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

Principal Act

Act. No. 2009-53

Commencement 1.12.2009
Assent 21.12.2009

Transposing:
Directive 2004/23/EC
Directive 2006/17/EC
Directive 2006/86/EC
Directive 2010/53/EU

ARRANGEMENT OF SECTIONS

Section

AN ACT TO TRANSPOSE INTO THE LAW OF GIBRALTAR 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; COMMISSION DIRECTIVE 2006/17/EC OF 8 FEBRUARY 2006 IMPLEMENTING DIRECTIVE 2004/23/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL AS REGARDS CERTAIN TECHNICAL REQUIREMENTS FOR THE DONATION, PROCUREMENT AND TESTING OF HUMAN TISSUES AND CELLS; COMMISSION DIRECTIVE 2006/86/EC OF 24 OCTOBER 2006 IMPLEMENTING DIRECTIVE 2004/23/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL AS REGARDS TRACEABILITY REQUIREMENTS, NOTIFICATION OF SERIOUS ADVERSE REACTIONS AND EVENTS AND CERTAIN TECHNICAL REQUIREMENTS FOR THE CODING, PROCESSING, PRESERVATION, STORAGE AND DISTRIBUTION OF HUMAN TISSUES AND CELLS; AND FOR CONNECTED PURPOSES.

Title and commencement.

1. This Act may be cited as the Public Health (Human Tissues and Cells) Act 2009 and shall be deemed to have come into operation on 1 December 2009.

Interpretation.

2.(1) In this Act, unless the context otherwise requires–

"allogeneic use" means cells or tissues removed from one person and applied to another;

"authorised person" means a person appointed under section 22(1);

"autologous use" means cells or tissues removed from and applied in the same person;

"cells" means individual human cells or a collection of human cells when not bound by any form of connective tissue;

"Commission" means the European Commission;

"critical" means potentially having an effect on the quality or safety or both of or having contact with the cells and tissues;

"direct use" means any procedure where cells are donated and used without any banking;

"distribution" means transportation and delivery of tissues or cells intended for human applications;

"donation" means donating human tissues or cells intended for human applications;

"donor" means every human source, whether living or deceased, of human cells or tissues;

"functions" includes powers and duties, and references to the performance of functions include, with respect to powers and duties, references to the exercise of powers and the carrying out of the duties;

"Gibraltar Health Authority" means the Gibraltar Health Authority established by section 3 of the Medical (Gibraltar Health Authority) Act, 1987;

"human application" means the use of tissues or cells on or in a human recipient and extra-corporal applications;

"implementing Directives" means Commission Directive 2006/17/EC of 8 February, 2006, implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells and Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells;

"inspect" includes search;

"inspection" means formal and objective control to identify problems in accordance with standards adopted to assess compliance with this Act;

"Minister" means the Minister with responsibility for Health;

"organ" means a differentiated and vital part of the human body, formed by different tissues, that maintains its structure, vascularisation and capacity to develop physiological functions with an important level of autonomy;

"organisation responsible for human application" means a health care establishment or a unit of a hospital or another body which carries out human application of human tissues and cells;

"partner donation" means the donation of reproductive cells between a man and a woman who declare that they have an intimate physical relationship;

"premises" means any place, ship or other vessel, aircraft, railway wagon or other vehicle, and includes a container used to transport relevant things;

"prescribed activity" means an activity to which this Act applies, and that is specified in section 4(1);

"preservation" means the use of chemical agents, alterations in environmental conditions or other means during processing to prevent or retard biological or physical deterioration of cells or tissues;

"principal Directive" means Directive 2004/23/EC of the European Parliament and of the Council of 31 March, 2004 setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells;

"processing" means all operations involved in the preparation, manipulation, preservation and packaging of tissues or cells intended for human applications;

"procurement" means a process by which tissue or cells are made available;

"procurement organisation" means a health care establishment or a unit of a hospital or another body that undertakes the procurement of human tissues and cells and that may not be accredited, designated, authorised or licensed as a tissue establishment;

"quality management" means the coordinated activities to direct and control an organisation with regard to quality;

"quality system" means the organisational structure, defined responsibilities, procedures, processes, and resources for implementing quality management and includes all activities which contribute to quality, directly or indirectly;

"quarantine" means the status of retrieved tissue or cells, or tissue isolated physically or by other effective means, whilst awaiting a decision on their acceptance or rejection;

"record" includes, in addition to a record in writing–

(a) a disc, tape, sound-track or other device in which information, sounds or signals are embodied so as to be capable (with or without the aid of some other instrument) of being reproduced in legible or audible form;

(b) a film, tape or other device in which visual images are embodied so as to be capable (with or without the aid of some other instrument) of being reproduced in visual form; and

(c) a photograph;

and any reference to a copy of a record includes–

(i) in the case of a record to which paragraph (a) of this definition applies, a transcript of the sounds or signals embodied therein;

(ii) in the case of a record to which paragraph (b) of this definition applies, a still reproduction of the images embodied therein; and

(iii) in the case of a record to which paragraphs (a) and (b) of this definition apply, such a transcript together with such a still reproduction;

"relevant thing" means–

(a) any tissue or cells; or

(b) any article or substance used in the donation, procurement, processing preservation or storage of any tissue or cells or products manufactured from tissues and cells;

"reporting year" means the period of 12 months ending on 31 December;

"reproductive cells" means all tissues and cells intended to be used for the purpose of assisted reproduction;

"responsible person", in relation to a tissue establishment, means the person who has been designated under section 8 as the responsible person for that tissue establishment;

"serious adverse event" means any untoward occurrence associated with the procurement, testing, processing, storage or distribution of tissues and cells–

(a) that might lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions for patients; or

(b) which might result in, or prolong, hospitalisation or morbidity;

"serious adverse reaction" means an unintended response, including a communicable disease, in the donor or in the recipient associated with procurement or human application of tissues and cells–

(a) that is fatal, life-threatening, disabling or incapacitating; or

(b) which results in, or prolongs, hospitalisation or morbidity;

"site" means any premises at which any prescribed activity or activities are carried out;

"Standard Operating Procedures" (SOPs) means written instructions describing the steps in a specific process, including the materials and methods to be used and the expected end product;

"storage" means maintaining the tissues and cells under appropriate controlled conditions until distribution;

"tissue" means all constituent parts of the human body formed by cells;

"tissue establishment" means a tissue bank or a unit of a hospital or another body where activities of processing, preservation, storage or distribution of human tissues and cells are undertaken which may also be responsible for procurement or testing of tissues and cells;

"traceability" means the ability to locate and identify the tissue or cell or both during any step from procurement, through processing, testing and storage, to distribution to the recipient or disposal, which also implies the ability to identify the donor and the tissue establishment or the manufacturing facility receiving, processing or storing the tissue or cells or both and the ability to identify the recipients at the medical facility or facilities applying the tissue or cells or both to the recipients; traceability also covers the ability to locate and identify all relevant data relating to products and materials coming into contact with those tissues or cells or both;

"validation" (or 'qualification' in the case of equipment or environments) means establishing documented evidence that provides a high degree of assurance that a specific process, SOP, piece of equipment or environment will consistently produce a product meeting its predetermined specifications and quality attributes; a process is validated to evaluate the performance of a system with regard to its effectiveness based on intended use.

(2) Any term used but not defined in this Act shall be construed in accordance with the provisions of the principal Directive and the implementing Directives.

Designation of the competent authority.

3.(1) The Minister is designated as the competent authority for the purpose of this Act.

(2) The Minister may enter into a contractual arrangement with a person for the purpose of that person assisting the Minister to perform any of his functions as competent authority under this Act.

Application of the Act.

4.(1) This Act shall, subject to subsection (2), apply to any activity as prescribed in this subsection that consists of any aspect of–

(a) the donation, procurement, testing, processing, preservation, storage or distribution of tissues or cells intended for human applications;

(b) the donation, procurement, testing, processing, preservation, storage or distribution of manufactured products derived from tissues and cells intended for human consumption,

save that, where manufactured products referred to in paragraph (b) are covered by other laws of Gibraltar implementing Community obligations, this Act shall only apply to the donation, procurement and testing of such manufactured products.

(2) This Act shall not apply to–

(a) tissues and cells used as an autologous graft within the same surgical procedure;

(b) blood and blood components as defined by the Public Health (Blood Safety and Quality) Act 2007;

(c) organs or parts of organs if it is their function to be used for the same purpose as the entire organ in the human body.

(3) This Act shall apply to tissues and cells that are applied to the human body in clinical trials.

(4) This Act shall apply to the coding, processing, preservation, storage and distribution of–

(a) human tissues and cells intended for human applications; and

(b) manufactured products derived from human tissues and cells intended for human applications, where those products are not covered by other EC Directives.

(5) The provisions of sections 5(2)(b), 9(1)(c) and 10(6) to (8) of this Act concerning traceability and the reporting of serious adverse reactions and events, shall also apply to the donation, procurement and testing of human tissues and cells.

(6) This Act shall apply without prejudice to the Data Protection Act 2004 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

Requirements for authorisation.

5.(1) No person shall carry out any prescribed activity–

(a) unless that person has been granted an authorisation under section 6; and

(b) otherwise than in accordance with any conditions to which the authorisation is subject.

(2) Tissue establishments shall comply with–

(a) the requirements for the accreditation, designation, authorisation or licensing of tissue establishments as required by Article 28(a) of the principal Directive; and

(b) the requirements set out in Schedule 5.

(3) Pending a decision on the requirements of Article 28(a) of the principal Directive, tissue establishments shall comply with the standards set by the competent authority under section 6(2).

Authorisation of tissue establishment or procurement, organisations.

6.(1) Subject to subsection (2), the competent authority may grant an authorisation to a tissue establishment to carry out any prescribed activity at a specified site or sites, having satisfied itself that the tissue establishment–

(a) complies with the requirements referred to in Article 28(a) of the principal Directive; and

(b) complies with other relevant requirements of the implementing Directives and this Act.

(2) Pending decisions on the requirements pursuant to paragraphs (a), (c), (g) and (h) of Article 28 of the principal Directive, the competent authority shall set appropriate standards of quality and safety in respect of the matters referred to in paragraphs (a), (c), (g) and (h) of Article 28 of the principal Directive and the competent authority will have regard to these standards in respect of the matters referred to in those paragraphs when granting authorisations until such decisions have been made.

(3) An application for authorisation under subsection (1) shall be made to the competent authority.

(4) All applications for authorisation shall–

(a) include all relevant information as determined by the competent authority; and

(b) be accompanied by the prescribed fee.

(5) The competent authority may–

(a) grant or refuse any authorisation applied for under subsection (3); and

(b) grant such authorisation–

(i) in respect of particular sites or prescribed activities only; and

(ii) subject to conditions.

(6) Where the competent authority grants an authorisation, in the case of prescribed activities the competent authority shall give notice in writing to the tissue establishment specifying the prescribed activities which the tissue establishment may undertake under this Act at each site in respect of which authorisation is granted, and if the grant is subject to conditions, the conditions which apply to the undertaking of those activities.

(7) Subject to the requirements of subsection (8), the competent authority may at any time remove or vary any of the conditions referred to in subsection 5(b)(ii), or may impose additional conditions.

(8) Where the competent authority removes or varies any condition or imposes any additional condition under subsection (7), the competent authority shall serve a notice on the tissue establishment concerned which shall–

(a) give details of the conditions which the competent authority proposes to remove, or of the variation which he proposes to make to any existing conditions, or of any additional condition which he proposes to impose;

(b) give the reasons for his decision; and

(c) specify the date, which shall be not less than 14 days from the date on which the notice is served, from which the removal or variation of any condition, or the imposition of any additional condition shall apply.

(9) A tissue establishment shall not make any substantial change in the prescribed activities which it undertakes without the prior written approval of the competent authority.

