SECOND SUPPLEMENT TO THE GIBRALTAR GAZETTE

No. 3960 of 1 November, 2012

LEGAL NOTICE NO. 151 OF 2012.

INTERPRETATION AND GENERAL CLAUSES ACT

PUBLIC HEALTH (HUMAN TISSUES AND CELLS) ACT 2009 (AMENDMENT) REGULATIONS 2012

In exercise of the powers conferred on it by section 23(g)(ii) of the Interpretation and General Clauses Act and in order to transpose into the law of Gibraltar Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation, the Government has made the following Regulations–

Title and commencement.

1. These Regulations may be cited as the Public Health (Human Tissues and Cells) Act 2009 (Amendment) Regulations 2012 and come into operation on the day of publication.

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

2. The Public Health (Human Tissues and Cells) Act 2006 (the Act) is amended in accordance with regulations 3 to 13.

Amendment of the long title.

3. The long title to the Act is amended by inserting "Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation;" before "and for connected purposes".

Insertion of part heading.

4. Immediately preceding section 1 of the Act insert the following part heading–

"**PRELIMINARY**"

Amendment of section 1.

5. The Act is amended in section 1 by substituting "Public Health (Human Tissues, Cells and Organs)" for "Public Health (Human Tissues and Cells)".

New sections 1A and 1B.

6. After section 1 of the Act insert−

"**Interpretation: general.**

1A. In this Act−

"Commission" means the European Commission;

"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;

"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;

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

"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;

"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.".

Consequential amendments.

7. The Act is amended−

(a) by substituting "this Part" for "this Act" on each occasion those words appear in sections 2 to 29, Schedule 5 and Schedule 6;

(b) by substituting "Part 1" for "the Act" in the heading to section 4; and

(c) by substituting "this Part" for "the Act" in section 16(7).

Insertion of part heading.

8. The Act is amended by inserting the following part heading after section 1A−

"**PART 1**
HUMAN TISSUES AND CELLS"

Amendment of section 2.

9. Section 2 of the Act is amended−

(a) in the section heading by inserting the words "of Part 1" after "Interpretation";

(b) by deleting the following definitions; Commission, functions, Gibraltar Health Authority, inspect, inspection, Minister, premises, quality management, quality system, and record.

Renumbering of section.

10. Section 3 is renumbered section 1B.

Insertion of a new Part.

11. The Act is amended by inserting the following Part after section 28−

"**PART 2**
HUMAN ORGANS

Subject matter and application of this Part.

28A.(1) This Part sets the standards of quality and safety for human organs intended for transplantation to the human body, in order to ensure a high level of human health protection.

(2) This Part applies to the donation, testing, characterisation, procurement, preservation, transport and transplantation of human organs intended for transplantation.

(3) Where human organs are used for research purposes, this Part only applies where they are intended for transplantation into the human body.

Interpretation of Part 2.

28B. In this Part, unless the context otherwise requires−

"Authority" means the competent authority within the meaning of section 1B;

"designated individual", in relation to a licence under section 28E, means the individual designated in the licence as the person under whose supervision the licensed activity is authorised to be carried on;

"disposal" means the final placement of an organ where it is not used for transplantation;

"donation" means donating organs for the purposes of transplantation;

"donor" means a person who donates one or several organs, whether donation occurs during lifetime or after death;

"donor characterisation" means the collection of relevant information on the characteristics of the donor needed to evaluate the donor's suitability for organ donation, in order to undertake a proper risk assessment and to minimise the risks for the recipient, and optimise organ allocation;

"duly authorised person", in the context of any provision, means a person authorised by the Authority to act for the purposes of that provision;

"European organ exchange organisation" means a non-profit organisation, whether public or private, dedicated to national and cross-border organ exchange, in which the majority of its member countries are Member States;

"licence holder" means a person who holds a licence granted under section 28E;

"licensed activity", in relation to a licence, means an activity which the licence authorises under section 28E;

"organ" means a differentiated part of the human body, formed by different tissues, that maintains its structure, vascularisation, and

capacity to develop physiological functions with a significant level of autonomy and a part of an organ is also considered to be an organ if its function is to be used for the same purpose as the entire organ in the human body, maintaining the requirements of structure and vascularisation;

"organ characterisation" means the collection of the relevant information on the characteristics of the organ needed to evaluate its suitability for transplantation, in order to undertake a proper risk assessment and minimise the risks for the recipient, and optimise organ allocation;

"Organ Directive" means Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation as amended from time to time;

"operating procedures" means written instructions describing the steps in a specific process, including the materials and methods to be used and the expected end outcome;

"preservation" means the use of chemical agents, alterations in environmental conditions or other means to prevent or retard biological or physical deterioration of organs from procurement to transplantation;

