Law of November 25, 1982, regulating the sampling of substances of human origin.

Amended Act

Type: Law

Signature: 25/11/1982

Publication: 03/12/1982

Memorial: A98

Author: Health, Finance, Justice

Main subjects: medical service

Secondary topics: organ donation, medical examination

Permalink ELI: http://legilux.public.lu/eli/etat/leg/loi/1982/11/25/n2/jo

We JEAN, by the grace of God, Grand Duke of Luxembourg, Duke of Nassau;

Our Council of State heard;

With the consent of the Chamber of Deputies;

Considering the decision of the Chamber of Deputies of October 19, 1982, and that of the Council of State of November 11, 1982, stating that there is no place for a second vote;

Have ordered and order:

Art. 1

This law applies to all removals of substances of human origin carried out for therapeutic and diagnostic purposes for the benefit of persons other than the donor and for research purposes.

The collection of blood or blood plasma, the transfer of embryos and the removal of testes and ovaries do not fall under the application of this law.

Chapter 1 – Collection of substances from living people.

Art. 2

With a view to graft or a transplant with a therapeutic aim on a humanbeing, a sample may be taken from a living person of full age and enjoying his or her mental integrity, having consented freely and in writing.

Art. 3

For the purposes referred to in Article 2, a sample may be taken from aminor, provided that the latter is capable of discernment and has given his consent in writing, that his representative

and a committee made up of at least three experts, including two doctors, and appointed by the Minister of Health authorized the collection and that the donation is intended for a brother or a sister of the donor.

If it concerns a minor over whom the father and mother jointly exercise parental authority, their dissent is deemed to refuse the sample's collection.

Art. 4

Before collection, appropriate medical examinations should be performed to assess and reduce the risk to the health and life of the donor.

Art. 5

In the case of a minor, the donor and his legal representative must be appropriately informed by the doctor, before the removal, of the possible consequences thereof, including medical, social, and psychological, as well as the interest that the sample presents for the recipient.

Chapter 2 – Collection of substances from deceased people.

Art. 6

Samples may be taken for therapeutic or scientific purposes from the corpse of a person who has not during his/her lifetime made known in writing his refusal to such a collection.

Art. 7

When the deceased was an incapable minor or adult, collection for the purposes indicated in article 6 can only be carried out after authorization by his legal representative and on condition that the deceased who was capable of discernment did not have during his lifetime make known in writing his refusal of such a collection.

In the case of a deceased minor over whom the father and mother jointly exercised parental authority, their disagreement is equivalent to refusing the removal.

Art. 8

The sample can only be taken if the deceased had his last legal domicile in Luxembourg. This condition is deemed to be fulfilled if the deceased does not carry a piece of identification showing his residence abroad. If the doctor carrying out the collection does not know any fact or any circumstance, making it appear with certainty or making the existence of the domicile abroad probable.

Art. 9

Before initiating the removal, the doctor must check whether the deceased has not objected to it.

Art. 10

Whenever a passport or identity card or foreigner's identity card is issued, the agent simultaneously provides the holder of this document a declaration form with two options that the interested can complete and sign if he intends to express that he is or is not an organ donor after his death.

The Minister of Health determines the form of this document and gives copies to the competent services which are required to issue them to individuals who request them, even without any issuance of an identity document.

Any declaration of authorization or refusal recorded in writing is equivalent to the permission or denial expressed in the document referred to in the preceding paragraph.

Art. 11

A collection can only occur after two doctors who are not involved in subsequenttransplantation or research operations have confirmed the death.

After the death has occurred, the removal can be performed even if the functions of specific organs other than the brain are artificially maintained.

A Grand-Ducal regulation adopted on the advice of the Medical College determines the procedures that physicians must personally follow to ascertainthe donor's death.

Art. 12

The doctor carrying out the removal shall record in a report the investigations he carried out under Articles 7, 8, 9 and 11 and records the findings therein.

Art. 13

It is prohibited to reveal the donor's identity to the recipient and that of the recipient to the donor's family.

Chapter 3 – Common provisions.

Art. 14

The collection referred to in this law may only occur in public or private hospitals or research institutes with specialized equipment and personnel. A Grand-Ducal regulation to be adopted on the advice of the Medical College and the Council of Hospitals determines the conditions that these establishments and institutes must meet to be authorized to take samples and be included on a list drawn up by the Minister of Health. This list indicates for each establishment and institute the type ofoperations that it is authorized to perform.