(10) Any application by a tissue establishment for approval to make a substantial change in its activities shall be–

(a) made in writing to the competent authority; and

(b) accompanied by the prescribed fee.

(11) For the purpose of this section, a substantial change in a tissue establishment's activities is any change–

(a) to the site or sites from which the tissue establishment operates or to the prescribed activities to be carried out at each site, and which would result in a failure to comply with the requirements of this Act; or

(b) to the quality system, as set out in accordance with Article 28(c) of the principal Directive, which is likely to have a substantial impact on the conduct of, or might compromise the safety of, any of the prescribed activities which the tissue establishment has been authorised to undertake under this section.

(12) The competent authority may authorise–

(a) the tissue and cell preparation processes, which the tissue establishment may carry out in accordance with the requirements set out in Article 28(g) of the principal Directive;

(b) the direct distribution of specific tissues and cells from where the procurement is carried out to a health care establishment for immediate transplantation in accordance with the requirements set out in Article 28(i) of the principal Directive;

(c) the procurement of tissues and cells in accordance with the requirements of this Act in respect of procurement organisations; and

(d) the laboratories that carry out the tests required for donors in accordance with this Act.

Suspension or revocation of authorisation.

7.(1) Subject to subsection (2), the competent authority may suspend or revoke the authorisation of a tissue establishment in respect of a site or sites or prescribed activity or both, on one or more of the following grounds–

(a) that the tissue establishment or process has not complied with the requirements of this Act;

(b) that a prescribed activity has not been or cannot be carried out pursuant to the requirements of this Act;

(c) that any tissues or cells cannot be supplied to hospitals for human application in such a state that they could be safely used; or

(d) that the information given by the tissue establishment under sections 6(4) and 19(3*)* was false or incomplete in any material respect.

(2) Subject to subsection (3), before suspending or revoking the authorisation of a tissue establishment, the competent authority shall serve notice on the tissue establishment stating that it intends to suspend or revoke the authorisation with effect from the date specified in the notice which shall be not less than 7 days from the date on which the notice is served.

(3) Where the competent authority considers that it is necessary in the interests of safety, it may, by a notice served on a tissue establishment, suspend or revoke its authorisation with immediate effect.

(4) Where–

(a) the tissue establishment has failed, in any material respect, to comply with the requirements of this Act; or

(b) the information given by the tissue establishment under sections 6(4) and 19(3) was false or incomplete in any material respect,

and the competent authority considers that the failure in question is not sufficiently serious to warrant suspension or revocation of the authorisation of the tissue establishment in the first instance, the competent authority may serve a notice on the responsible person of the tissue establishment in accordance with subsection (5).

(5) A notice served under this subsection shall–

(a) identify the requirements of this Act in respect of which the tissue establishment has failed to comply with or, in the case of false or incomplete information, the further information which is required;

(b) identify the action which the tissue establishment is required to take; and

(c) give the timescale within which the tissue establishment shall take the action identified in paragraph (b).

(6) If the tissue establishment fails to comply with the requirements set out in the notice within the specified timescale, the competent authority may, by a notice served on the tissue establishment, suspend or revoke the authorisation of the tissue establishment.

(7) A suspension or revocation under subsection (6*)* shall take effect–

(a) in a case where the competent authority considers that it is necessary in the interests of safety, immediately; or

(b) in all other cases, from a date specified in the notice.

(8) Any suspension under subsection (1*)* or (6) shall be for such period as the competent authority shall consider necessary having regard to the reasons for the suspension.

(9) The suspension or revocation of an authorisation under subsection (1) or (6) may be total, or may be limited to a particular prescribed activity or to one or more prescribed activities carried out at a particular site or sites, or to a particular tissue or cell.

Responsible person for tissue establishment.

8.(1) Subject to subsection (2), a tissue establishment shall designate a person who is responsible for the following functions–

(a) ensuring that all prescribed activities are carried out in accordance with the requirements of this Act;

(b) providing information to the competent authority as required under section 6; and

(c) the implementation in the tissue establishment of the requirements under sections 9, 10, 11, 12, 14, 15, 16, 18, 19 and 20.

(2) A tissue establishment shall not designate a person under subsection (1) unless that person has–

(a) a diploma, certificate or other evidence of formal qualification in the field of medical or biological sciences awarded on completion of–

(i) a university course of study; or

(ii) a course recognised as an equivalent course by the competent authority; and

(b) practical post-graduate experience in areas of work relevant to the responsibilities of the responsible person under this Act for at least 2 years, in an establishment (or more than one establishment) in any Member State lawfully undertaking activities related to the collection or testing (or both) of tissues and cells, or to their procurement, storage and distribution.

(3) The competent authority shall, from time to time, publish in the Gazette details of courses recognised by it for the purpose of subsection (2)(a)(ii).

(4) Tissue establishments shall inform the competent authority of the name of the responsible person referred to in subsection (1).

(5) The responsible person may delegate any of the functions specified in subsection (1) to other persons who shall be qualified by training and experience to perform them.

(6) Tissue establishments shall notify the competent authority of the name of any persons to whom functions have been delegated by the responsible person under subsection (5), and the specific functions which have been delegated to such persons.

(7) Where the responsible person or a person to whom functions have been delegated under subsection (5) is permanently or temporarily replaced, the tissue establishment shall, without delay, provide the competent authority with the name of the replacement, details of his qualifications and the date on which the replacement began his duties.

(8) If the competent authority considers that the responsible person does not meet the requirements of subsection (2), it shall serve a notice to that effect on the tissue establishment.

(9) If, within 14 days of receiving a notice in accordance with subsection (8), a tissue establishment is not able to demonstrate to the reasonable satisfaction of the competent authority that the responsible person meets the requirements of subsection (2), it shall, without delay–

(a) relieve him of the duties of responsible person in respect of the tissue establishment;

(b) appoint a new responsible person in his place; and

(c) notify the competent authority that it has appointed a new responsible person and provide details of the name and qualifications of the person appointed.

Requirements for the procurement and supervision of procurement of human tissues and cells.

9.(1) Tissue establishments shall ensure that–

(a) tissue and cell procurement and testing–

(i) take place in conditions authorised for that purpose;

(ii) are carried out by persons with appropriate training and expertise;

(b) the tests required for donors are carried out by a qualified laboratory authorised by the competent authority; and

(c) the preparation process at the tissue establishment complies with the requirements set out in Schedule 6.

(2) The competent authority shall ensure that the tissue and cell donation and procurement procedures and the reception of tissues and cells at the tissue establishment comply with the requirements set out in Schedule 4.

(3) A tissue establishment shall ensure that appropriate control measures are in place for the procurement of tissues and cells.

(4) With the exception of partner donation of reproductive cells for direct use, the competent authority shall authorise the procurement of human tissues and cells only when the following requirements are met–

(a) procurement of human tissues and cells shall be carried out by persons who have successfully completed a training programme specified by a clinical team specialising in the tissues and cells to be procured, or a tissue establishment authorised for procurement;

(b) the tissue establishment or procurement organisation shall have written agreements with the staff or clinical teams responsible for donor selection, unless they are employed by the same organisation or establishment, specifying the procedures to be followed to assure compliance with the selection criteria for donors set out in Schedule 1;

(c) the tissue establishment or procurement organisation shall have written agreements with the staff or clinical teams responsible for tissue or cell procurement, unless they are employed by the same establishment or organisation, specifying the type or types of tissues or cells or test samples to be procured and the protocols to be followed;

(d) there shall be Standard Operating Procedures (SOPs)–

(i) for the verification of–

(aa) donor identity;

(bb) the details of donor or donor family consent or authorisation;

(cc) the assessment of the selection criteria for donors as detailed in section 13;

(dd) the assessment of the laboratory tests required for donors as detailed in section 13;

(ii) describing the procedures for procurement, packaging, labelling and transportation of the tissues and cells to the point of arrival at the tissue establishment or, in the case of direct distribution of tissues and cells, to the clinical team responsible for their application, or in the case of tissue or cell samples, to the laboratory for testing, in accordance with Schedule 4;

(e) procurement shall take place in appropriate facilities, following procedures that minimise bacterial or other contamination of procured tissues and cells, in accordance with Schedule 4;

(f) procurement materials and equipment shall be managed in accordance with the standards and specifications laid down in point 1.3 of Schedule 4 and with due regard to relevant national and international regulations, standards and guidelines covering the sterilisation of medicines and medical devices. Qualified, sterile instruments and procurement devices shall be used for tissue and cell procurement;

(g) procurement of tissues and cells from living donors shall take place in an environment that ensures their health, safety and privacy;

(h) where appropriate, the staff and equipment necessary for body reconstruction of deceased donors shall be provided. Such reconstruction shall be completed effectively;

(i) the procedures for the procurement of tissues and cells shall be carried out in accordance with the requirements specified in Schedule 4;

(j) a unique identifying code shall be allocated to the donor and the donated tissues and cells, during procurement or at the tissue establishment, to ensure proper identification of the donor and the traceability of all donated material and the coded data shall be entered in a register maintained for the purpose;

(k) donor documentation shall be maintained in accordance with point 1.4 of Schedule 4.

Quality management and notification and reporting to the competent authority of serious adverse events and reactions.

10.(1) A tissue establishment shall–

(a) establish and maintain a quality system based on the principles of good practice and in accordance with the requirements set out under Article 28(c) of the principal Directive;

(b) ensure that all testing and processes are validated;

(c) take all necessary measures to ensure that the quality system includes at least documentation on the following–

(i) SOPs,

(ii) guidelines,

(iii) training and reference manuals,

(iv) reporting forms,

(v) donor records, and

(vi) information on the final destination of tissues and cells,

and that this documentation is readily available for inspection by the competent authority.

(2) Tissue establishments shall ensure that the data necessary to ensure traceability are in accordance with section 16.

(3) Tissue establishments, through the responsible person, shall notify the competent authority of, and provide the competent authority with, a report analysing the cause of and ensuing outcome of–

(a) any serious adverse events and reactions, which may influence the quality and safety of tissues and cells and which may be attributable to any prescribed activity; and

(b) any serious adverse reactions observed during or after clinical applications, which may be linked to the quality and safety of tissues and cells.

(4) A tissue establishments, through the responsible person, shall–

(a) ensure that an accurate, rapid and verifiable procedure is in place, which will enable the establishment to recall from distribution any product which may be related to any notification referred to in subsection (3);

(b) keep a record of its activities, including the types and quantities of tissues or cells or both procured, tested, preserved, processed, stored and distributed, or otherwise disposed of, and on the origin and destination of the tissues and cells intended for human applications, in accordance with Schedule 4; and

(c) submit an annual report on its activities, which will be publicly accessible, to the competent authority.

(5) All persons using human tissues and cells regulated by this Act shall report any relevant information to establishments engaged in the donation, procurement, testing processing, storage or distribution of human tissue and cells in order to facilitate traceability and ensure quality and safety control.

Notification of serious adverse reactions.

11.(1) The competent authority shall ensure that–

(a) procurement organisations have procedures in place to retain the records of tissues and cells procured and to notify tissue establishments without delay of any serious adverse reactions in the living donor which may influence the quality and safety of tissues and cells;

(b) organisations responsible for human application of tissues and cells have procedures in place to retain the records of tissues and cells applied and to notify tissue establishments without delay of any serious adverse reactions observed during and after clinical application which may be linked to the quality and safety of tissues and cells; and

(c) tissue establishments that distribute tissues and cells for human application provide information to the organisation responsible for human application of tissues and cells about how that organisation should report serious adverse reactions as referred to in paragraph (b).

(2) The competent authority shall ensure that tissue establishments–

(a) have procedures in place to communicate to the competent authority without delay all relevant available information about suspected serious adverse reactions as referred to in subsection (1)(a) and (b); and

(b) have procedures in place to communicate to the competent authority without delay the conclusion of the investigation to analyse the cause and the ensuing outcome.