"procurement" means a process by which a donated organ becomes available for transplantation;

"procurement activity" means any of the following activities, undertaken for the purposes of procurement−

(a) donor characterisation;

(b) organ characterisation;

(c) preservation of an organ;

(d) making arrangements to transport an organ; or

(e) retrieval of an organ;

"procurement organisation" means a healthcare establishment, a team or a unit of a hospital, a person, or any other body which undertakes or coordinates the procurement of organs, and is authorised to do so by the Authority;

"recipient" means a person who receives a transplant of an organ;

"serious adverse event" means any undesired and unexpected occurrence associated with any stage of the chain from donation to transplantation that might lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity;

"serious adverse reaction" means an unintended response, including a communicable disease, in the living donor or in the recipient that might be associated with any stage of the chain from donation to transplantation that is fatal, life-threatening, disabling, incapacitating, or which results in, or prolongs, hospitalisation or morbidity;

"traceability" means the ability to locate and identify the organ at each stage in the chain from donation to transplantation or disposal, including the ability to−

(a) identify the donor and the licence holder who retrieved the organ from the donor;

(b) identify the licence holder who implanted the organ in the recipient;

(c) identify the recipient at the premises that the organ is implanted into the recipient; and

(d) locate and identify all relevant non-personal information relating to products and materials coming into contact with that organ;

"transplantation" means a process which is intended to restore certain functions of the human body by transferring an organ from a donor to a recipient; and

"transplantation activity" means any of the following activities, undertaken for the purposes of transplantation−

(a) donor characterisation;

(b) organ characterisation;

(c) preservation of an organ;

(d) making arrangements to transport an organ; or

(e) implantation of an organ;

"transplantation centre" means a healthcare establishment, a team or a unit of a hospital or any other body which undertakes the transplantation of organs and is authorised to do so by the Authority.

Framework and compliance with licensing conditions and directions.

28C.(1) The Authority shall establish and keep updated a Framework which shall specify how the requirements for the quality and safety of organs for transplantation shall be ensured to secure compliance with the Organ Directive.

(2) The Framework shall–

(a) cover all stages of the chain from donation to transplantation or disposal; and

(b) include information about the−

(i) procurement activities and transplantation activities that are required to be carried on under the authority of a licence granted under section 28E,

(ii) licensing application process,

(iii) requirements that licensees must comply with, including the licensing conditions and any directions that the Authority has given under section 28H(4) to (7), and

(iv) guidance that the Authority has given under section 28H(1) to (3).

(3) The Framework shall provide for the adoption and implementation of operating procedures for−

(a) the verification of donor identity;

(b) the verification of the details of the donor's or the donor's family's consent, authorisation or absence of any objection;

(c) the verification of the completion of the organ and donor characterisation;

(d) the procurement, preservation, packaging and labelling of organs;

(e) the transportation of organs;

(f) ensuring traceability, guaranteeing compliance with the European Union and Gibraltar provisions on the protection of personal data and confidentiality;

(g) the accurate, rapid and verifiable reporting of serious adverse events and reactions; and

(h) the management of serious adverse events and reactions,

in accordance with the provisions in this Part.

(4) The operating procedures referred to in paragraphs (f), (g) and (h) shall specify, inter alia, the responsibilities of procurement organisations, European organ exchange organisations and transplantation centres.

(5) The Authority shall–

(a) ensure that the healthcare personnel involved at all stages of the chain from donation to transplantation or disposal are suitably qualified or trained and competent; and

(b) develop specific training programmes for such personnel.

Licensing requirement for procurement and transplantation activity.

28D.(1) No person shall carry out a procurement activity or a transplantation activity otherwise than under the authority of a licence granted under section 28E.

(2) A person who contravenes subsection (1) commits an offence unless that person reasonably believes that−

(a) the activity being undertaken is not an activity to which subsection (1) applies; or

(b) he is acting under the authority of a licence granted under section 28E.

Granting of licences.

28E.(1) The Authority may, on the application of any person, grant a licence for the purposes of section 28D.

(2) A licence granted under subsection (1) must−

(a) designate an individual as the designated individual; and

(b) not authorise a procurement activity or a transplantation activity to be carried on under the supervision of more than one such individual.

