SECOND SUPPLEMENT TO THE GIBRALTAR GAZETTE

No. 4913 GIBRALTAR Thursday 4th November 2021

LEGAL NOTICE NO.445 OF 2021

EUROPEAN UNION (WITHDRAWAL) ACT 2019

HUMAN TISSUE AND ORGANS (QUALITY AND SAFETY FOR HUMAN APPLICATION) (AMENDMENT) (EU EXIT) REGULATIONS 2021

In exercise of the powers conferred upon her by section 11 and paragraph 1(b) of Schedule 3 of the European Union (Withdrawal) Act 2019 the Minister has made the following Regulations-

Title.

1. These Regulations may be cited as the Human Tissue and Organs (Quality and Safety for Human Application)(Amendment) (EU Exit) Regulations 2021.

Commencement.

2. These Regulations come into operation on the day of publication.

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

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

(2) In section 1A, omit the definition of "Commission".

(3) In section 2-

(a) in subsection (1)-

(i) omit the definitions of-

"donation identification sequence";
"EU Coding Platform";
"EU Tissue and Cell Product Compendium";
"EU tissue establishment code";
"EU Tissue Establishment Compendium"
"EUTC";
"expiry date";
"product code";
"product identification sequence";
"released for circulation";

"Single European Code";
"split number";
"unique donation number";
"within the same centre";

(ii) after the definition of "storage" insert-

""third country" means any country or territory other than Gibraltar;";

(b) after subsection (2) insert-

"(3) For the purposes of this Act any requirement of the principal or implementing Directives is to be read as a reference to a requirement which that provision is expressed as requiring to be imposed (ignoring the fact that the Directives do not form part of domestic law).".

(4) In section 4(1) for "implementing Community obligations" substitute "or retained EU law".

(5) Omit section 5(3).

(6) In section 6-

(a) for subsection (1)(a) substitute-

"(a) complies with the requirements for the accreditation, designation, authorisation or licensing of tissue establishments set out in this Act or regulations made under this Act; and";

(b) omit subsection (2);

(c) in subsection (12)(a), after "Article 28(g) of the principal Directive" insert "and Schedule 6".

(7) In section 8, in subsection (2)(b), after "in any Member State" insert ", the United Kingdom or Gibraltar".

(8) In section 10(1)(a) after "Article 28(c) of the principal Directive" insert "and Schedule 5".

(9) In section 14-

(a) in subsections (8)(b) and (e), after "Article 28(h) of the principal Directive" insert "and Schedule 6";

(b) in subsection 11(b), after "Article 28(h) of the principal Directive" insert "and Schedule 6".

(10) In section 16-

(a) for subsection (1) substitute-

"(1) Every tissue establishment shall ensure that it has in place an effective and accurate system to uniquely identify, trace and label all tissues and cells, which it procures, processes, stores or distributes, from donor to end user, or disposal, and vice versa, and this traceability will also apply to all relevant data relating to products and materials coming into contact with these tissues and cells.";

(b) in subsection (6)(a), for "the European Union" substitute "Gibraltar";

(c) omit subsection (9).

(11) Omit section 16A.

(12) In section 21, omit subsections (6), (8) and (9).

(13) Omit section 24(3).

(14) Omit section 25.

(15) Omit section 26(3).

(16) In section 27, for "country or territory outside the European Union" substitute "third country".

(17) After section 27 insert-

"**Power to make regulations in relation to standards of quality and safety**.

27A.(1) The Minister may, by regulations make provision specifying requirements to be met for the purposes of ensuring traceability.

(2) The Minister may by regulations make provision in relation to the notification of serious adverse events and reactions (whether to the Minister for Health or such other person as may be specified in the regulations).

(3) The Minister may by regulations make provision specifying requirements to be met for the purposes of verifying that standards of quality and safety equivalent to those required by this Act apply in relation to imports by tissue establishments of tissues and cells from third countries.

