

L.N. 141 of 2014**HUMAN BLOOD AND TRANSPLANTS ACT
(CAP. 483)****Information Procedures for the Exchange, between Member
States, of Human Organs intended for Transplantation
Regulations, 2014**

BY VIRTUE of article 16 of the Human Blood and Transplants Act, the Minister for Energy and Health, after consultation with the Licensing Authority, has made the following regulations:-

Citation and
scope.

1. (1) The title of these regulations is the Information Procedures for the Exchange, between Member States, of Human Organs intended for Transplantation Regulations, 2014.

(2) The scope of these regulations is to transpose 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.

Applicability.

2. These regulations shall apply to the cross-border exchange of human organs intended for transplantation within the European Union.

Objectives.

3. These regulations set out:

(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.

Interpretation.

4. In these regulations unless the context otherwise requires:

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"delegated body" means a body to which tasks have been delegated in accordance with regulation 3(3) of the Organ Transplants (Quality and Safety) Regulations or a European organ exchange organisation to which tasks have been delegated in accordance with regulation 19 of the Organ Transplants (Quality and Safety) Regulations;

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

"Member State of origin" means the Member State where the organ is procured with 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 at national level pursuant to regulation 10(1)(b) of the Organ Transplants (Quality and Safety) Regulations; S.L. 483.06

"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.

5. (1) The Superintendent of Public Health shall be the Licensing Authority for the purposes of these regulations. Licensing Authority.

(2) The Licensing Authority may delegate any of its functions to any other body it deems competent.

6. (1) Information transmitted between the Licensing Authority, or the delegated bodies, procurement organisations and, or transplantation centres shall: Common procedural rules.

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

(b) be 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) be transmitted without undue delay;

(d) be recorded and can be made available upon request;

(e) indicate the date and time of the transmission;

(f) include the contact details of the person responsible for the transmission;

(g) contain the following reminder:

‘Contains personal data. To be protected against unauthorised disclosure or access’.

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(2) In case of urgency, the information may be exchanged in a verbal form, in particular for exchanges pursuant to regulation 7 of the Organ Transplants (Quality and Safety) Regulations. These verbal contacts must be followed by a transmission in writing in accordance with those regulations.

(3) The receipt of the information transmitted in accordance with these regulations shall be confirmed to the sender, in accordance with the requirements set out in sub-regulation (1).

(4) Organ procurement centres and transplant centres shall ensure that designated personnel -

(a) are available 24 hours a day and 7 days a week, for urgent situations;

(b) are able to receive and transmit information pursuant to these regulations without undue delay.

Information on organ and donor characterisation.

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7. (1) Where organs are envisaged for exchange between Member States, prior to exchanging the organ, the transplant centre of origin shall transmit the information collected to characterise the procured organs and the donor, as specified in regulation 7 of, and in the Schedule to, the Organ Transplants (Quality and Safety) Regulations, 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 sub-regulation (1) is not available at the time of the initial transmission and becomes available later, the transplant centre of origin must ensure that it is transmitted in due time to allow for medical decisions:

(a) by the Licensing Authority or its delegated body when Malta is Member State of origin to the competent authority or delegated body of the Member State of destination; or

(b) directly by the procurement organisation to the transplantation centre.

(3) Procurement organisations and transplantation centres shall transmit to the Licensing Authority a copy of the information

pursuant to sub-regulation (2)(b).

8. (1) When Malta is the Member State of origin, the Licensing Authority or its delegated body shall inform the competent authority or delegated body of the Member State of destination of:

Information to ensure the traceability of organs.

- (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) When Malta is the Member State of origin, the competent authority or delegated body of the Member State of destination shall inform the Licensing Authority or delegated body 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;
- (c) name and contact details of the transplantation centre.

9. The Licensing Authority shall ensure that:

Reporting of serious adverse events and reactions.

(a) whenever as a Member State of destination, the Licensing Authority or its delegated body is notified of a serious adverse event or reaction that it suspects to relate to an organ that was received from another 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 I, in so far as this information is available;

(b) whenever as a Member State of origin, the Licensing Authority or its delegated body 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, the Licensing Authority or its delegated body, 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 I;

(c) when additional information becomes available following the initial report, it shall be transmitted without undue delay;

(d) whenever Malta is the Member State of origin, the Licensing Authority or its delegated body shall, as a rule within three months of the initial report transmitted pursuant to paragraph (a) or (b), 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 II. The competent authorities or delegated bodies of the Member States of destination shall provide relevant information in a timely manner to the Licensing Authority or its delegated body. The final report shall be drawn up after collecting relevant information from all Member States involved.

Interconnection
between
Member States.

10. (1) The Licensing Authority shall communicate to the Commission its contact details or those of the delegated bodies to which the relevant information shall be transmitted for the purpose of, on the one hand, regulation 6, and, on the other hand, regulations 7 and 8. These contact details shall include at least the following data: the organisation's name, telephone number, e-mail address, fax number and postal address.

(2) The Licensing Authority or the delegated bodies shall ensure that the information received by one of them pursuant to regulations 6, 7 or 8 is forwarded to the Licensing Authority or delegated body at national level, in accordance with the repartition of competences.

(3) The Licensing Authority shall be responsible for updating the information related to the competent authorities and delegated bodies designated by it in the list made available by the Commission or any third party entrusted by it to establish and maintain the list updated.

SCHEDULE I

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 regulation 7
 9. All Member States of destination (if known)
 10. National recipient identification number(s), as communicated under regulation 7
 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
 14. Immediate measures taken/proposed
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SCHEDULE II

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) (Schedule 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
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