(3) A licence granted under this section must include at least the following conditions−

(a) that the licensed activities shall be carried on only under the supervision of the designated individual;

(b) that the procurement activity or the transplantation activity−

(i) shall have in place operating procedures for the management of a serious adverse event or a serious adverse reaction,

(ii) shall ensure to rapidly report to the Authority−

(A) any serious adverse event that may influence the quality and safety of an organ, or any serious adverse reaction observed during or after transplantation, which may be attributed to the testing, characterisation, procurement, preservation and transport of an organ, and

(B) the management measures taken with regard to such a serious adverse event or reaction;

(c) that the healthcare personnel directly involved in the chain from donation to the transplantation or disposal of an organ are suitably qualified or trained and competent to perform their tasks and are provided with relevant training;

(d) that training programmes are developed for the personnel referred to in subparagraph (c);

(e) that the data required to ensure the traceability of organs is kept for 30 years from the date of the retrieval of the organ;

(f) to comply with the Data Protection Act 2004; and

(g) to have in place operating procedures demonstrating how the requirements in paragraphs (b), (e) and (f) shall be complied with.

(4) A licence granted under this section must require for a procurement activity–

(a) that medical activities are performed under the advice and guidance of a registered medical practitioner;

(b) that procurement material and equipment which could affect the quality and safety of an organ are managed in accordance with relevant European Union or other international obligations and Gibraltar legislation, standards and guidelines on the sterilisation of medical devices; and

(c) to have in place operating procedures demonstrating how the requirements in paragraphs (a) and (b) shall be complied with.

(5) It shall be a condition of a licence for the procurement activity of retrieval of an organ−

(a) that the retrieval take place in an operating theatre which is designed, constructed, maintained and operated in accordance with adequate standards and best medical practices so as to ensure the quality and safety of the organs procured;

(b) to make endeavours to follow-up a living donor for the purposes of identifying and managing any event potentially relating to the quality and safety of the donated organ and any serious adverse reaction in the living donor that may result from the donation;

(c) to identify, report to the Authority, and manage any event or reaction referred to in paragraph (b); and

(d) to have in place operating procedures demonstrating how the requirement in paragraph (a) shall be complied with.

(6) A licence granted under this section must require for a procurement activity or transplantation activity of donor characterisation or organ characterisation to ensure−

(a) that a registered medical practitioner, or a person acting under the supervision of a registered medical practitioner, has endeavoured to obtain−

(i) all necessary information from the living person and for that purpose has provided that person with the information that person needs to understand the consequences of donation, or

(ii) where possible and appropriate in the case of a deceased donor, such information from relatives of the deceased donor or other persons and has explained to such persons the importance of swift transmission of that information;

(b) subject to subsection (8), that donors and organs are characterised before implantation by−

(i) the collection of at least the information specified in Part A of Schedule 12, and

(ii) where considered appropriate by a registered medical practitioner, or a person acting under the supervision of a registered medical practitioner, the collection of the information specified in Part B of Schedule 12;

(c) that tests required for donor and organ characterisation are carried out by laboratories with suitably qualified or trained and competent personnel and adequate facilities and equipment; and

(d) that any organisation, body or laboratory involved in organ and donor characterisation has appropriate operating procedures in place to ensure that information on organ and donor characterisation reaches the person who will be implanting an organ in a recipient within a time period that would not compromise the quality and safety of the organ.

(7) It shall be a condition of a licence for the transplantation activity of implantation−

(a) that, subject to subsection (8), the following are verified before proceeding to implant an organ in a recipient−

(i) identification and consent of the donor,

(ii) the collection of information prescribed in subsection (6)(b), and

(iii) compliance with the conditions in subsection (9) about the preservation and transportation of shipped organs; and

(b) to have in place operating procedures demonstrating how the requirements in paragraph (a)(i) and (ii) shall be complied with.

(8) Where any of the information specified in Part A of Schedule 12 is not available, it shall be a licensing condition for the transplantation activity of implantation to be permissible following the conduct of a risk-benefit analysis to determine whether the expected benefits for the recipient of the

organ outweigh the risks posed by the lack of any information and the particular circumstances of the case.

(9) It shall be a condition of a licence for a procurement activity or a transplantation activity making arrangements to transport an organ−

(a) that appropriate procedures are in place to ensure the integrity of the organ during transport and that the transport time is suitable to ensure the quality and safety of the organ;

(b) that, subject to subsection (10), the shipping containers used for transporting organs are labelled with the following information−

(i) identification of the licence holder who retrieved the organ and the place where the retrieval took place, including their addresses and telephone numbers,

(ii) identification of the place that an organ will be implanted in a recipient, including its address and telephone number,

(iii) a statement that the package contains an organ, specifying the type of organ and, where applicable, its left or right location and marked "HANDLE WITH CARE", and

(iv) recommended transport conditions, including instructions for keeping the container at an appropriate temperature and position;

(c) that the organs transported are accompanied by a report on the organ and donor characterisation; and

(d) to have in place operating procedures demonstrating how the requirements in subparagraphs (a) to (c) shall be complied with.

(10) The conditions in subsection (9)(b) do not apply where transportation is carried out in the same establishment.

(11) The Authority shall specify in the licence granted under this section as to which procurement activity or transplantation activity a licence holder may undertake.