(4) The Minister may by regulations prescribe technical requirements in relation to the following-

(i) the licensing or authorisation of tissue establishments;

(ii) the procurement of tissues or cells;

(iii) selection criteria for the donor of tissues or cells;

(iv) laboratory tests required for donors;

(v) procedures for the receptions of tissues and cells at the tissue establishment;

(vi) the tissue and cell preparation process;

(vii) tissue and cell processing, storage and distribution;

(viii) the direct distribution to the recipient of specific tissues and cells.

(5) Any power in this regulation to make regulations includes a power to make-

(a) different provision for different purposes;

(b) consequential, supplementary, incidental, transitional, transitory or saving provision.".

(18) Omit section 28.

(19) In section 28B-

(a) the existing text becomes subsection (1);

(b) omit the definition of-

"European organ exchange organisation";

(c) after subsection (1) insert-

"(2) In this Act, a reference to ensuring compatibility with the provisions of the Act includes a reference to ensuring compatibility with the principles set out in Article 13 of the Organ Directive.".

(20) In section 28C-

(a) in subsection (3)(f), for "European Union" substitute "retained EU law";

(b) in subsection (4), omit ", European organ exchange organisations".

(21) In section 28E(4)(b), for "European Union" substitute "retained EU law".

(22) In section 28I-

(a) in subsection (1)(a) for "applicable European Union measure" substitute "retained EU law";

(b) omit subsection (2).

(23) In section 28K(3), for "European Union measure" substitute "retained EU law".

(24) In section 28M(2)(b), for "European Union" substitute "retained EU law".

(25) In section 28N-

(a) omit subsections (1) and (2);

(b) for subsection (3) substitute-

"(3) The Authority shall ensure that any organs sent to, or received from countries outside Gibraltar can-

(a) be traced from the donor to the recipient;

(b) meet quality and safety standards that are equivalent to those required by this Part.";

(c) in subsection (4) for "countries that are not in the European Union" substitute "third countries".

(26) In section 28O-

(a) in the title omit "European" and "organisations";

(b) omit subsections (1), (2), (3) and (6);

(c) in subsection (5) omit "and the European organ exchange organisations".

(27) Omit section 28W.

(28) In section 29(1)-

(a) in paragraph (b), omit "or any European Union Directive or Regulation"

(b) after paragraph (c) insert-

"(2) The Minister may by regulations amend–

(a) the minimum data set specified in Schedule 12 (organ and donor characterisation) where the Authority considers, on the basis of

scientific evidence, that the amendment is justified by a serious risk to human health;

(b) the complementary data set specified in Schedule 12 where the Authority considers, on the basis of scientific evidence, that it is appropriate to do so.".

(29) In Schedule 6-

(a) in paragraph E-

(i) omit paragraph (g);

(ii) for "points (d),(e) and (g)" substitute "points (d) and (e)";

(b) in paragraph (2), omit (j).

(30) In Schedule 7-

(a) in Part A, omit the following entries-

"EU tissue establishment code (if applicable)";

"Single European Code of tissues or cells involved in the suspected serious adverse reaction (if applicable)";

(b) in Part B, omit the following entries-

"EU tissue establishment code (if applicable)";

"Single European Code of tissues or cells involved in the confirmed serious adverse reaction (if applicable)".

(31) In Schedule 8, in Parts A and B, omit "EU tissue establishment code (if applicable)".

(32) In Schedule 10-

(a) for the title substitute "Information on the minimum donor or recipient (or both) data set to be kept";

(b) in part A-

(i) in point (2) for "Unique donation number" substitute "Unique donation ID number";

(ii) omit point (4);

(c) in part B, omit point (7).

(33) Omit Schedules 11 and 11A.

Amendment of the Safety of Imported Human Tissues and Cells Regulations 2017.

4.(1) The Safety of Imported Human Tissues and Cells Regulations 2017 are amended in accordance with this regulation.

(2) In regulation 2-

(a) in subregulation (1)(b), for "European Union legislation" substitute "retained EU law";

(b) in subregulation (2)-

(i) omit "not";

(ii) for "European Union legislation" substitute "retained EU law";

(iii) for "outside of the European Union" substitute "outside Gibraltar".