(3) The competent authority shall ensure that–

(a) the responsible person designated under section 8 notifies the competent authority of the information included in the notification set out in Part A of Schedule 7;

(b) tissue establishments notify the competent authority of the actions taken with respect to other implicated tissues and cells that have been distributed for human applications; and

(c) tissue establishments notify the competent authority of the conclusion of the investigation, supplying at least the information set out in Part B of Schedule 7.

Notification of serious adverse events.

12. The competent authority shall ensure that–

(a) procurement organisations and tissue establishments have procedures in place to retain the records and to notify tissue establishments without delay of any serious adverse events that occur during procurement which may influence the quality or safety or both of human tissues and cells;

(b) organisations responsible for human application of tissues and cells have procedures in place to notify tissue establishments without delay of any serious adverse events that may influence the quality and safety of the tissues and cells; and

(c) tissue establishments provide to the organisation responsible for human application information about how that organisation should report serious adverse events to them that may influence the quality and safety of the tissues and cells.

(2) In the case of assisted reproduction, any type of gamete or embryo misidentification or mix-up shall be considered to be a serious adverse event. All persons or procurement organisations or organisations responsible for human application performing assisted reproduction shall report such events to the supplying tissue establishments for investigation and notification to the competent authority.

(3) The competent authority shall ensure that tissue establishments–

(a) have procedures in place to communicate to the competent authority without delay all relevant available information about suspected serious adverse events as referred to in subsection (1)(a) and (b); and

(b) have procedures in place to communicate to the competent authority without delay the conclusion of the investigation to analyse the cause and the ensuing outcome.

(4) The competent authority shall ensure that–

(a) the responsible person designated under section 8 notifies the competent authority of the information included in the notification set out in Part A of Schedule 8;

(b) tissue establishments evaluate serious adverse events to identify preventable causes within the process; and

(c) tissue establishments notify the competent authority of the conclusion of the investigation, supplying at least the information set out in Part B of Schedule 8.

Donor selection, evaluation and testing criteria.

13.(1) Tissue establishments shall ensure that–

(a) donors of tissues and cells, except donors of reproductive cells, undergo the biological tests set out in point 1 of Schedule 2;

(b) the tests referred to in paragraph (a) are carried out in compliance with the general requirements set out in point 2 of Schedule 2;

(c) donors of reproductive cells undergo the biological tests set out in points 1, 2 and 3 of Schedule 3; and

(d) the tests referred to in paragraph (c) are carried out in compliance with the general requirements set out in point 4 of Schedule 3.

(2) Tissue establishments shall ensure that donors comply with the selection criteria set out in–

(a) Schedule 1 for donors of tissues and cells, except donors of reproductive cells; and

(b) Schedule 3 for donors of reproductive cells.

(3) Tissues and cells shall not be procured unless the information required under subsection (4) has been provided by the tissue establishment or procurement organisation to the donor (in the case of a living adult donor) or the next of kin (in the case of a deceased donor or a person who is unable to give consent) and informed consent has been given for such procurement.

(4) The person in charge of the donation process in a tissue establishment or procurement organisation, prior to the procurement of such tissues or cells or both, in relation to living donors, shall ensure that–

(a) the donor, or the donor's next of kin, (in the case of a person who is unable to give consent) has been properly informed of at least those aspects relating to the donation and procurement process outlined in paragraph (c);

(b) the information is given by a trained person able to transmit it in an appropriate and clear manner, using terms that are easily understood by the donor;

(c) the information covers–

(i) the purpose and nature of the procurement, its consequences and risks,

(ii) analytical tests, if they are performed,

(iii) recording and protection of donor data,

(iv) medical confidentiality,

(v) therapeutic purpose and potential benefits,

(vi) the applicable safeguards intended to protect the donor;

(d) the donor is informed that he has the right to receive the confirmed results of the analytical tests, clearly explained; and

(e) information is given on the necessity for requiring the applicable mandatory consent, certification and authorisation in order that the tissue or cell or both procurement can be carried out.

(5) The person in charge of the donation and procurement processes in a tissue establishment or procurement organisation, prior to the procurement of such tissues or cells or both, in relation to deceased donors, shall ensure that–

(a) all information is given and all necessary consents and authorisations are obtained in accordance with this Act; and

(b) the confirmed results of the donor's evaluation are communicated and clearly explained to the relevant persons in accordance with this Act.

(6) The tissue establishment or procurement organisation shall, in relation to the donation and procurement of tissues and cells–

(a) put and keep in place procedures for the evaluation of donors;

(b) apply selection and evaluation criteria for all donors of tissues or cells or both in accordance with this section; and

(c) maintain records of the results of donor evaluations and tests and report to donors any relevant abnormal findings from the evaluations, and tests.

(7) In the case of autologous donation, the suitability criteria of the donor shall be established in accordance with the requirements in point 2.1 of Schedule 1.

Tissue and cell reception, processing, storage and distribution.

14.(1) Tissue establishments shall ensure that human tissue and cells and associated documentation comply with the requirements set out in Schedule 4.

(2) Tissue establishments shall ensure that the reception of tissues and cells at the tissue establishment complies with the requirements set out in Schedule 4.

(3) Tissue establishments shall verify and record the fact that the packaging of tissues and cells received complies with the requirements of point 1.5 of Schedule 4.

(4) Tissues and cells that do not comply with point 1.5 of Schedule 4, shall be discarded.

(5) Tissue establishments shall document the acceptance or rejection of received tissues or cells.

(6) Tissue establishments shall ensure that human tissues and cells are correctly identified at all times. Each delivery or batch of tissues or cells shall be assigned an identifying code, in accordance with section 16.

(7) Tissue establishments shall hold tissue and cells in quarantine until such time as the requirements relating to donation, testing and information have been met in accordance with section 13.

(8) Tissue establishments shall–

(a) include in their SOPs all processes that affect quality and safety and shall ensure that they are carried out under controlled conditions;

(b) ensure that the equipment used, the working environment and process design, validation and control conditions are in compliance with the requirements in Article 28(h) of the principal Directive;

(c) ensure that any modifications to the processes used in the preparation of tissues and cells shall also meet the criteria laid down in paragraphs (a) and (b) of this subsection;

(d) include in their SOPs special provisions for the handling of tissue and cells to be discarded, in order to prevent the contamination of other tissues or cells, the processing environment or personnel;

(e) ensure that all procedures associated with the storage of tissues and cells are documented in the SOPs and that the storage conditions comply with the requirements under Article 28(h) of the principal Directive;

(f) ensure that all storage processes are carried out under controlled conditions;

(g) establish and apply procedures for the control of packaging and storage areas, in order to prevent any situation arising that might adversely affect the functioning or integrity of tissues and cells; and

(h) not distribute processed tissues or cells until the requirements laid down in this Act are met.

(9) Tissue establishments shall have agreements and procedures in place to ensure that, in the event of termination of activities for whatever reason, stored tissues and cells shall be transferred to other tissue establishment or establishments authorised in accordance with section 6 without prejudice to any Gibraltar law concerning the disposal of donated tissues or cells, according to the consent pertaining to them.

(10) Tissue establishments shall ensure that personnel directly involved in activities relating to the procurement, processing, preservation, storage and distribution of tissues and cells shall be qualified to perform such tasks and shall be provided with the training referred to in Article 28(c) of the principal Directive.

(11) Tissue establishments shall ensure–

(a) the quality and safety of tissues and cells during distribution; and

(b) that distribution conditions comply with the requirements referred to in Article 28(h) of the principal Directive.

Principles governing tissue and cell donation and voluntary unpaid donation.

15.(1) The Government shall draw up guidelines setting out the conditions under which promotion and publicity activities in support of the donation of human tissues and cells may be carried out. Such guidelines shall include appropriate restrictions or prohibitions on advertising the need for, or availability of, human tissues and cells, with a view to offering or seeking financial gain or comparable advantage.

(2) The guidelines referred to in subsection (1) shall endeavour to ensure that the procurement of tissues and cells is carried out on a non-profit basis.

(3) Tissue establishments shall–

(a) comply with guidelines laid down for the promotion and publicity activities in support of the donation of human tissues and cells; and

(b) make every effort to ensure voluntary and unpaid donations of tissues and cells.

(4) Without prejudice to subsection (3), the tissue establishments may make good the expenses and inconveniences related to the donation in accordance with the guidelines.

Traceability and labelling of tissues and cells.

16.(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.

(2) Every tissue establishment shall implement a donor identification system which assigns a unique code to each tissue or cell donation and to each of the products associated with it.

(3) A single European identifying code shall be allocated to all donated material at the tissue establishment to–

(a) ensure proper identification of the donor and the traceability of all donated material; and

(b) provide information on the main characteristics and properties of tissues and cells,

and the code shall incorporate at least the information set out in Schedule 11.

(4) Subsection (3) shall not apply to partner donation of reproductive cells.

(5) Every tissue establishment must use a labelling system that contains the information or references allowing a link to the information referred to in Schedule 4 and Article 28(h) of the principal Directive.

(6) Every tissue establishment shall keep such records of the information referred to in Schedule 4 and such additional records as are necessary–

(a) for the identification and traceability of each single tissue or cell donation and each single tissue or cell unit and its components (including tissues and cells which are imported into the European Union), and products coming into contact with these tissues and cells; and

(b) to ensure full traceability from donation and procurement, processing or storage to the point of delivery to a hospital or site, and at all stages, for a period of not less than 30 years after clinical use, and data storage may also be in electronic form.

(7) Every tissue establishment shall ensure that the labelling, documentation and packaging on each tissue or cell supplied by it, shall conform to the requirements of the Act.

(8) Tissue establishments and organisations responsible for human application shall retain the data set out in Schedule 10 for at least 30 years, in an appropriate and readable storage medium.

Import and export of human tissues and cells.

17.(1) The competent authority shall ensure that–

(a) all imports of tissues and cells from third countries; and

(b) all exports of tissues and cells to third countries,

are undertaken by authorised tissue establishments.

(2) Tissue establishments shall ensure that imported tissues and cells–

(a) can be traced from donor to the recipient and vice versa in accordance with the procedures and requirements laid down by section 16; and

(b) meet standards of quality and safety equivalent to those laid down in this Act.

(3) Tissue establishments shall ensure that all exports to third countries comply with the requirements of this Act.

(4) The competent authority may directly authorise the import or export of–

(a) tissues and cells referred to in section 6(12)(b); and

(b) certain tissues and cells, in case of emergency.

(5) The competent authority shall take all necessary measures to ensure that imports and exports of tissues and cells referred to in subsection (4) meet the quality and safety standards equivalent to those laid down in this Act.

Relations between tissue establishments and third parties.

18.(1) Tissue establishments shall establish written agreements with a third party each time an external activity takes place which influences the quality and safety of tissues and cells processed in cooperation with a third party, and in particular in the following circumstances–

(a) where a tissue establishment entrusts one of the stages of tissue or cell processing to a third party;

(b) where a third party provides goods and services that affect tissue or cell quality and safety assurance, including their distribution;

(c) where a tissue establishment provides services to a tissue establishment which is not authorised; and

(d) where a tissue establishment distributes tissue or cells processed by third parties.

(2) Agreements between tissue establishments and third parties shall be examined by the competent authority within the authorisation framework of section 6.

(3) Tissue establishments shall evaluate and select third parties on the basis of their ability to meet the standards laid down in this Act.

(4) Tissue establishments shall keep a complete list of the agreements referred to in subsection (1) that they have established with third parties.

(5) Agreements between tissue establishments and third parties shall specify the responsibilities of third parties and detailed procedures.

(6) Tissue establishments shall provide copies of agreements with third parties at the request of the competent authority.