(12) The Authority shall permit a person making an application for two or more−

(a) procurement activities;

(b) transplantation activities; or

(c) procurement activities and transplantation activities,

to make a single application in respect of the activities.

Preconditions to grant of a licence.

28F.(1) The Authority may not grant a licence under section 28E unless the requirements set out in this section are met.

(2) In the application for a licence, an individual must be designated who shall−

(a) be the applicant for the licence; or

(b) consent to an application for a licence.

(3) The Authority must be satisfied that the proposed designated individual−

(a) is a suitable person to supervise the activity to be authorised by the licence;

(b) will perform the duty imposed by section 28E;

(c) either−

(i) has a diploma, certificate or other evidence of formal qualification in the fields of medical or biological sciences awarded on completion of a university course of study, or other courses of study recognised in Gibraltar as equivalent, or

(ii) is otherwise considered by the Authority to be suitably qualified on the basis of academic qualification and practical experience; and

(d) has at least two years' practical experience which is directly relevant to the activity to be authorised by the licence.

(4) Where the applicant for the licence is not the proposed designated individual, the Authority must be satisfied that the applicant is a suitable person to be the holder of the licence.

(5) The Authority must be satisfied that the premises in which an applicant seeks to carry out the procurement activity of retrieval or the transplantation activity of implantation are suitable for the carrying out of that activity and it complies with the provisions of this Part and the Organ Directive.

(6) The Authority must be satisfied that the applicant meets−

(a) the relevant conditions in section 28E and will continue to do so; and

(b) any other conditions or requirements that the Authority has imposed.

(7) A copy of the conditions to be imposed by the licence must have been shown to, and acknowledged in writing by−

(a) the applicant for the licence; and

(b) where different, the proposed designated individual.

(8) In this section, references to the proposed designated individual are to the individual whom the application proposes that the licence should designate as the person under whose supervision the activity to be authorised is to be carried on.

(9) It shall be the duty of a designated individual to secure that−

(a) the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;

(b) suitable practices are used in the course of carrying on that activity; and

(c) conditions of the licence are complied with.

(10) The designated individual and licence holder shall take all necessary measures to ensure the highest possible protection of living donors in order to fully guarantee the quality and safety of organs for transplantation.

Consequences of failure, etc.

28G.(1) Where an inspection under this Part demonstrates that the designated person or the licence holder has failed to comply with the conditions of the licence, the Authority may−

(a) suspend the licence for a period not exceeding 6 months;

(b) withdraw the licence permanently; or

(c) prohibit the licence holder from carrying on any licensed activity until the failures or defects are remedied.

(2) The Authority shall not take any action under subsection (1) unless the licence holder and the designated individual are given a notice to show cause within seven days and his explanations are considered.

(3) A person aggrieved by a decision of the Authority under this section may appeal to the Supreme Court within thirty days and the decision of the Supreme Court shall be final.

Guidance and directions.

28H.(1) The Authority shall publish such guidance to licence holders, designated individuals, and healthcare personnel referred to in section 28E(3)(c) as it considers necessary to ensure compliance with the Organ Directive.

(2) The Authority shall keep the guidance published under subsection (1) under review and prepare revised guidance when it considers necessary.

(3) The Authority shall publish the guidance under this section in such a way as, in its opinion, is likely to bring it to the attention of licensees.

(4) A guidance published under this section must include guidance for the collection of relevant post-transplantation information to evaluate the quality and safety of the organs transplanted.

(5) The Authority may give directions for any purpose for which directions may be given under this Part.

(6) Any power under this Part to give directions–

(a) includes power to vary or revoke directions given in previous exercise of the power; and

(b) is exercisable by instrument in writing.

(7) Directions under this Part–

(a) to a particular person, shall be given by serving notice of the directions on the person; and

(b) in respect of any licence (including one which has ceased to have effect) may be given−

(i) by serving notice of the directions on the person who is (or was immediately before the cessation) the designated individual or holder of the licence, or

(ii) if it appears to the Authority that it is not practicable to give notice in that way, by publishing the directions in such way as, in its opinion, is likely to bring them to the attention of the persons to whom they are applicable.

(8) Directions under this Part which appear to the Authority to be general directions may be given by publishing them as mentioned in subsection (7)(b)(ii).

Records, reports and information.

28I.(1) The Authority shall−

(a) in accordance with the provisions of the Data Protection Act 2004 and any applicable European Union measure, keep a

record of activities that licence holders are carrying on, which shall include−

(i) the aggregate number of living and deceased donors, and

(ii) the types and quantities of organs procured and transplanted, or otherwise disposed of;

(b) publish an annual report on the activities referred to in paragraph (a); and

(c) establish and keep updated a record of persons who carry out a procurement activity or a transplantation activity.