(3) In regulation 3-

(a) omit the definition of "Directive 2006/86/EC";

(b) in the definition of "emergency", for "the European Union" substitute "Gibraltar";

(c) in the definition of "importing tissue establishment"-

(i) for "within the European Union" substitute "in Gibraltar";

(ii) for "the European Union" substitute "Gibraltar";

(d) in the definition of "principal Directive", after "cells" insert "as it had effect immediately before 1 January 2021";

(e) after the definition of "principal Directive" insert-

""third country" means any country or territory other than Gibraltar;

"third country competent authority" means the authority or authorities in the third country responsible for regulating tissue establishments in that country";";

(f) in the definition of "third country supplier" for "the European Union" on the three occasions it appears, substitute "Gibraltar".

(4) In regulation 4(4), for "the certificate set out in Schedule 2" substitute "a certificate in such form as the competent authority considers appropriate".

(5) Omit regulation 5(4) to (8).

(6) For regulation 7(4) substitute-

"(4) Pursuant to subregulation (3), the information laid out in Schedules 7 and 8 of the Public Health (Human Tissues, Cells and Organs) Act 2009 shall be included in such notifications.".

(7) In regulation 8-

(a) in subregulation (1), for "of the European Union" substitute "Gibraltar";

(b) in paragraph (g) for "export to the European Union" substitute "export to Gibraltar";

(c) after subregulation (1) insert-

"(1A) The requirement set out in subregulation (1) does not apply to one-off imports as defined in regulation 3 provided that the applicant has provided the competent authority with any information or documents as may be specified by the competent authority for the purposes of demonstrating-

(i) traceability;

(ii) that the import is a one-off import within the meaning of regulation 3.".

(8) In regulation 9-

(a) in subregulation (3), omit "annual";

(b) after subregulation (3), insert-

"(3A) Article 10 of the principal Directive shall be read as if -

(a) for the reference to "the requirements referred to in Article 28(f) there were substituted a reference to "the requirements in Schedule 4 of the Public Health (Human Tissues, Cells and Organs) Act 2009";

(b) the reference to the competent authority were a reference to the Minister for Health;

(c) for "an annual report on these activities" there were substituted "a report on these activities upon request";

(d) the words "This report shall be publicly accessible" were omitted.";

(c) omit subregulations (4) and (5).

(9) In Schedule 1-

(a) in section A, paragraph 4, for "TE compendium code" substitute "reference number previously allocated to the tissue establishment by the competent authority";

(b) in section B, paragraph 4, for "Responsible Person" substitute "person appointed under section 8 of the Public Health (Human Tissues, Cells and Organs) Act 2009;

(c) in section C, paragraph 2, omit "(where applicable, in accordance with the EU generic list)".

(10) Omit Schedule 2.

(11) In Schedule 3, section A-

(a) in paragraph 1 for "principal Directive" substitute "Public Health (Human Tissues, Cells and Organs) Act 2009";

(b) in paragraph 3 omit "applying the Single European Code".

(12) In Schedule 4-

(a) in paragraph 1, for "laid down in the principal Directive" substitute "required by the Public Health (Human Tissues, Cells and Organs) Act 2009";

(b) in paragraph 8, for "requirements of the EU quality and safety standards laid out in the principal Directive" substitute "quality and safety standards required by the Public Health (Human Tissues, Cells and Organs) Act 2009".

Dated: 4th November 2021.

S.SACRAMENTO,
Minister with Responsibility for Health.

EXPLANATORY NOTE

These Regulations are made in exercise of the powers conferred by section 11 of the European Union (Withdrawal) Act 2019 in order to address failures of EU law to operate effectively and other deficiencies arising from the withdrawal of the United Kingdom and Gibraltar from the European Union.

These Regulations make amendments to legislation concerning human tissue, cells and organs intended for use in human application. These Regulations amend legislation relating to technical requirements for the storage, procurement, testing, processing, distribution of tissues, cells and organs into, and their import to and export from, Gibraltar.