

Subsidiary Legislation made under s.29.

## **Exchange of Information on Human Organs Regulations 2014**

**LN.2014/085**

*Commencement*                      **29.5.2014**

**Transposing:**  
Implementing Directive 2012/25/EU

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### **ARRANGEMENT OF REGULATIONS**

Regulation

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9. Interconnection between Member States.

#### **SCHEDULE 1**

This Schedule reproduces Annex I to the Directive

#### **SCHEDULE 2**

This Schedule reproduces Annex II to the Directive

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*In exercise of the powers conferred upon him under section 29 of the Public Health (Human Tissues, Cells and Organs) Act 2009, and for the purpose of transposing into the law of Gibraltar Commission Implementing Directive 2012/25/EU of 9 October 2012 laying down information procedures for the exchange, between Member States, of human organs intended for transplantation, the Minister has made the following Regulations—*

**Title and commencement.**

1. These Regulations may be cited as the Exchange of Information on Human Organs Regulations 2014 and come into operation on the day of publication.

**Scope and purpose.**

2.(1) These Regulations apply in relation to the cross-border exchange of human organs intended for transplantation within the European Union, and provide for—

- (a) procedures for the transmission of information on organ and donor characterisation;
- (b) procedures for the transmission of the necessary information to ensure the traceability of organs;
- (c) procedures for ensuring the reporting of serious adverse events and reactions.

(2) The exchange of information referred to in section 28N of the Act shall be conducted in accordance with the procedures set out in these Regulations.

**Interpretation.**

3. In these Regulations—

“Act” means the Public Health (Human Tissues, Cells and Organs) Act 2009;

“competent authority” means the person or body appointed under regulation 4;

“a delegated body” means a body to which tasks have been delegated in accordance with Article 17(1) of Directive 2010/53/EU or a European organ exchange organisation to which tasks have been delegated in accordance with Article 21 of Directive 2010/53/EU;

“Directive” means Commission Implementing Directive 2012/25/EU of 9 October 2012 laying down information procedures for the exchange, between Member States, of human organs intended for transplantation, as the same may be amended from time to time;

“Member State of origin” means the Member State where the organ is procured with the purpose of transplantation;

“Member State of destination” means the Member State to which the organ is sent for the purpose of transplantation;

“national donor/recipient identification number” means the identification code attributed to a donor or a recipient in accordance with the identification system established pursuant to section 28M of the Act;

“specification of the organ” means–

- (a) the anatomical description of an organ including: its type (e.g. heart, liver);
- (b) where applicable, its position (left or right) in the body; and
- (c) whether it is a whole organ or a part of an organ, mentioning the lobe or segment of the organ.

#### **Competent Authority.**

4.(1) The Gibraltar Health Authority is designated as the competent authority for the purposes of these Regulations.

(2) The Minister may, by Notice in the Gazette, designate any other person or body as the competent authority in place of the Gibraltar Health Authority.

#### **Common procedural rules.**

5.(1) The competent authority shall ensure that the information transmitted pursuant to these Regulations between itself and other competent authorities or delegated bodies, procurement organisations, transplantation centres or both–

- (a) is transmitted in writing either electronically or by fax;

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- (b) is written in a language mutually understood by the sender and the addressee or, in absence thereof, in a mutually agreed language, or, in absence thereof, in English;
- (c) is transmitted without undue delay;
- (d) is recorded and can be made available upon request;
- (e) indicates the date and time of the transmission;
- (f) includes the contact details of the person responsible for the transmission;
- (g) contains the following reminder–

“Contains personal data. To be protected against unauthorised disclosure or access.”.

(2) In urgent cases, the information can be exchanged in a verbal form, in particular for exchanges pursuant to regulations 6 and 8 but those verbal contacts must be followed by a transmission in writing in accordance with those regulations.

(3) Where Gibraltar is the origin or the destination of human organs intended for transplantation, the competent authority shall ensure that the receipt of the information transmitted in accordance with these regulations is confirmed to the sender, in accordance with the requirements set out in subregulation (1).

(4) Designated personnel in competent authorities or delegated bodies must–

- (a) be available 24 hours a day and 7 days a week, for urgent situations;
- (b) be able to receive and transmit information pursuant to these Regulations without undue delay.

**Information on organ and donor characterisation.**

6.(1) Where organs are to be exchanged and Gibraltar is the place of origin, the competent authority shall, prior to exchanging the organ, transmit the information collected to characterise the procured organs and the donor, as specified in sections 28E, 28M and Schedule 12 to the Act, to the competent authorities or delegated bodies of the potential Member States of destination.