(2) The Authority shall, upon the request of the Commission or any Member State provide information on–

(a) the requirements in Gibraltar for the authorisation of–

(i) procurement organisations;

(ii) transplantation centres; and

(b) the record of procurement organisations and transplantation centres.

The principles of organ donation.

28J.(1) The Authority shall ensure that every donation of organs from a deceased or a living person must be voluntary and unpaid.

(2) A living donor may be paid compensation to make good the expenses and loss of income related to the donation which must not be such as to become financial incentives or benefit for a potential donor.

(3) No person shall advertise the need for, or availability of, organs where that advertisement is with a view to offering or seeking financial gain or a comparable advantage.

(4) The Authority shall ensure that the procurement of organs is carried out on a non-profit basis.

The quality and safety of living donation.

28K.(1) Every living donor must be selected by suitably qualified or trained and competent professionals on the basis of an assessment of the health and medical history of that living donor.

(2) An assessment referred to in subsection (1) may provide for the exclusion of persons whose donation could present unacceptable health risks.

(3) The Authority shall keep a record or register of living donors for the purposes of ensuring the follow up of living donors, in accordance with the Data Protection Act 2004 and any applicable European Union measure relating to the protection of personal data and statistical confidentiality.

(4) The Authority shall make arrangements which−

(a) ensure that reasonable endeavours are made to follow-up all living donors for the purposes of identifying and managing any event potentially relating to the quality and safety of the donated organ and any serious adverse reaction in the living donor that may result from the donation; and

(b) identify, report and manage any event or reaction identified under paragraph (a).

(5) In subsection (4), a relevant donor means a living donor from whom the person who has ceased to be licensed retrieved an organ.

(6) The provisions of this section shall be applied so as to ensure the highest possible protection of living donors in order to fully guarantee the quality and safety of organs for transplantation.

Serious adverse events and serious adverse reactions.

28L.(1) The Authority shall ensure that there is a reporting system in place to report, investigate, register and transmit relevant and necessary information concerning serious adverse events that may influence the quality and safety of organs and that may be attributed to the testing, characterisation, procurement, preservation and transport of organs, as well as any serious adverse reaction observed during or after transplantation which may be connected to those activities.

(2) For the purposes of subsection (1), the Authority shall ensure that there is an operating procedure in place for the management of serious adverse events and reactions as provided for in the framework for quality and safety.

(3) The operating procedure referred to in subsection (2) must include a system for the notification, in due time, of−

(a) any serious adverse event and reaction to the Authority and to the concerned procurement organisation or transplantation centre; and

(b) the management measures with regard to serious adverse events and reactions to the Authority.

(4) For the purposes of this section, when a licence holder reports a serious adverse event or a serious adverse reaction to the Authority, or the Authority is otherwise made aware of such an event or reaction, the Authority shall−

(a) rapidly notify that information to such persons that the Authority considers may be affected by that information;

(b) investigate the matter where the Authority considers that an investigation will promote the quality and safety of organs; and

(c) register that information.

(5) There shall be an interconnection between the reporting system established under this section and the notification system established in accordance with sections 11 and 12.

Traceability.

28M.(1) The Authority shall ensure that a traceability system is established for the purposes of ensuring−

(a) that all organs procured, allocated and transplanted in Gibraltar can be traced from the donor to the recipient and vice versa in order to safeguard the health of donors and recipients; and

(b) notification of serious adverse events or reactions in accordance with section 28L(1)(a).

(2) The Authority shall ensure–

(a) the implementation of a donor and recipient identification system in Gibraltar that can identify each donation and each of the organs and recipients associated with it; and

(b) that confidentiality and data security measures are in place with regard to such a system n compliance with European Union law and the Data Protection Act 2004.

(3) The Authority shall ensure that−

(a) any person who is licensed to carry out a procurement activity or a transplantation activity that is involved in the chain from donation to transplantation or disposal keeps the data needed to ensure traceability at all stages of the chain from donation to transplantation or disposal and the information on organ and donor characterisation as specified in Schedule 12, in accordance with the framework for quality and safety;

(b) data required for full traceability is kept for a minimum of 30 years after donation and that data may be stored in electronic form.

(4) Where any person who is licensed to carry out a procurement activity or a transplantation activity ceases to be licensed, the Authority shall make arrangements to ensure that the data collected by that person under the licensing condition pursuant to section 28E (3) (e) is kept for 30 years from the date of the retrieval of the organ.

Organs sent to another country.