Objections to refusals of authorisation or suspension or revocation of authorisation.

19.(1) A tissue establishment which objects to–

(a) the refusal of authorisation, or the imposition of any condition under section 6(5*)*; or

(b) any suspension or revocation of authorisation, or any notice served, under section 6(8) or (7),

may notify the competent authority of its desire to make written representations to, or to appear before and be heard by, a person appointed by the competent authority for that purpose pursuant to subsection (3).

(2) Any notification of an objection under subsection (1) shall be made within 14 days of service on the tissue establishment of the notice to which the notification under subsection (1) relates.

(3) Where the competent authority receives a notification under subsection (1), competent authority shall appoint a person to consider the matter.

(4) The person appointed under subsection (3) shall determine the procedure to be followed with respect to the consideration of any objection.

(5) The person appointed under subsection (3) shall consider any written or oral objections made by the tissue establishment in support of its objection, and shall make a recommendation to the competent authority.

(6) A recommendation made under subsection (5) shall be made in writing to the competent authority, and a copy of it shall be sent to the tissue establishment concerned, or to its nominated representative.

(7) The competent authority shall take into account any recommendation made under subsection (5).

(8) Within 14 days of receipt of any recommendation made under subsection (5), the competent authority shall inform the tissue establishment whether it (the competent authority) accepts the recommendation and, if it does not accept it, of the reasons for its decision.

(9) Subject to subsection (11), where the competent authority is notified of an objection under subsection (1)(b) before the date upon which the suspension or revocation or the notice is due to take effect, the suspension or revocation or notice in respect of which the objection is made shall not take effect until–

(a) the person appointed under subsection (3) has considered the matter in accordance with the provisions of this section and made a recommendation; and

(b) the competent authority has informed the tissue establishment concerned of its decision with regard to the recommendation under subsection (8).

(10) Subject to subsection (11), where the competent authority is notified of an objection under subsection (1)(b), within the period specified in subsection (2), to a suspension, revocation or other notice which has already taken effect on the date the notification was made, the suspension, revocation or notice in respect of which the objection is made shall cease to have effect until–

(a) the person appointed under subsection (3) has considered the matter in accordance with this section and made a recommendation; and

(b) the competent authority has informed the tissue establishment concerned of its decision with regard to the recommendation under subsection (8).

(11) Subsections (9) and (10) shall not apply–

(a) in relation to a suspension or revocation, which takes immediate effect in accordance with section 7(3); or

(b) in any other case, where the competent authority determines that it is necessary in the interests of public safety for the suspension, revocation or notice to take effect on the date originally specified, and serves a notice in writing to that effect on the tissue establishment concerned.

Disclosure of information by tissue establishments and data protection.

20.(1) A tissue establishment shall ensure that all information, including genetic information which is collected for the purposes of this Act is held securely so that it is–

(a) available for the purpose of tracing donations;

(b) not disclosed except–

(i) in accordance with one or more of the requirements of subsection (2); or

(ii) where it has been rendered anonymous so that donors and recipients are no longer identifiable; and

(c) subject to safeguards against unauthorised additions, deletions or modifications to donor files or deferral records and transfer of information.

(2) The requirements of this section are–

(a) the disclosure is made in accordance with an order of a court or is otherwise required by law;

(b) the disclosure is to an authorised person; or

(c) the disclosure is for the purpose of tracing a donation from donor to recipient or recipient to donor.

(3) Where a disclosure is made to an authorised person under subsection (2)(b), the authorised person shall not further disclose the information received unless–

(a) the disclosure is made in accordance with an order of a court or is otherwise required by law;

(b) the disclosure is to another authorised person or an officer of the Gibraltar Health Authority where this is necessary for the proper performance of any function of any such officer; or

(c) the information has been rendered anonymous so that the donors are no longer identifiable.

(4) Where a disclosure is made under subsection (3), the person to whom the disclosure is made shall not further disclose the information he receives other than in accordance with the requirements of that subsection.

(5) The responsible person shall ensure that he puts in place procedures to resolve data discrepancies.

(6) The responsible person shall ensure that the identity of the recipient is not disclosed to the donor or his family and vice versa, without prejudice to any provision of law on the conditions for disclosure, notably in the case of gametes donation.

Inspections.

21.(1) The competent authority shall conduct a regular inspection of each site of a tissue establishment, not less than once every 2 years, for the purpose of ensuring that–

(a) the procedures and activities carried out by tissue establishments comply with the requirements of this Act;

(b) documents or other records relating to the requirements of the this Act are examined;

(c) problems relating to compliance with those requirements are identified; and

(d) the site complies with the requirements of this Act.

(2) The competent authority may conduct such additional inspections of tissue establishment sites or facilities of third parties, as the competent authority considers necessary for the purpose of ensuring compliance with the requirements of this Act.

(3) The competent authority may also serve a notice on a tissue establishment requiring that it furnish the competent authority with such information concerning its compliance with this Act and as shall be specified in the notice within such period as shall be specified in the notice.

(4) Any tissue establishment which receives a request for information in accordance with subsection (3) shall provide the information requested within the period specified in the notice.

(5) In the event of any serious adverse event or any serious adverse reaction or suspicion thereof, the competent authority shall request such information, conduct such inspections, or carry out control measures, in accordance with this section, as it shall consider appropriate.

(6) Any reference to an inspection of a site which the competent authority is required or empowered to conduct by virtue of this section, shall be construed so as to include an inspection of premises within a Member State at which any of the prescribed activities are carried out by any person on behalf of, and pursuant to a contractual arrangement with, a tissue establishment.

(7) The competent authority's functions under this section in relation to a tissue establishment are also applicable in the case of a tissue establishment seeking authorisation under section 6.

(8) The competent authority, on receipt of a duly justified request from the competent authority in a Member State, shall organise such inspection or carry out control measures.

(9) The competent authority shall, upon the request of a Member State, or the Commission, provide information on the results of inspections and control measures carried out, in relation to the requirements of this Act.

Authorised persons.

22.(1) The competent authority–

(a) may appoint such and so many persons as it (the competent authority) thinks fit to be authorised persons for the purposes of this Act; and

(b) shall furnish each such authorised person with a warrant of the authorised person's appointment.

(2) An authorised person shall, when performing a function imposed under this Act on an authorised person, produce his warrant for inspection if requested to do so by a person affected by the performance of that function.

(3) For the purposes of enforcing compliance with this Act or conducting inspections under section 19, an authorised person may–

(a) subject to subsection (5), enter (if necessary by the use of reasonable force), at all reasonable times, any premises at which he has reasonable grounds to believe that it is necessary to visit, including–

(i) any premises owned or managed by a tissue establishment, or at which the tissue establishment carries out any prescribed activities,

(ii) any premises of any person who carries out any prescribed activities on behalf of, and pursuant to a contractual arrangement with a tissue establishment,

(iii) where any facilities for donor evaluation and testing are in the premises of any person other than a tissue establishment, those facilities in that person's premises, and

(iv) any premises at which books, records or other documents (including documents stored in non-legible form) relating to any prescribed activities are stored or kept,

(b) at such premises inspect and take copies of, any books, records, other documents (including documents stored in non-legible form) or extracts therefrom, which he finds in the course of his inspection;

(c) remove any such books, records or other documents from such premises and detain them for such period as he reasonably considers to be necessary for the purposes of his functions under this Act;

(d) carry out, or have carried out, such tests, examinations, analyses, inspections and checks of–

(i) the premises,

(ii) any relevant thing at the premises, or

(iii) any equipment, machinery or plant at the premises, as he reasonably considers to be necessary for the purposes of his functions under this Act;

(e) require any person at the premises or the owner or person in charge of the premises and any person employed there to give to him such assistance and information and to produce to him such books, records or other documents (and in the case of documents stored in non-legible form, produce to him a legible reproduction thereof) that are in that person's power or procurement, as he may reasonably require for the purposes of his functions under this Act;

(f) without payment, take samples of any relevant thing found at the premises for the purposes of any test, examination or analysis;

(g) direct that such relevant thing found at the premises as he, upon reasonable grounds, believes does not comply with the requirements of this Act not be sold or distributed or moved from the premises, without his consent;

(h) secure for later inspection any premises or part of any premises in which a relevant thing is found or ordinarily kept, or books, records or other documents are found or ordinarily kept, for such period as may reasonably be necessary for the purposes of his functions under this Act;

(i) without payment, take possession of and remove from the premises for any test, examination or analysis any relevant thing found there, and detain it for such period as he considers reasonably necessary for the purposes of performing his functions under this Act;

(j) without payment, take samples of any relevant thing, detained under paragraph (i*)*, for the purposes of any test, examination, or analysis; or

(k) where the taking of samples of any relevant thing under paragraph (f) or (j) is, for whatever reason, not practicable, without payment take the relevant thing concerned for the purposes of any test, examination or analysis.

(4) In performing a function under this Act, an authorised person may, subject to any warrant under subsection (6), be accompanied by any–

(a) other authorised person; or

(b) persons with expertise relating to any relevant thing, as he considers appropriate in the circumstances of the case.

(5) An authorised person shall not enter a dwelling, other than–

(a) with the consent of the occupier; or

(b) in accordance with a warrant issued under subsection (6).

(6) Upon the application of an authorised person, the Stipendiary Magistrate, if satisfied that there are reasonable grounds for believing that–

(a) a relevant thing is to be found in any dwelling, or is being or has been subjected to any process or stored in any dwelling;

(b) books, records or other documents (including documents stored in non-legible form) referred to in subsection (3)(a)(iv) are being stored or kept in any dwelling; or

(c) a dwelling is occupied in whole or in part by an undertaking carrying out any prescribed activity,

may issue a warrant authorising a police officer accompanied by the applicant and such other authorised persons or persons with expertise relating to any relevant thing, as may be necessary, at any time or times, within one month of the date of issue of the warrant, to enter the dwelling and perform any of the functions of an authorised person under paragraphs (b) to (k) of subsection (3).

(7) Where a police officer or an authorised person, upon reasonable grounds, believes that a person has committed an offence under this Act, he may require that person to provide him with his name and the address at which he ordinarily resides.

(8) A statement or admission made by a person pursuant to a requirement under subsection (3)(e) shall not be admissible as evidence in proceedings brought against that person for an offence (other than an offence under section 26(6)).

(9) Nothing in this section shall be taken to compel the production by any person of a document of which he would be exempt from production in proceedings in a court on the ground of legal professional privilege.

Taking of samples by authorised persons.

23.(1) Subject to subsection (3), where an authorised person takes a sample of a relevant thing, he shall–

(a) divide the sample into 3 approximately equal parts;

(b) place each part into separate containers; and

(c) forthwith seal and mark each such container in such a manner as to identify it as part of the sample taken by that authorised person.

(2) Where an authorised person has complied with subsection (1), he shall–

(a) offer one of the sealed containers to the owner or person for the time being in charge or possession of the relevant thing from which the sample concerned was taken;

(b) retain one of the sealed containers; and

(c) forward, or cause to be forwarded, the other sealed containers for test, examination or analysis of the sample.

(3) Where a relevant thing is contained in a container and its division into parts under subsection (1) is, for whatever reason, not practicable, an authorised person, who wishes to take samples of such relevant things for the purposes of any test, examination or analysis, shall take possession of 3 such containers belonging to the same batch, and each such container shall be deemed to be part of a sample for the purposes of subsection (1), and subsections (1) and (2) shall apply to it accordingly.

(4) Where an authorised person takes a relevant thing under section 22(3)(k), he shall–

(a) place the relevant thing in a container; and

(b) forthwith seal and mark the container in such a manner as to identify it as a relevant thing taken pursuant to that section.

Records to be kept by the competent authority.