(2) Where some of the information to be transmitted in accordance with subregulation (1) is not available at the time of the initial transmission and becomes available later, the competent authority shall ensure that it is transmitted in due time—

- (a) to the competent authority or delegated body of the Member State of destination;  
or
- (b) directly by the procurement organisation to the transplantation centre,

to allow for medical decisions.

(3) Procurement organisations and transplantation centres must transmit to the competent authority a copy of the information pursuant to this regulation in sufficient time to enable the competent authority to comply with the provisions of this regulation.

(4) The competent authority may issue a notice in writing for the purposes of securing the information required under this regulation and a person who is served with such a notice shall comply with its terms.

#### **Information to ensure the traceability of organs.**

7.(1) Where Gibraltar is the origin of an organ intended for transplantation the competent authority must inform the competent authority or delegated body of the Member State of destination of—

- (a) the specification of the organ;
- (b) the national donor identification number;
- (c) the date of procurement;
- (d) name and contact details of the procurement centre.

(2) Where Gibraltar is the Member State of destination the competent authority must inform the competent authority or delegated body of the Member State of origin of—

- (a) the national recipient identification number or, if the organ was not transplanted, of its final use;
- (b) the date of transplantation, if applicable;

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(c) name and contact details of the transplantation centre.

**Reporting of serious adverse events and reactions.**

8.(1) The procedures set out in this regulation shall be implemented by the competent authority.

(2) Whenever the competent authority is notified of a serious adverse event or reaction that it suspects to relate to an organ that was received from a Member State, it shall immediately inform the competent authority or delegated body of the Member State of origin and transmit without undue delay to that competent authority or delegated body an initial report containing the information set out in Schedule 1, in so far as this information is available.

(3) Where Gibraltar is the Member State of origin the competent authority shall immediately inform the competent authorities or delegated bodies of each concerned Member State of destination and transmit them each an initial report containing the information set out in Schedule 1, whenever it is notified of a serious adverse event or reaction that it suspects to be related to a donor whose organs were also sent to other Member States;

(4) When additional information becomes available following the initial report referred to in subregulation (3), the competent authority must transmit it without undue delay;

(5) Where Gibraltar is the Member State of origin the competent authority shall, as a rule within 3 months of the initial report transmitted pursuant to subregulations (2) or (3), transmit to the competent authorities or delegated bodies of all Member States of destination, a common final report containing the information set out in Schedule 2, after collecting relevant information from all Member States involved.

(6) Where Gibraltar is the Member State of destination in a case to which subregulations (2) and (3) apply, the competent authority shall provide relevant information in a timely manner to the competent authority or delegated body of the Member State of origin.

**Interconnection between Member States.**

9.(1) The Minister shall ensure that the Commission is provided with the contact details of the competent authority or delegated bodies to which the relevant information shall be transmitted for the purpose of regulations 6, 7 and 8.

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(2) For the purposes of subregulations (1) the contact details include at least the following data: the organisation's name, telephone number, e-mail address, fax number and postal address.

(3) Where the Commission makes available a list of all competent authorities and delegated bodies designated by Member States in accordance with Article 8(1) of the Directive the Minister shall ensure that the information in that list relating to Gibraltar is up to date.

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**SCHEDULE 1**

**This Schedule reproduces Annex I to the Directive**

Initial Report for suspected serious adverse events or reactions

1. Reporting Member State

2. Report identification number:

country (ISO)/national number

3. Contact details of the reporter (competent authority or delegated body in the reporting Member State):

telephone, e-mail and, when available, fax

4. Reporting centre/organisation

5. Contact details of coordinator/contact person (transplant/procurement centre in the reporting Member State):

telephone, e-mail and, when available, fax

6. Reporting date and time (yyyy/mm/dd/hh/mm)

7. Member State of origin

8. National donor identification number, as communicated under Article 6

9. All Member States of destination (if known)

10. National recipient identification number(s), as communicated under Article 6

11. Onset date and time of serious adverse event or reaction (yyyy/mm/dd/hh/mm)

12. Detection date and time of serious adverse event or reaction (yyyy/mm/dd/hh/mm)

13. Description of serious adverse event or reaction



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14. Immediate measures taken/proposed

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**SCHEDULE 2**

**This Schedule reproduces Annex II to the Directive**

**Final Report of serious adverse events or reactions**

1. Reporting Member State
2. Report identification number:  
country (ISO)/national number
3. Contact details of the reporter:  
telephone, e-mail and, when available, fax
4. Reporting date and time (yyyy/mm/dd/hh/mm)
5. Identification number(s) of initial report(s) (Annex I)
6. Description of case
7. Involved Member States
8. Outcome of the investigation and final conclusion
9. Preventive and corrective actions taken
10. Conclusion/Follow-up, if required