28N.(1) Where an organ is sent to a Member State, the Authority shall ensure that−

(a) information on organ and donor characterisation that is specified in Part A of Schedule 12 is transmitted to that State;

(b) such information in Part B of the Schedule 12 that has been collected by a registered medical practitioner or a person acting under their supervision; and

(c) information to ensure the traceability of the organ is transmitted to that State in conformity with procedures established by the Commission under Article 29 of the Organ Directive.

(2) Where an organ is sent to, or received from, a Member State, the Authority shall ensure the reporting of serious adverse events and reactions in conformity with procedures established by the Commission under Article 29 of the Organ Directive.

(3) The Authority shall ensure that any organs sent to, or received from, countries which are not in the European Union can−

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

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

(4) For the purposes of subsection (3), the Authority may enter into agreements with countries that are not in the European Union.

The Authority and European organ exchange organisations.

28O.(1) The Authority as defined in section 28B(1) is designated the competent authority for the purposes of Article 17 of the Organ Directive.

(2) The Authority shall, whenever reasonably practicable−

(a) participate in the network of competent authorities established by the European Commission; and

(b) co-ordinate Gibraltar's input into the activities of that network.

(3) The Authority may conclude agreements with European organ exchange organisations, if such organisations ensure compliance with the requirements of this Part, delegating to those organisations−

(a) the performance of activities provided for under the framework for quality and safety;

(b) specific tasks in relation to the exchanges of organs to and from Gibraltar and third countries.

(4) The Authority shall supervise each organ exchange with third countries.

(5) For the purpose of subsection (4), the Authority and the European organ exchange organisations may conclude agreements with counterparts in third countries.

(6) The Authority may delegate the supervision of organ exchange with third countries to European organ exchange organisations.

(7) Organ exchange with third countries shall be allowed only where the organs−

(a) can be traced from the donor to the recipient and vice versa; and

(b) meet quality and safety requirements equivalent to those laid down in the Organ Directive.

Control and audit by way of inspections.

28P.(1) The Authority shall put in place an inspection regime for the regular inspection of procurement organisations and transplantation centres in order to ascertain compliance with the requirements of this Part.

(2) For the purposes of subsection (1), a duly authorised person may require a person to produce for inspection any documents relevant for compliance with this Part.

(3) Where records or documents to which subsection (2) applies are stored in electronic form, the power under this section includes power to require the records or documents to be made available for inspection in a visible and legible form or in a form from which they can readily be produced in a visible and legible form.

(4) A duly authorised person may inspect and take copies of any documents produced for inspection in pursuance of a requirement under subsection (2).

(5) For the purposes of subsection (1), the Authority may arrange for any premises in which a licensed activity is being carried out to be inspected on its behalf, and for a report of the inspection to be made to it, for the purpose of ensuring compliance−

(a) with this Part;

(b) with the conditions of the licence; and

(c) by the designated individual with the duty under section 28F(9).

(6) If a justice of the peace is satisfied on sworn information that there are reasonable grounds for believing that−

(a) an offence under this Part is being, or has been, committed on any premises; and

(b) any of the conditions in subsection (7) is met in relation to the premises,

he may, by a signed warrant, authorise a duly authorised person to enter the premises, if need be by force, and search them.

(7) The conditions referred to in subsection (6) are that−

(a) entry to the premises has been, or is likely to be, refused and notice of the intention to apply for a warrant under this section has been given to the occupier;

(b) the premises are unoccupied;

(c) the occupier is temporarily absent; or

(d) an application for admission to the premises or the giving of notice of the intention to apply for a warrant under this subsection would defeat the object of entry.

(8) A warrant under this section shall continue in force until the end of the period of 31 days beginning with the day on which it is issued.

(9) Entry and search under a warrant under this section is unlawful if any of subsections (10) to (12) and (14) is not complied with.

(10) Entry and search shall be at a reasonable time unless the person exercising the warrant thinks that the purpose of the search may be frustrated on an entry at a reasonable time.

(11) If the occupier of the premises to which the warrant relates is present when the person executing the warrant seeks to enter them, the person executing the warrant shall−

(a) produce the warrant to the occupier; and

(b) give the occupier−

(i) a copy of the warrant, and

(ii) an appropriate statement.

(12) If the occupier of the premises to which the warrant relates is not present when the person executing the warrant seeks to enter them, but some other person is present who appears to the person executing the warrant to be in charge of the premises, the person executing the warrant shall−

(a) produce the warrant to that other person;

(b) give that other person−

(i) a copy of the warrant,

(ii) an appropriate statement, and

(c) leave a copy of the warrant in a prominent place on the premises.

(13) In subsections (11)(b)(ii) and (12)(b)(ii) the references to an appropriate statement are to a statement in writing containing the information set out section 28Q.

(14) If premises to which the warrant relates are unoccupied, the person executing the warrant shall leave a copy of it in a prominent place on the premises.