24.(1) The competent authority shall keep such records of information which the competent authority receives from, or relating to, tissue establishments as are considered appropriate in accordance with section 14 and shall, in particular, keep records relating to–

(a) authorisations under section 6;

(b) the designation of responsible persons under section 8; and

(c) notification of serious adverse events and serious adverse reactions by tissue establishments under section 10(3); and

(d) inspections or requests for information under section 19.

(2) The competent authority shall maintain a publicly accessible register of tissue establishments, specifying the activities for which the establishments have been authorised.

(3) The competent authority shall provide the assistance necessary to enable the Commission to establish a network linking all the tissue establishment registers in the Union.

Communication of information between competent authorities and to the Commission.

25. The competent authority shall ensure that such information as is appropriate with regard to serious adverse reactions and events is communicated to the competent authorities of Member States and to the Commission in order to guarantee that adequate actions are taken.

Offences and penalties.

26.(1) A person who contravenes any of the provisions of section 5(1), 6(9), 8 (other than subsection (3)), 9, 10, 11, 12, 15(3), 16 (other than subsection (3)), 17(3) or 19 (4) shall be guilty of an offence and liable on summary conviction to a fine not exceeding level 4 on the standard scale, or to imprisonment for a term not exceeding 6 months, or to both.

(2) Any person who fails to comply with a notice of suspension or revocation of the person's authorisation served under section 7, except where the operation of that notice has been suspended under section 19 or has been withdrawn or revoked by the competent authority, shall be guilty of an offence and liable on summary conviction to a fine not exceeding level 3 on the standard scale, or to a term of imprisonment not exceeding 6 months, or to both.

(3) Any person who knowingly supplies tissue or cells which are not labelled in accordance with the requirements of section 16(3) shall be guilty of an offence and liable on summary conviction to a fine not exceeding level 2 on the standard scale, or to a term of imprisonment not exceeding 3 months, or to both.

(4) Any person who–

(a) contravenes section 20; or

(b) discloses any information referred to in section 20(1) to which he has access by virtue of this Act, otherwise than in accordance with the provision of section 20(2) and (3),

shall be guilty of an offence and liable on summary conviction to a fine not exceeding level 2 on the standard scale, or to a term of imprisonment not exceeding 3 months, or to both.

(5) Any person who–

(a) obstructs or interferes with an authorised person or a person with expertise relating to any relevant thing (within the meaning of section 2), in the course of performing a function conferred on him by this Act or a warrant under section 22(6); or

(b) impedes the performance by the authorised person or person with expertise, of such function or fails or refuses to comply with a request or requirement of, or to answer a question asked by, the authorised person or person with expertise, under section 22;

(c) in purported compliance with such request or requirement or in answer to such question gives information to the authorised person or person with expertise, that he knows to be false or misleading in any material respect,

shall be guilty of an offence and liable on summary conviction to a fine not exceeding level 2 on the standard scale, or to imprisonment for a term not exceeding 3 months, or to both.

(6) A person who falsely represents himself to be an authorised person shall be guilty of an offence and liable on summary conviction to a fine not exceeding level 2 on the standard scale, or to imprisonment for a term not exceeding 3 months, or to both.

(7) Nothing in subsection (5)(b) shall be construed as requiring any person to answer any question or to give any information if to do so might incriminate him or, in the case of a person who is married, his or her spouse.

(8) On conviction for an offence under this Act (including an offence under section 27), the court may, in addition to any other penalty–

(a) order any relevant thing (within the meaning of section 2) to which the offence relates to be forfeited to the competent authority for destruction or other disposal as the competent authority thinks fit;

(b) upon application made to it by or on behalf of the competent authority, order the person convicted of the offence to pay to the relevant person all or part of the costs of such destruction or other disposal subject to such conditions, if any, as are specified in the order.

Offence to import below standard tissues and cells into Gibraltar.

27. Any person who imports into Gibraltar any tissues or cells (including tissues or cells intended for use as a starting material or raw material in manufactured products) from a country or territory outside the European Union which do not meet standards of quality and safety equivalent to those laid down in this Act is guilty of an offence and liable on summary conviction to a fine not exceeding level 4 on the standard scale, or to imprisonment for a term not exceeding 6 months, or to both.

Reports by the competent authority.

28.(1) The competent authority shall ensure that, as soon as practicably possible after the coming into operation of this Act, a report is sent to the Commission on the activities undertaken in relation to the provisions of this Act, including an account of the measures taken in relation to inspection and control. A further such report shall be sent to the Commission on 7 April 2012 and thereafter at regular intervals of three years.

(2) The competent authority shall–

(a) ensure that each year, and by 30 June of the following year, a report is submitted to the Commission on the notification of serious adverse reactions and events received by the competent authority; and

(b) make this report available to tissue establishments.

(3) Any data transmission under this Act shall–

(a) comply with the data exchange format specifications as set out in Schedule 9, Part A and B; and

(b) provide all the information necessary to identify the sender and maintain its reference data.

Regulations.

29.(1) The Minister may make Regulations–

(a) prescribing fees to be paid under this Act;

(b) giving effect to or implementing any International Convention, Protocol or Agreement or any European Union Directive or Regulation that relate to the subject-matter of this Act; or

(c) providing for generally carrying out the purposes of this Act.

SCHEDULE 1

Section 13(2) (a) and 13 (7)

SELECTION CRITERIA FOR DONORS OF TISSUES OR CELLS OR BOTH (EXCEPT DONORS OF REPRODUCTIVE CELLS).

Selection criteria for donors are based on an analysis of risks related to the application of the specific cells/tissues. Indicators of these risks must be identified by physical examination, review of the medical and behavioural history, biological testing, post-mortem examination (for deceased donors) and any other appropriate investigation. Unless justified on the basis of a documented risk assessment approved by the responsible person as defined in section 2(1), donors must be excluded from donation if any of the following criteria applies:

1. Deceased Donors.

1.1. *General criteria for exclusion*

1.1.1. Cause of death unknown, unless autopsy provides information on the cause of death after procurement and none of the general criteria for exclusion set out in the present section applies.

1.1.2. History of a disease of unknown aetiology.

1.1.3. Presence, or previous history, of malignant disease, except for primary basal cell carcinoma, carcinoma in situ of the uterine cervix, and some primary tumours of the central nervous system that have to be evaluated according to scientific evidence. Donors with malignant diseases can be evaluated and considered for cornea donation, except for those with retinoblastoma, haematological neoplasm, and malignant tumours of the anterior segment of the eye.

1.1.4. Risk of transmission of diseases caused by prions. This risk applies, for example, to–

(a) people diagnosed with Creutzfeldt-Jakob Disease, or variant Creutzfeld-Jakob Disease, or having a family history of non-iatrogenic Creutzfeldt-Jakob disease.

(b) People with a history of rapid progressive dementia or degenerative neurological disease, including those of unknown origin;

(c) Recipients of hormones derived from the human pituitary gland (such as growth hormones) and recipients of grafts of cornea, sclera and dura mater, and persons that have undergone undocumented neurosurgery (where dura mater may have been used).

For variant Creutzfeld-Jakob Disease, further precautionary measures may be recommended.

1.1.5. Systemic infection which is not controlled at the time of donation, including bacterial diseases, systemic viral, fungal or parasitic infections, or significant local infection in the tissue and cells to be donated. Donors with bacterial septicaemia may be evaluated and considered for eye donation, but only where the corneas are to be stored by organ culture to allow detection of any bacterial contamination of the tissue.

1.1.6. History, clinical evidence, or laboratory evidence of HIV, acute or chronic hepatitis B (except in the case of persons with a proven immune status) hepatitis C and HTLV I/II, transmission risk or evidence of risk factors for these infections.

1.1.7. History of chronic, systemic autoimmune disease that could have a detrimental effect on the quality of the tissue to be retrieved.

1.1.8. Indications that test results of donor blood samples will be invalid due to: (a) the occurrence of haemodilution, according to the specifications in section 2 of Schedule 2, where a pre-transfusion sample is not available; or (b) treatment with immunosuppressive agents.

1.1.9. Evidence of any other risk factors for transmissible diseases on the basis of a risk assessment, taking into consideration donor travel and exposure history and local infectious disease prevalence.

1.1.10. Presence on the donor's body of physical signs implying a risk of transmissible disease(s) as described in point 1.2.3 of Schedule 4.

1.1.11. Ingestion of, or exposure to, a substance (such as cyanide, lead, mercury, gold) that may be transmitted to recipients in a dose that could endanger their health.

1.1.1 Recent history of vaccination with a live attenuated virus where a risk of transmission is considered to exist.

1.1.13. Transplantation with xenografts.

1.2. *Additional exclusion criteria for deceased child donors.*

1.2.1. Any children born from mothers with HIV infection or that meet any of the exclusion criteria described in section 1.1 must be excluded as donors until the risk of transmission of infection can be definitely ruled out.

(a) Children aged less than 18 months born from mothers with HIV, hepatitis B, hepatitis C or HTLV infection or at risk of such infection, and who have been breastfed by their mothers during the previous 12 months, cannot be considered as donors regardless of the results of the analytical tests;

(b) Children of mothers with HIV, hepatitis B, hepatitis C or HTLV infection or at risk of such infection, and who have not been breastfed by their mothers during the previous 12 months and for whom analytical tests, physical examinations and reviews of medical records do not provide evidence of HIV, hepatitis B, hepatitis C or HTLV infection, can be accepted as donors.

2. Living Donors.

2.1. *Autologous Living Donor*

2.1.1. If the removed tissues and cells are to be stored or cultured, the same minimum set of biological testing requirements must apply as for an allogeneic living donor. Positive test results will not necessarily prevent the tissues or cells or any product derived from them being stored, processed and re-implanted, if appropriate isolated storage facilities are available to ensure no risk of cross-contamination with other grafts or no risk of contamination with adventitious agents or mix-ups or both.

2.2. *Allogeneic Living Donor*

2.2.1. Allogeneic living donors must be selected on the basis of their health and medical history, provided on a questionnaire and through an interview performed by a qualified and trained healthcare professional with the donor, in compliance with point 2.2.2. This assessment must include relevant factors that may assist in identifying and screening our persons whose donation could present a health risk to others, such as the possibility of transmitting diseases or health risks to themselves. For any donation, the collection process must not interfere with or compromise the health or care of the donor. In the case of cord blood or amniotic membrane donation, this applies to both mother and baby.

2.2.2. Selection criteria for allogeneic living donors must be established and documented by the tissue establishment (and the transplanting clinician in the case of direct distribution to the recipient) based on the specific tissue or cells to be donated, together with the donor's physical status and medical

and behavioural history and the results of clinical investigations and laboratory tests establishing the donor's state of health.

2.2.3. The same exclusion criteria must be applied as for deceased donors with the exception of point 1.1.1 Depending on the tissue or cell to be donated, other specific exclusion criteria may need to be added, such as:

(a) pregnancy (except for donors of umbilical cord blood cells and amniotic membrane and sibling donors of haematopoietic progenitors);

(b) breastfeeding;

(c) in the case of haematopoietic progenitor cells, the potential for transmission of inherited conditions.

SCHEDULE 2

Section 13(1)(a) and (b)

LABORATORY TESTS REQUIRED FOR DONORS (EXCEPT DONORS OF REPRODUCTIVE CELLS).

1. Biological tests required for donors.

1.1. The following biological tests must be performed for all donors as a minimum requirement;

HIV 1 and 2	Anti-HIV-1,2
Hepatitis B	HbsAg Anti HBc
Hepatitis C	Anti- HCV- Ab
Syphilis	See 1.4 (below)

1.2. HTLV-1 antibody testing must be performed for donors living in or originating from high-incidence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas.

1.3. When anti-HBc is positive and HbsAg is negative, further investigations are necessary with a risk assessment to determine eligibility for clinical use.

