, in part or in full, the activity or activities for which it is authorised, accredited, designated or licensed;

(e) alert the competent authority of a Member State when they observe incorrect information in the EU Tissue Establishment Compendium relating to the Member State or when they observe a situation of significant non-compliance with the provisions relating to the Single European Code relating to the Member State;

(f) alert the European Commission and the competent authorities of Member States when in their assessment the EU Tissue and Cell Product Compendium requires an update.

(11) If a tissue establishment has different physical locations, but has one system for allocating unique donation numbers, it may be deemed to be one and the same tissue establishment.

(12) If a tissue establishment uses two or more systems to allocate unique donation numbers, such an entity shall be allocated separate tissue establishment numbers corresponding to the number of allocation systems used.

(13) In this section "without undue delay" means not later than 10 working days for any changes substantially affecting the authorisation, accreditation, designation or licence of the tissue establishments concerned.

(14) The application of the Single European Code does not preclude the additional application of other codes in accordance with Gibraltar requirements.

(15) The following tissues and cells are exempted from the obligations relating to the Single European Code-

(a) tissues and cells already in storage on 29 October 2016, provided the tissues and cells are released for circulation in the European Union within five years following that date and under the condition that full traceability is ensured by alternative means;

(b) tissues and cells which remain in storage and which are only released for circulation after the expiry of the five-year period in paragraph (a) and for which the application of the Single European Code is not possible, in particular because the tissues and cells are stored under deep-freeze conditions,

and instead the tissue establishment shall use the procedures applicable to products with small labels as laid down in subsection (9).".

(4) Section 26 is amended as follows-

(a) in subsection (1) delete the second use of "(other than subsection (3))";

(b) in subsection (3) for "section 16(3)" substitute "16A".

(5) Schedule 6 is amended as follows-

(a) in Part E at paragraph (f) for "marked as:" substitute "marked as BIOLOGICAL HAZARD;";

(b) in Part E after paragraph (f) delete "BIOLOGICAL HAZARD." and insert-

"(g) Single European Code as applicable to the tissues and cells being distributed for human application or the donation identification sequence as applicable to the tissues and cells released for circulation, other than distributed for human application.";

(c) in Part E at the proviso after paragraph (g) for "under points (d) and (e)" substitute "under points (d), (e) and (g)";

(d) in Part E at paragraph 2(i) for the full-stop substitute a semi-colon;

(e) in Part E after paragraph 2(i) insert-

"(j) for imported tissues and cells, the country of procurement and the exporting country (if different from the procurement country).".

(6) For Schedule 7 substitute-

"SCHEDULE 7

Section 11(3)

NOTIFICATION OF SERIOUS ADVERSE REACTIONS

PART A

Rapid notification for suspected serious adverse reactions

Tissue establishment
EU tissue establishment code (if applicable)
Report identification

Reporting date (year/month/day)
Individual affected (recipient or donor)
Date and place of procurement or human application (year/month/day)
Unique donation identification number
Date of suspected serious adverse reaction (year/month/day)
Type of tissues and cells involved in the suspected serious adverse reaction
Single European Code of tissues or cells involved in the suspected serious adverse reaction (if applicable)
Type of suspected serious adverse reaction(s)

PART B

Conclusions of Serious Adverse Reactions Investigation

Tissue establishment
EU tissue establishment code (if applicable)
Report identification
Confirmation date (year/month/day)
Date of serious adverse reaction (year/month/day)
Unique donation identification number

Confirmation of serious adverse reaction (Yes/No)
Single European Code of tissues or cells involved in the confirmed serious adverse reaction (if applicable)
Change of type of serious adverse reaction (Yes/No) If YES, specify
Clinical outcome (if known) — Complete recovery — Minor sequelae — Serious sequelae — Death
Outcome of the investigation and final conclusions
Recommendations for preventive and corrective actions

".

(7) In Parts A and B of Schedule 8 below the row entitled "Tissue establishment" insert a new row entitled "EU tissue establishment code (if applicable)".

(8) For Schedule 10 substitute-

"**SCHEDULE 10**

Section 16(8)

Minimum data to be kept in accordance with Article 9(2)

A. BY TISSUE ESTABLISHMENTS

(1) Donor identification

(2) Donation identification that will include at least:

-Identification of the procurement organisation (including contact details) or the tissue establishment

-Unique donation number

-Date of procurement

-Place of procurement

-Type of donation (e.g. single v multi-tissue; autologous v allogenic; living v deceased)

(3) Product identification that will include at least:

-Identification of the tissue establishment

-Type of tissue and cell/product (basic nomenclature)

-Pool number (in case of pooling)

-Split number (if applicable)

-Expiry date (if applicable)

-Tissue/cell status (i.e. quarantined, suitable for use, etc.)

-Description and origin of the products, processing steps applied, materials and additives coming into contact with tissues and cells and having an effect on their quality and/or safety

-Identification of the facility issuing the final label

(4) Single European Code (if applicable)

(5) Human application identification that will include at least:

-Date of distribution/disposal

-Identification of the clinician or end-user/facility

B. BY ORGANISATIONS RESPONSIBLE FOR HUMAN APPLICATION

(1) Identification of the supplier tissue establishment

(2) Identification of the clinician or end-user/facility

(3) Type of tissues and cells

(4) Product identification

(5) Identification of the recipient

(6) Date of application

(7) Single European Code (if applicable)".

(9) For Schedule 11 substitute-

"**SCHEDULE 11**

Section 16A(4)

THE STRUCTURE OF THE SINGLE EUROPEAN CODE

DONATION IDENTIFICATION SEQUENCE			**PRODUCT IDENTIFICATION SEQUENCE**			
EU TISSUE ESTABLISHMENT CODE		UNIQUE DONATION NUMBER	PRODUCT CODE		SPLIT NUMBER	EXPIRY DATE (YYYYMMDD)
ISO country code	Tissue establishment number		Product Coding System identifier	Product number		
2 alphabetic characters	6 alpha-numeric characters	13 alpha-numeric characters	1 alphabetic character	7 alpha-numeric characters	3 alpha-numeric characters	8 numeric characters

".

(10) After Schedule 11 insert-

"Schedule 12

Data to be recorded in the EU Tissue Establishment Compendium

A. Tissue establishment information

1. Name of the tissue establishment

2. National or international code of tissue establishment

3. Name of the organisation in which the tissue establishment is located (if applicable)

4. Address of the tissue establishment

5. Publishable contact details: functional e-mail address, phone and fax

B. Details on the authorisation, accreditation, designation, or license of the tissue establishment

1. Name of the authorising, accrediting, designating or licensing competent authority or authorities

2. Name of the national competent authority or authorities responsible for maintenance of the EU Tissue Establishment Compendium

3. Name of the authorisation, accreditation, designation or licence holder (if applicable)

4. Tissues and cells for which the authorisation, accreditation, designation or license was granted

5. Activities actually carried out for which the authorisation, accreditation, designation or licence was granted

6. Status of the authorisation, accreditation, designation or license (authorised, suspended, revoked, in part or in full, voluntary cessation of activities)

7. Details of any conditions and exemptions added to the authorisation (if applicable)".

Dated 20th April, 2017.

N F COSTA,
For the Government.

EXPLANATORY MEMORANDUM

These Regulations transpose into the law of Gibraltar 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.