(15) Where the premises in relation to which a warrant under this section is executed are unoccupied, or the occupier is temporarily absent and no other person is present who appears to the person executing the warrant to be in charge of the premises, the person executing the warrant shall, when leaving the premises, leave them as effectively secured as the person executing the warrant found them.

Appropriate statements.

28Q. An appropriate statement for the purposes of section 28P must contain the following information−

(a) a statement that the duly authorised person has been authorised by the Authority for the purposes of section 28P;

(b) a statement that the duly authorised person's rights of entry and search are subject to that person producing evidence of entitlement to exercise them, if required;

(c) a statement that the duly authorised person is entitled, if need be, to enter premises by force;

(d) a description of the duly authorised person's powers under section 28R(2) to (4) of inspection and seizure of property;

(e) a description of the requirement under section 28R(5) for the duly authorised person to leave a statement giving particulars of what the duly authorised person has seized and a statement of what has been seized;

(f) a description of the powers of the duly authorised person−

(i) under section 28R(6), to bring with the duly authorised person such other persons and equipment as is considered by the duly authorised person necessary, and

(ii) under section 28R(7), to inspect equipment and inspect and take copies of records, and in the case of premises in respect of which a licence under this Part is in force, to observe the carrying-on of licensed activity;

(g) a description of the duly authorised person's obligations under section 28S(2) to prepare a written report of the search and, if requested to do so by the appropriate person, give the appropriate person a copy of the report; and

(h) a statement that a person commits an offence under section 28U if that person fails without reasonable excuse to comply with requirements under section 28R(8).

Seizure in the course of inspection or search.

28R.(1) A duly authorised person entering and inspecting premises under this Part may seize anything on the premises which the duly authorised person has reasonable grounds to believe may be required for purposes of the Authority's functions relating to the grant, revocation, variation and suspension of licences under this Part and to the investigation of serious adverse events and serious adverse reactions.

(2) A duly authorised person entering and searching premises under a warrant under section 28P may seize anything on the premises which he has reasonable grounds to believe may be required for the purpose of being used in evidence in any proceedings for an offence under this Part.

(3) Where a person has power under subsection (1) or (2) to seize anything, that person may take such steps as appear to be necessary for preserving the thing or preventing interference with it.

(4) The power under subsection (1) or (2) includes a power to retain anything seized in the exercise of the power for so long as it may be required for the purpose for which it was seized.

(5) Where by virtue of subsection (1) or (2) a person seizes anything, that person shall leave on the premises from which the thing was seized a statement giving particulars of what has been seized and stating the name of the person who has seized it.

(6) Any power under this Part to enter and inspect or search any premises includes a power to take such other persons and equipment as the person exercising the power reasonably considers necessary.

(7) Any power under section 28P or 28Q to inspect or search any premises includes, in particular−

(a) power to inspect any equipment found on the premises;

(b) power to inspect and take copies of any records found on the premises; and

(c) in the case of premises in respect of which a licence under section 28E is in force, power to observe the carrying-on on the premises of the licensed activity.

(8) Any power under this Part to enter, inspect or search premises includes power to require any person to afford such facilities and assistance with respect to matters under that person's control as are necessary to enable the power of entry, inspection or search to be exercised.

Requirements when exercising power of inspection or search.

28S.(1) A person's right to exercise a power under this Part is subject to that person producing evidence of their entitlement to exercise it, if required.

(2) As soon as reasonably practicable after having exercised a power under this Part to inspect or search premises, the duly authorised person shall–

(a) prepare a written report of the inspection or search; and

(b) if requested to do so by the appropriate person, give the appropriate person a copy of the report.

(3) In subsection (2), the "appropriate person", in relation to premises where a licensed activity is being carried out, means the designated individual or the licence holder.

Protection of personal data, confidentiality and security of processing.

28T.(1) The holder of a licence issued under this Part shall ensure that the fundamental right to protection of personal data is fully and effectively protected in all organ donation and transplantation activities, in accordance with sections 8(2)(h), 11 and 12 of the Data Protection Act 2004.

(2) The holder of a licence issued under this Part shall take all necessary measures to ensure that-

(a) the data processed are kept confidential and secure in accordance with sections 11 and 12 of the Data Protection Act 2004;
(b) donors and recipients whose data are processed within the scope of this Part are not identifiable, except as permitted by section 8(2) of the Data Protection Act 2004; and

(c) the principles relating to data quality, as set out in section 6 of the Data Protection Act 2004 are met.

Offences and penalties.

28U.(1) A person who contravenes section 28D, commits an offence and is liable−

(a) on summary conviction to a fine not exceeding level 5 on the standard scale; or

(b) on conviction on indictment−

(i) to imprisonment for a term not exceeding 2 years,

(ii) to a fine, or

(iii) to both.