1.4. A validated testing algorithm must be applied to exclude the presence of active infection with *Treponema pallidum*. A non-reactive test, specific or non-specific, can allow tissues and cells to be released. When a non-specific test is performed, a reactive result will not prevent procurement or release if a specific *Treponema* confirmatory test is non-reactive. A donor whose specimen tests reactive on a *Treponema*-specific test will require a thorough risk assessment to determine eligibility for clinical use.

1.5. In certain circumstances, additional testing may be required depending on the donor's history and the characteristics of the tissue or cells donated (e.g. RhD, HLA, malaria, CMV, toxoplasma, EBV, *Trypanosoma cruzi*).

1.6. For autologous donors, point 2.1.1. in Schedule 1 applies.

2. General requirements to be met for determining biological markers.

2.1. The tests must be carried out by a qualified laboratory, authorised as a testing centre by the competent authority, using CE marked testing kits

where appropriate. The type of test used must be validated for the purpose in accordance with current scientific knowledge.

2.2. The biological tests will be carried out on the donor's serum or plasma; they must not be performed on other fluids or secretions such as the aqueous or vitreous humour unless specifically justified clinically using a validated test for such a fluid.

2.3. When potential donors have lost blood and have recently received donated blood, blood components, colloids or crystalloids, blood testing may not be valid due to haemodilution of the sample. An algorithm must be applied to assess the degree of haemodilution in the following circumstances–

(a) ante-mortem blood sampling: if blood, blood components or colloids were infused in the 48 hours preceding blood sampling or if crystalloids were infused in the hour preceding blood sampling;

(b) post-mortem blood sampling: if blood, blood components or colloids were infused in the 48 hours preceding death or if crystalloids were infused in the hour preceding death.

Tissue establishments may accept tissues and cells from donors with plasma dilution of more than 50% only if the testing procedures used are validated for such plasma or if a pre-transfusion sample is available.

2.4. In the case of a deceased donor, blood samples must have been obtained just prior to death, or if not possible, the time of sampling must be as soon as possible after death and in any case within 24 hours after death.

2.5.–

(a) In the case of living donors (except allogeneic bone marrow stem-cell and peripheral blood stem-cell donors, for practical reasons), blood samples must be obtained at the time of donation or if not possible, within 7 days post donation (this is the 'donation sample').

(b) Where tissues and cells of allogeneic living donors can be stored for long periods, repeat sampling and testing is required after an interval of 180 days. In these circumstances of repeat testing, the donation sample can be taken up to 30 days prior to and 7 days post donation.

(c) Where tissues and cells of allergenic living donors cannot be stored for long periods and repeat sampling is therefore not possible, paragraph 2.5(a) above applies.

2.6. If, in a living donor (except bone marrow stem-cell and peripheral blood stem-cell donors) the 'donation sample' as defined in paragraph 2.5(a) above, is additionally tested by the nucleic acid amplification technique (NAT) for HIV, HBV and HCV, testing of a repeat blood sample is not required. Retesting is also not required if the processing includes an inactivation step that has been validated for the viruses concerned.

2.7. In the case of bone marrow and peripheral blood stem-cell collection, blood samples must be taken for testing within 30 days prior to donation.

2.8. In the case of neonatal donors, the biological tests may be carried out on the donor's mother to avoid medically unnecessary procedures upon the infant.

SCHEDULE 3

Section 13(1)(c) and (d) and 13(2)(b)

SELECTION CRITERIA AND LABORATORY TESTS REQUIRED FOR DONORS OF REPRODUCTIVE CELLS

1. Partner donation for direct use.

Donor selection criteria and laboratory testing do not need to be applied in the case of partner donation of reproductive cells for direct use.

2. Partner donation (not direct use).

Reproductive cells that are processed or stored or both and reproductive cells that will result in the cryopreservation of embryos must meet the following criteria–

2.1. The clinician responsible for the donor must determine and document, based on the patient's medical history and therapeutic indications, the justification for the donation and its safety for the recipient and any child(ren) that might result.

2.2. The following biological tests must be carried out to assess the risk of cross contamination–

HIV 1 and 2	Anti-HIV-1,2
Hepatitis B	HbsAg Anti HBc
Hepatitis C	Anti- HCV- Ab

In case of sperm processed for intrauterine insemination, not to be stored and if the tissue establishment can demonstrate that the risk of cross contamination and staff exposure has been addressed through the use of validated processes, the biological testing may not be required.

2.3. Where HIV 1 and 2, hepatitis B or hepatitis C test results are positive or unavailable, or where the donor is known to be a source of infection risk, a system of separate storage must be devised.

2.4. HTLV-1 antibody testing must be performed for donors living in or originating from high-incidence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas.

2.5. In certain circumstances, additional testing may be required depending on the donor's travel and exposure history and the characteristics of the tissue or cells donated (e.g. RhD, malaria, CMV, T *cruzi*).

2.6. Positive results will not necessarily prevent partner donation in accordance with national rules.

3. Donations other than by partners.

The use of reproductive cells other than for partner donation must meet the following criteria–

3.1. Donors must be selected on the basis of their age, health and medical history, provided on a questionnaire and through a personal interview performed by a qualified and trained healthcare professional. This assessment must include relevant factors that may assist in identifying and screening out persons whose donation could present a health risk to others, such as the possibility of transmitting diseases (such as sexually transmitted infections), or health risks to themselves (e.g; superovulation, sedation or the risks associated with the egg collection procedure or the psychological consequences of being a donor).

3.2. The donors must be negative for HIV 1 and 2, HCV, HBV and syphilis on a serum or plasma sample, tested in accordance with point 1.1 of Schedule 2 and sperm donors must additionally be negative for Chlamydia on a urine sample tested by the nucleic acid amplification technique (NAT).

3.3. HTLV-1 antibody testing must be performed for donors living in or originating from high-incidence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas.

3.4. In certain circumstances, additional testing may be required depending on the donor's history and the characteristics of the tissue or cells donated (e.g. RhD, malaria, CamV, T.*cruzi*).

3.5. For autologous donors, point 2.1.1 in Schedule 1 applies.

3.6. Genetic screening for autosomal recessive genes known to be prevalent, according to international scientific evidence, in the donor's ethnic background and an assessment of the risk of transmission of inherited conditions known to be present in the family must be carried out, after consent is obtained. Complete information must be provided, in accordance with the requirements in this Act. Complete information on the associated risk and on the measures undertaken for its mitigation must be communicated and clearly explained to the recipient.

4. General requirements to be met for determining biological markers.

4.1. The tests must be carried out in accordance with points 2.1 and 2.2 of Schedule 2.

4.2. Blood samples must be obtained at the time of donation.

4.3. Sperm donations other than by partners will be quarantined for a minimum of 180 days, after which repeat testing is required. If the blood donation sample is additionally tested by the nucleic acid amplification technique (NAT) for HIV, HBV and HCV, testing of a repeat blood sample is not required. Retesting is also not required if the processing includes an inactivation step that has been validated for the viruses concerned.

SCHEDULE 4

Sections 9, 10 and 14

CELL OR TISSUE OR BOTH DONATION AND PROCUREMENT PROCEDURES AND RECEPTION AT THE TISSUE ESTABLISHMENT

1. Donation and procurement procedures.

1.1. *Consent and donor identification*

1.1.1. Before the procurement of tissues and cells proceeds, an authorised person must confirm and record–

(a) that consent for the procurement has been obtained in accordance with section 13; and

(b) how and by whom the donor has been reliably identified.

1.1.2. In the case of living donors, the health professional responsible for obtaining the health history must ensure that the donor has–

(a) understood the information provide,

(b) had an opportunity to ask questions and been provided with satisfactory responses;

(c) confirmed that all the information provided is true to the best of his/her knowledge.

1.2. *Donor evaluation* (*this paragraph does not apply to partner donation of reproductive cells or to autologous donors*)

1.2.1. An authorised person must collect and record the donor's relevant medical and behavioural information according to the requirements described in point 1.4

1.2.2. In order to acquire the appropriate information, different relevant sources must be used, including at least an interview with the donor, for living donors, and the following when appropriate:

(a) the medical records of the donor;

(b) an interview with a person who knew the donor well, for deceased donors;

(c) an interview with the treating physician;

(d) an interview with the general practitioner;

(e) the autopsy report.

1.2.3. In addition, in the case of a deceased donor, and in the case of a living donor when justified, a physical examination of the body must be performed to detect any signs that may be sufficient in themselves to exclude the donor or which must be assessed in the light of the donor's medical and personal history.

1.2.4. The complete donor records must be reviewed and assessed for suitability and signed by a qualified health professional.

1.3. Procurement procedures for tissues and cells

1.3.1. The procurement procedures must be appropriate for the type of donor and the type of tissue/cells donated. There must be procedures in place to protect the safety of the living donor.

1.3.2. The procurement procedures must protect those properties of the tissues/cells that are required for their ultimate clinical use, and at the same time minimise the risk of microbiological contamination during the process, particularly when tissues and cells cannot subsequently be sterilised.

1.3.3. For deceased donation, the area of access must be restricted. A local sterile field using sterile drapes must be used. Staff conducting procurement must be clothed appropriately for the type of procurement. Usually, this will extend to being scrubbed, gowned in sterile clothing and wearing sterile gloves, face shields and protective masks.

1.3.4. In the case of a deceased donor, the place of procurement must be recorded and the time interval from death to procurement must be specified so as to ensure that the required biological or physical properties of the tissues/cells are retained.

1.3.5. Once the tissues and cells have been retrieved from a deceased donor body, it must be reconstructed so that it is as similar as possible to its original anatomical appearance.

1.3.6. Any adverse event occurring during procurement that has or may have resulted in harm to a living donor and the outcome of any investigation to determine the cause must be recorded and reviewed.

1.3.7. Policies and procedures must be in place to minimise the risk of tissue or cell contamination by staff who might be infected with transmissible diseases.

1.3.8. Sterile instruments and devices must be used for tissue and cell procurement. Instruments or devices must be of good quality, validated or specifically certified and regularly maintained for the procurement of tissues and cells.

1.3.9. When reusable instruments must be used, a validated cleaning and sterilisation procedure for removal of infectious agents has to be in place.

1.3.10. Wherever possible, only CE marked medical devices must be used and all concerned staff must have received appropriate training on the use of such devices.

1.4. *Donor documentation*

1.4.1. For each donor, there must be a record containing–

(a) the donor identification (first name, family name and date of birth – if a mother and child are involved in the donation, both the name and date of birth of the mother and the name, if known, and date of birth of the child);

(b) age, sex, medical and behavioural history (the information collected must be sufficient to allow application of the exclusion criteria, where required);

(c) outcome of body examination, where applicable;

(d) haemodilution formula, where applicable;

(e) the consent/authorisation form, where applicable;

(f) clinical data, laboratory test results, and the results of other tests carried out;

(g) if an autopsy was performed, the results must be included in the record (for tissues and cells that cannot be stored for extended periods, a preliminary verbal report of the autopsy must be recorded);

(h) for haematopoietic progenitor cell donors, the donor's suitability for the chosen recipient must be documented. For unrelated donations, when the organisation responsible for procurement has limited access to recipient data, the

transplanting organisation must be provided with donor data relevant for confirming suitability.

1.4.2. The organisation performing the procurement must produce a procurement report, which is passed on to the tissue establishment. This report must contain at least:

(a) the identification, name and address of the tissue establishment to receive the cells/tissues;

(b) donor identification data (including how and by whom the donor was identified);

(c) description and identification of procured tissues and cells (including samples for testing);

(d) identification of the person who is responsible for the procurement session, including signing;

(e) date, time(where relevant, start and end) and location of procurement and procedure (SOP) used, including any incidents that occurred; where relevant, environmental conditions at the procurement facility (description of the physical area where procurement took place);

(f) for deceased donors, conditions under which the cadaver is kept: refrigerated (or not), time of start and end of refrigeration;

(g) ID/batch numbers of reagents and transport solutions used.

The report must also contain the date and time of death where possible.

Where sperm is procured at home, the procurement report must state this and must contain only–

(a) the name and address of the tissue establishment to receive the cells/tissues;

(b) the donor identification. The date and time of procurement may be included, where possible.

1.4.3. All the records must be clear and readable, protected from unauthorised amendment and retained and readily retrieved in this condition throughout their specified retention period in compliance with data protection legislation.

1.4.4. Donor records, required for full traceability must be kept for a minimum of 30 years after clinical use, or the expiry date, in an appropriate archive acceptable to the competent authority.

1.5. *Packaging*

1.5.1. Following procurement, all recovered tissues and cells must be packaged in a manner which minimises the risk of contamination and must be stored at temperature that preserve the required characteristics and biological function of the cells/tissues. The packaging must also prevent contamination of those responsible for packaging and transportation of the tissues or cells.

1.5.2. The packaged cells/tissues must be shipped in a container which is suitable for the transport of biological materials and which maintains the safety and quality of the contained tissue or cells.

1.5.3. Any accompanying tissue or blood samples for testing must be accurately labelled to ensure identification with the donor, and must include a record of the time and place the specimen was taken.

1.6. *Labelling of the procured tissues or cells or both*

At the time of procurement, every package containing tissues and cells must be labelled. The primary tissue/cell container must indicate the donation identification or code and the type of tissues and cells. Where the size of the package permits, the following information must also be provided–

(a) date (and time where possible) of donation;

(b) hazard warnings;

(c) nature of any additives (if used);

(d) in the case of autologous donations, the label must state ‘for autologous use only’;

(e) in the case of directed donations, the label must identify the intended recipient.

If any of the information under points (a) to (e) above cannot be included on the primary package label, it must be provided on a separate sheet accompanying the primary package.

1.7. *Labelling of the shipping container*

When tissues/cells are shipped by an intermediary, every shipping container must be labelled at least with–

(a) TISSUES AND CELLS and HANDLE WITH CARE;

(b) The identification of the establishment from which the package is being transported (address and phone number) and the contact person in the event of problems;

(c) the identification of the tissue establishment of destination (address and phone number) and the person to be contacted to take delivery of the container;

(d) the date and time of the start of transportation;

(e) specifications concerning conditions of transport relevant to the quality and safety of the tissues and cells;

(f) in the case of all cellular products, the following indication: DO NOT IRRADIATE;

(g) when a product is known to be positive for relevant infectious disease marker, the following indication: BIOLOGICAL HAZARD;

(h) in the case of autologous donors, the following indication: FOR AUTOLOGOUS USE ONLY.

(i) specifications concerning storage conditions (such as DO NOT FREEZE).

2. Receipt of the tissue/cells at the tissue establishment.

2.1. When the retrieved tissues/cells arrive at the tissue establishment, there must be documented verification that the consignment, including the transport conditions, packaging, labelling and associated documentation and samples, meet the requirements of this Schedule and the specifications of the receiving establishment.

2.2. Each establishment must ensure that the tissue and cells received are quarantined until they, along with the associated documentation, have been inspected or otherwise verified as conforming to requirements. The review of relevant donor/procurement information and thus acceptance of the donation needs to be carried out by specified/authorised persons.

2.3. Each tissue establishment must have a documented policy and specifications against which each consignment of tissues and cells,

including samples, are verified. These must include the technical requirements and other criteria considered by the tissue establishment to be essential for the maintenance of acceptable quality. The tissue establishment must have documented procedures for the management and segregation of non-conforming consignments, or those with incomplete test results, to ensure that there is no risk of contamination of other tissues and cells being processed, preserved or stored.

2.4. The data that must be registered at the tissue establishment (except for donors of reproductive cells intended for partner donation) include–

(a) consent/authorisation; including the purpose(s) for which the tissues and cells may be used (i.e. therapeutic or research, or both therapeutic use and research) and any specific instructions for disposal if the tissue or cells are not used for the purpose for which consent was obtained;

(b) all required records relating to the procurement and the taking of the donor history, as described in the donor documentation section;

(c) results of physical examination, of laboratory tests and of other tests (such as the autopsy report, if used in accordance with point 1.2.2.);

(d) for allogeneic donors, a properly documented review of the complete donor evaluation against the selection criteria by an authorised and trained person;

(e) in the case of cell cultures intended for autologous use, documentation of the possibility of medicinal allergies (such as to antibiotics) of the recipient.

2.5. In the case of reproductive cells intended for partner donation, the data to be registered at the tissue establishment include–

(a) consent; including the purpose(s) for which the tissues and cells may be used (such as reproductive only or for research or both) and any specific instructions for disposal if the tissue or cells are not used for the purpose for which consent was obtained;

(b) donor identification and characteristics: type of donor, age, sex and presence of risk factors and, in the case of a deceased donor, the cause of death;

(c) partner identification;

(d) place of procurement;

(e) tissues and cells obtained and relevant characteristics.

SCHEDULE 5

Section 5(2)

Requirements for authorisation of tissue establishments

A. ORGANISATION AND MANAGEMENT

1. A responsible person must be appointed having qualifications and responsibilities as provided in section 8 of this Act.

2. A tissue establishment must have an organisational structure and operational procedures appropriate to the activities for which authorisation is sought; there must be an organisational chart which clearly defines accountability and reporting relationships.

3. Every tissue establishment must have access to a nominated medical registered practitioner to advise on and oversee the establishment's medical activities such as donor selection, review of clinical outcomes of applied tissues and cells or interaction as appropriate with clinical users.

4. There must be a documented quality management system applied to the activities for which authorisation is sought, in accordance with the standards laid down in this Act

5. It must be ensured that the risks inherent in the use and handling of biological material are identified and minimised, consistent with maintaining adequate quality and safety for the intended purpose of the tissues and cells. The risks include those relating in particular to the procedures, environment, and staff health status specific to the tissue establishment.

6. Agreements between tissue establishments and third parties must comply with section 18 of this Act. Third party agreements must specify the terms of the relationship and responsibilities as well as the protocols to be followed to meet the required performance specification.

7. There must be a documented system in place, supervised by the responsible person, for ratifying that tissues or cells or both meet appropriate specifications for safety and quality for release and for their distribution.

8. In the event of termination of activities the agreements concluded and the procedures adopted in accordance with section 14(9) of this Act shall include traceability data and material concerning the quality and safety of tissues and cells.

9. There must be a documented system in place that ensures the identification of every unit of tissue or cells at all stages of the activities for which authorisation is sought.

B. **PERSONNEL**

1. The personnel in tissue establishments must be available in sufficient number and be qualified for the tasks they perform. The competency of the personnel must be evaluated at appropriate intervals specified in the quality system.

2. All personnel should have clear, documented and up-to-date job descriptions. Their tasks, responsibilities and accountability must be clearly documented and understood.

3. Personnel must be provided with initial or basic training, updated training as required when procedures change or scientific knowledge develops and adequate opportunities for relevant professional development. The training programme must ensure and document that each individual–

(a) has demonstrated competence in the performance of their designated tasks;

(b) has an adequate knowledge and understanding of the scientific or technical processes and principles relevant to their designated tasks;

(c) understands the organisational framework, quality system and health and safety rules of the establishment in which they work; and

(d) is adequately informed of the broader ethical, legal and regulatory context of their work.

C. **EQUIPMENT AND MATERIALS**

1. All equipment and material must be designed and maintained to suit its intended purpose and must minimise any hazard to recipients or staff or to both.

2. All critical equipment and technical devices must be identified and validated, regularly inspected and preventively maintained in accordance with the manufacturers' instructions. Where equipment or materials affect critical processing or storage parameters (e.g. temperature, pressure, particle counts, microbial contamination levels), they must be identified and must be the subject of appropriate monitoring, alerts, alarms and corrective action, as required, to detect malfunctions and defects and to ensure that the critical

parameters are maintained within acceptable limits at all times. All equipment with a critical measuring function must be calibrated against a traceable standard if available.

3. New and repaired equipment must be tested when installed and must be validated before use. Test results must be documented.

4. Maintenance, servicing, cleaning, disinfection and sanitation of all critical equipment must be performed regularly and recorded accordingly.

5. Procedures for the operation of each piece of critical equipment, detailing the action to be taken in the event of malfunctions or failure, must be available.

6. The procedures for the activities for which authorisation is sought, must detail the specifications for all critical materials and reagents. In particular, specifications for additives (e.g. solutions) and packaging materials must be defined. Critical reagents and materials must meet documented requirements and specifications.

D. **FACILITIES OR PREMISES**

1. A tissue establishment must have suitable facilities to carry out the activities for which authorisation is sought, in accordance with the standards laid down in this Act.

2. When these activities include processing of tissues and cells while exposed to the environment, this must take place in an environment with specified air quality and cleanliness in order to minimise the risk of contamination, including cross-contamination between donations. The effectiveness of these measures must be validated and monitored.

3.Unless otherwise specified in point 4, where tissues and cells are exposed to the environment during processing, without a subsequent microbial inactivation process, an air quality with particle counts and microbial colony counts equivalent to those of Grade A as defined in the current European Guide to Good Manufacturing Practice (GMP), Annex 1 and Directive 2003/94/EC is required with a background environment appropriate for the processing of the tissue/cell concerned but at least equivalent to GMP Grade D in terms of particles and microbial counts.

4. A less stringent environment than specified in point 3 may be acceptable where–

(a) a validated microbial inactivation or validated terminal sterilisation process is applied;

(b) or, where it is demonstrated that exposure in a Grade A environment has a detrimental effect on the required properties of the tissue or cell concerned;

(c) or, where it is demonstrated that the mode and route of application of the tissue or cell to the recipient implies a significantly lower risk of transmitting bacterial or fungal infection to the recipient than with cell and tissue transplantation;

(d) or, where it is not technically possible to carry out the required process in a Grade A environment (for example, due to requirements for specific equipment in the processing area that is not fully compatible with Grade A).

5. In point 4(a), (b), (c) and (d), an environment must be specified. It must be demonstrated and documented that the chosen environment achieves the quality and safety required, at least taking into account the intended purpose, mode of application and immune status of the recipient. Appropriate garments and equipment for personal protection and hygiene must be provided in each relevant department of the tissue establishment along with written hygiene and gowning instructions.

6. When the activities for which authorisation is sought involve storage of tissues and cells, the storage conditions necessary to maintain the required tissue and cell properties, including relevant parameters such as temperature, humidity or air quality must be defined.

7. Critical parameters (e.g. temperature, humidity, air quality) must be controlled, monitored, and recorded to demonstrate compliance with the specified storage conditions.

8. Storage facilities must be provided that clearly separate and distinguish tissues and cells prior to release in quarantine from those that are released and from those that are rejected, in order to prevent mix-up and cross-contamination between them. Physically separate areas or storage devices or secured segregation within the device must be allocated in both quarantine and released storage locations for holding certain tissue and cells collected in compliance with special criteria.

9. The tissue establishment must have written policies and procedures for controlled access, cleaning and maintenance, waste disposal and for the re-provision of services in an emergency situation.

E. **DOCUMENTATION AND RECORDS**

1. There must be a system in place that results in clearly defined and effective documentation, correct records and registers and authorised Standard Operating Procedures (SOPs), for the activities for which authorisation is sought. Documents must be regularly reviewed and must conform to the standards laid down in this Act. The system must ensure that work performed is standardised, and that all steps are traceable; i.e. coding, donor eligibility, procurement, processing, preservation, storage, transport, distribution or disposal, including aspects relating to quality control and quality assurance.

2. For every critical activity, the materials, equipment and personnel involved must be identified and documented.

3. In the tissue establishments all changes to documents must be reviewed, dated, approved, documented and implemented promptly by authorised personnel.