(2) A person commits an offence if that person-

(a) fails without reasonable excuse to comply with a requirement under section 28P(2); or

(b) intentionally obstructs the exercise of any right or powers under sections 28P or 28R.

(3) A person guilty of an offence under subsection (2) is liable on summary conviction to a fine not exceeding level 4 on the standard scale.

(4) A person commits an offence if that person in contravention of section 28T−

(a) accesses any data or systems that makes identification of donor or recipients possible; or

(b) uses any system or data that makes the identification of donors or recipients possible with a view to tracing donors or recipients other than for the purposes permitted by section 8(2) of the Data Protection Act 2004.

(5) A person who commits an offence under subsection (4) is liable–

(a) on summary conviction, to a fine not exceeding level 4 on the standard scale; or

(b) on conviction on indictment to a fine not exceeding level 5 on the standard scale.

(6) Where a person is convicted of an offence under subsection (4), the court may order any data material which appears to the court to be connected with the commission of the offence to be forfeited or destroyed and any relevant data to be erased.

(7) The court shall not make an order under subsection (6) in relation to data material or data where it considers that some person other than the person convicted of the offence may be the owner of, or otherwise interested in, the data unless such steps as are reasonably practicable have been taken for notifying that person and giving him an opportunity to show cause why the order should not be made.

Offences by bodies corporate.

28V.(1) Where an offence under this Part is committed by a body corporate and is proved to have been committed with the consent or connivance of or to be attributable to any neglect on the part of–

(a) any director, manager, secretary or other similar officer of the body corporate; or

(b) any person who was purporting to act in any such capacity,

that person (as well as the body corporate) commits the offence and shall be liable to be proceeded against and punished accordingly.

(2) Where the affairs of a body corporate are managed by its members, subsection (1) applies in relation to the acts and defaults of a member in connection with that member's functions of management as if that member were a director of the body corporate.

Reports to the Commission.

28W. The Authority shall ensure that a report is sent to the Commission before 27 August 2013 and every three years thereafter on the activities undertaken in relation to the provisions of the Organ Directive, and on experience gained in implementing it.".

Insertion of Part heading.

12. The Act is amended by inserting the following part heading after section 28W−

"**PART 3**
MISCELLANEOUS"

Addition of new schedules.

13. The Act is amended by adding the following schedule after Schedule 11−

"**SCHEDULE 12**

Sections 28E and 28M

ORGAN AND DONOR CHARACTERISATION
PART A

Minimum data set

Minimum data – information for the characterisation of organs and donors which has to be collected for each donation in accordance with the second subparagraph of Article 7(1) of the Organ Directive and without prejudice to Article 7(2) of the Organ Directive.

Minimum data set

The establishment where the procurement takes place and other general data

Type of donor

Blood group

Gender

Cause of death

Date of death

Date of birth or estimated age

Weight

Height

Past or present history of IV drug abuse

Past or present history of malignant neoplasia

Present history of other transmissible disease

HIV; HCV; HBV tests

Basic information to evaluate the function of the donated organ

PART B

Complementary data set

Complementary data – information for the characterisation of organs and donors to be collected in addition to minimum data specified in Part A, based on the decision of the medical team, taking into account the availability of such information and the particular circumstances of the case, in accordance with the second subparagraph of Article 7(1) of the Organ Directive .

Complementary data set

General data

Contact details of the procurement organisation/the establishment where the procurement takes place necessary for coordination, allocation and traceability of the organs from donors to recipients and vice versa.

Donor data

Demographic and anthropometrical data required in order to guarantee an appropriate matching between the donor/organ and the recipient.

Donor medical history

Medical history of the donor, in particular the conditions which might affect the suitability of the organs for transplantation and imply the risk of disease transmission.

Physical and clinical data

Data from clinical examination which are necessary for the evaluation of the physiological maintenance of the potential donor as well as any finding revealing conditions which remained undetected during the examination of the donor's medical history and which might affect the suitability of organs for transplantation or might imply the risk of disease transmission.

Laboratory parameters

Data needed for the assessment of the functional characterisation of the organs and for the detection of potentially transmissible diseases and of possible contraindications with respect to organ donation.

Image tests

Image explorations necessary for the assessment of the anatomical status of the organs for transplantation.

Therapy

Treatments administered to the donor and relevant for the assessment of the functional status of the organs and the suitability for organ donation, in particular the use of antibiotics, inotropic support or transfusion therapy.".

Dated 1st November, 2012.

DR J CORTES,
For the Government.

EXPLANATORY MEMORANDUM

These Regulations seek to transpose into the law of Gibraltar Directive 2010/53/EC of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation. These Regulations impose quality and safety requirements in relation to the procurement and transplantation of organs intended for transplantation.