4. A document control procedure must be established to provide for the history of document reviews and changes and to ensure that only current versions of documents are in use.

5. Records must be shown to be reliable and a true representation of the results.

6. Records must be legible and indelible and may be handwritten or transferred to another validated system, such as a computer or microfilm.

7. Without prejudice to section 16(8) of this Act, all records, including raw data, which are critical to the safety and quality of the tissues and cells shall be kept so as to ensure access to these data for at least 10 years after expiry date, clinical use or disposal.

8. Records must meet the confidentiality requirements laid down in section 20. Access to registers and data must be restricted to persons authorised by the responsible person, and to the competent authority for the purpose of inspection and control measures.

F. **QUALITY REVIEW**

1. An audit system must be in place for the activities for which authorisation is sought. Trained and competent persons must conduct the audit in an independent way, at least every two years, in order to verify compliance with the approved protocols and the regulatory requirements. Findings and corrective actions must be documented.

2. Deviations from the required standards of quality and safety must lead to documented investigations, which include a decision on possible

corrective and preventive actions. The fate of non-conforming tissues and cells must be decided in accordance with written procedures supervised by the responsible person and recorded. All affected tissues and cells must be identified and accounted for.

3. Corrective actions must be documented, initiated and completed in a timely and effective manner. Preventive and corrective actions should be assessed for effectiveness after implementation.

4. The tissue establishment should have processes in place for review of the performance of the quality management system to ensure continuous and systematic improvement.

SCHEDULE 6

Section 9(1)(c)

Requirements for the authorisation of tissue and cell preparation processes at the tissue establishments

The competent authority shall authorise each tissue and cell preparation process after evaluation of the donor selection criteria and procurement procedures, the protocols for each step of the process, the quality management criteria, and the final quantitative and qualitative criteria for tissues and cells. This evaluation must comply at least with the requirements set out in this Schedule.

A. RECEPTION AT THE TISSUE ESTABLISHMENT

Upon reception of procured tissues and cells at the tissue establishment, the tissues and cells must comply with the requirements defined in this Act.

B. PROCESSING

When the activities for which the authorisation is sought include processing of tissues and cells, the tissue establishment procedures must comply with the following criteria–

1. The critical processing procedures must be validated and must not render the tissues or cells clinically ineffective or harmful to the recipient. This validation may be based on studies performed by the establishment itself, or on data from published studies or, for well-established processing procedures, by retrospective evaluation of the clinical results for tissues supplied by the establishment.

2. It has to be demonstrated that the validated process can be carried out consistently and effectively in the tissue establishment environment by the staff.

3. The procedures must be documented in SOPs which must conform to the validated method and to the standards laid down in this Act accordingly with Schedule 1 (E), points 1 to 4.

4. It must be ensured that all processes are conducted in accordance with the approved SOPs.

5. Where a microbial inactivation procedure is applied to the tissue or cells it must be specified, documented, and validated.

6. Before implementing any significant change in processing, the modified process must be validated and documented.

7. The processing procedures must undergo regular critical evaluation to ensure that they continue to achieve the intended results.

8. Procedures for discarding tissues and cells must prevent the contamination of other donations and products, the processing environment or personnel. These procedures must comply with national regulations.

C. STORAGE AND RELEASE OF PRODUCTS

When the activities for which the authorisation is sought include storage and release of tissues and cells, the authorised tissue establishment procedures must comply with the following criteria–

1. Maximum storage time must be specified for each type of storage condition. The selected period must reflect among others possible deterioration of the required tissue and cell properties.

2. There must be a system of inventory hold for tissues and cells to ensure that they cannot be released until all requirements laid down in this Act have been satisfied. There must be a standard operating procedure that details the circumstances, responsibilities and procedures for the release of tissues and cells for distribution.

3. A system for identification of tissues and cells throughout any phase of processing in the tissue establishment must clearly distinguish released from non-released (quarantined) and discarded products.

4. Records must demonstrate that before tissues and cells are released all appropriate specifications are met, in particular all current declaration forms, relevant medical records, processing records and test results have been verified according to a written procedure by a person authorised for this task by the responsible person as specified in section 8 of this Act. If a computer is used to release results from the laboratory, an audit trail should indicate who was responsible for their release.

5. A documented risk assessment approved by the responsible person as defined in section 8 of this Act must be undertaken to

determine the fate of all stored tissues and cells following the introduction of any new donor selection or testing criterion or any significantly modified processing step that enhances safety or quality.

D. **DISTRIBUTION AND RECALL**

When the activities for which the authorisation is sought include distribution of tissues and cells, the authorised tissue establishment procedures must comply with the following criteria–

1. Critical transport conditions, such as temperature and time limit must be defined to maintain the required tissue and cell properties.

2. The container and the package must be secure and ensure that the tissue and tissues and cells are maintained in the specified conditions. All containers and packages need to be validated as fit for purpose.

3. Where a contracted third party carries out distribution, a documented agreement must be in place to ensure that the required conditions are maintained.

4. There must be personnel authorised within the tissue establishment to assess the need for recall and to initiate and coordinate the necessary actions.

5. An effective recall procedure must be in place, including a description of the responsibilities and actions to be taken. This must include notification to the competent authority.

6. Actions must be taken within pre-defined periods of time and must include tracing all relevant tissues and cells and, where applicable, must include trace-back. The purpose of the investigation is to identify any donor who might have contributed to causing the reaction in the recipient and to retrieve available tissues and cells from that donor, as well as to notify consignees and recipients of tissues and cells procured from the same donor in the event that they might have been put at risk.

7. Procedures must be in place for the handling of requests for tissues and cells. The rules for allocation of tissues and cells to certain patients or health care institutions must be documented and made available to these parties upon request.

8. A documented system must be in place for the handling of returned products including criteria for their acceptance into the inventory, if applicable.

E. **FINAL LABELLING FOR DISTRIBUTION**

The primary tissue or cell container must provide–

(a) type of tissues and cells, identification number or code of the tissue or cells, and lot or batch number where applicable;

(b) identification of the tissue establishment;

(c) expiry date;

(d) in the case of autologous donation, this has to be specified (for autologous use only) and the donor/recipient has to be identified;

(e) in the case of directed donations - the label must identify the intended recipient;

(f) when tissues and cells are known to be positive for a relevant infectious disease marker, it must be marked as:

BIOLOGICAL HAZARD.

If any of the information under points (d) and (e) above cannot be included on the primary container label, it must be provided on a separate sheet accompanying the primary container. This sheet must be packaged with the primary container in a manner that ensures that they remain together.

2. The following information must be provided either on the label or in accompanying documentation–

(a) description (definition) and, if relevant, dimensions of the tissue or cell product;

(b) morphology and functional data where relevant;

(c) date of distribution of the tissue or cells;

(d) biological determinations carried out on the donor and results;

(e) storage recommendations;

(f) instructions for opening the container, package, and any required manipulation or reconstitution;

(g) expiry dates after opening or manipulation;

(h) instructions for reporting serious adverse reactions or events or both as set out in sections 11 and 12 of this Act;

(i) presence of potential harmful residues (e.g. antibiotics, ethylene oxide etc).

F. EXTERNAL LABELLING OF THE SHIPPING CONTAINER

For transport, the primary container must be placed in a shipping container that must be labelled with at least the following information–

(a) identification of the originating tissue establishment, including an address and phone number;

(b) identification of the organisation responsible for human application of destination, including address and phone number;

(c) a statement that the package contains human tissues or cells and HANDLE WITH CARE;

(d) where living cells are required for the function of the graft, such as stem cells gametes and embryos, the following must be added: 'DO NOT IRRADIATE';

(e) recommended transport conditions (e.g. keep cool, in upright position, etc.);

(f) safety instructions or method of cooling (when applicable).

SCHEDULE 7

Section 11(3)

NOTIFICATION OF SERIOUS ADVERSE REACTIONS

PART A
Rapid notification for suspected serious adverse reactions

Tissue establishment
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
Type of suspected serious adverse reaction(s)

PART B

Conclusions of serious adverse reactions investigation

Tissue establishment
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)
Change of type of serious adverse reaction (Yes/No) If Yes, *Specify*
Critical outcome (if known) -Complete recovery -Minor sequelae -Death
Outcome of the investigation and final conclusions
Recommendations for preventive and corrective actions

SCHEDULE 8

Section 12(4)

NOTIFICATION OF SERIOUS ADVERSE EVENTS

PART A
Rapid notification for suspected serious adverse events

Tissue establishment				
Report identification				
Reporting date (year/month/day)				
Date of serious adverse event (year/month/day)				
Serious adverse event, which may affect quality and safety of tissues and cells due to a deviation in:	Specification			
	Tissues and cells defect	Equipment failure	Human error	Other (specify)
Procurement				
Testing				
Transport				
Processing				
Storage				
Distribution				
Materials				
Others (*specify*)				

PART B

Conclusions of Serious Adverse Events investigation

Tissue establishment
Report identification
Confirmation date (year/month/day)
Date of serious adverse event (year/month/day)
Root cause analysis (details)
Corrective measures taken (details)

SCHEDULE 9

Section 28(3)

ANNUAL NOTIFICATION FORMAT

PART A
Annual notification format for serious adverse reactions

Reporting country			
Reporting date 1 January-31 December (*year*)			
Number of serious adverse reaction(s) per type of tissue and cell (or product in contact with the tissues and cells)			
	Type of tissue/cell (or product in contact with the tissues and cells)	Number of serious adverse reaction(s)	Total number of tissues/cells of this type distributed (if available)
1			
2			
3			
4			
…			
Total			
Total number of tissues and cells distributed (including type of tissue and cell for which no serious adverse reactions were reported):			
Number of recipients affected (total number of recipients):			
Number of serious adverse reactions reported		Total number of serious adverse reaction(s)	
Transmitted bacterial infection			
Transmitted viral Infection	HBV		
	HCV		
	HIV-1/2		

	Other (*Specify)*	
Transmitted parasitical	Malaria	
	Other *(Specify)*	
Transmitted malignant diseases		
Other disease transmissions		
Other serious reactions (*Specify)*		

PART B
Annual notification format for serious adverse events

Reporting country				
Reporting date 1 January-31 December (*year)*				
Total number of tissues and cells processed				
Total number of serious adverse events, which may have affected quality and safety of tissues and cells due to a deviation in:	Specification			
	Tissues and cells defect (*specify)*	Equipment failure (*Specify)*	Human error	Other *(specify)*
Procurement				
Testing				
Processing				
Storage				
Distribution				
Materials				

Others (*specify*)				

SCHEDULE 10

Section 16(8)

Information on the minimum donor or recipient or both data set to be kept

A. **BY TISSUE ESTABLISHMENTS**

Donor identification

Donation identification that will include at least–

— Identification of the procurement organisation or Tissue establishment

— Unique Donation ID number

— Date of procurement

— Place of procurement

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

Product identification that will include at least–

— Identification of the tissue establishment

— Type of tissue and cell or product (basic nomenclature)

— Pool number (if applicable)

— Split number (if applicable)

— Expiry date

— 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 or safety or both.

— Identification of the facility issuing the final label
Human application identification that will include at least:

— Date of distribution or disposal

— Identification of the clinician or end user or facility

B. **BY ORGANISATIONS RESPONSIBLE FOR HUMAN APPLICATION**

(a) Identification of the supplier tissue establishment

(b) Identification of the clinician or end user or facility

(c) Type of tissues and cells

(d) Product identification

(e) Identification of the recipient

(f) Date of application

SCHEDULE 11

Section 16(3)

Information contained in the European Coding System

(a) Donation identification–

— Unique ID number

— Identification of the tissue establishment

(b) Product identification–

— Product code (basic nomenclature)

— Split number (if applicable)

— Expiry date.