Art. 15

Kidney removal for therapeutic purposes can only occur within the framework of a national coordination service for kidney removal. A Grand-Ducal regulation determines the organization and working methods of this service.

Art. 16

Without prejudice to the reimbursement of lost income and all costs that may arise from the removals referred to in this law, the donation of any substance must be free.

Anyone who makes or accepts payment in contravention of the rule stated in the preceding paragraph is liable to the penalties provided for in article 18.

Art. 17

The loss of income of the living donor and the costs of the intervention on himare compensated by the health fund of the recipient according to terms to be determined by Grand-Ducal regulation.

The State bears the costs of the intervention on the deceased donor.

Art. 18

Without prejudice to the harsher penalties dictated by other laws, breaches of this law and its regulations are punishable by imprisonment from eight days to three years and a fine of 2,501 to 200,000 francs or one of these penalties only.

Book 1st of the Criminal Code and the Law of June 18, 1879, allowing courts and tribunals to assess mitigating circumstances, as amended by the Actof May 16, 1904, shall apply.

Art. 19

The provisions of the law of November 17, 1958, concerning the autopsy, the casting, and the use of human corpses in scientific or therapeutic interests, which relate to removing original human substances, are repealed.

Let us mandate and order that the present law be inserted in the Memorandum to be carried out and observed by all those concerned.

The Minister of Health, Berg Castle, December 25, 1982.

Emile Krieps Jeans

The Minister of Justice,

Colette Flesch

The Minister of Finance,

Jacques Santer

Law of June 25, 2015, amending the law of November 25, 1982, regulating the sampling of substances of human origin.

Amending Act

Type: Law

Signature: 06/25/2015

Publication: 07/02/2015

Effective: 07/06/2015

Memorial: A125

Author: Health

Main subjects: medical service

Secondary topics: organ donation

Permalink ELI:http://data.legilux.public.lu/eli/etat/leg/loi/2015/06/25/n1/jo

We Henri, Grand Duke of Luxembourg, Duke of Nassau, Our Council of State heard;

With the consent of the Chamber of Deputies;

Considering the decision of the Chamber of Deputies of May 20, 2015, and that of the Council of State of June 2, 2015, that there is no need for a second vote;

Have ordered and are ordering:

Art. 1

The title of the law of November 25, 1982, regulating the sampling of substances of human origin (hereinafter "the law") is replaced as follows: "Law of November 25, 1982, relating to organs intended fortransplantation."

Art. 2

The heading of chapter 1 of the law is replaced as follows: "Organ harvesting from living people."

Art. 3

The heading of Chapter 2 of the Act is replaced as follows: "Organ removal from deceased people."

Art. 4

Sections 1 to 3 of the Act are as follows:

"Art. 1:This law applies to any organ removal from living persons carried out for

therapeutic purposes for the benefit of a person other than the donorand to any organ removal for medicinal or scientific purposes from deceased persons."

Art. 2:

1. An organ harvesting can only be carried out on a living person who donates it if the following conditions are all met:
    a. The donation is in the direct therapeutic interest of a recipient named by name at the time of the donation;
    b. The transplant of the organ on the prospective recipient is capable of preserving the life of that person or of curing a severe disease from which he is afflicted or of preventing its aggravation, and a suitable organ is not available from a deceased person and no alternative therapeutic method of comparable efficacy is available;
    c. The donor is of legal age and enjoys his mental integrity;
    d. The donor does not present any medical or psychological contraindication for the removal and does not run, given his state of health, a risk disproportionate to the benefit that the donation provides to the recipient;
    e. The donor is spouse, direct parent, brother or sister, uncle or aunt, first cousin or first cousin of the recipient or linked to him by a declaration of partnership within the meaning of the law of July 9, 2004, relating to the legal effects of certain partnerships.
2. By way of derogation from point (e) of the preceding paragraph, an organ removal for the purposes of this law can also be operated if the donor and the recipient have maintained very close emotional relations for at least one year or if there is a relationship between them. Community of interest is based on considerations other than financial or economic.
3. When an organ is removed from a person for a purpose other than a donation for transplant, it may only be transplanted if the consequences and possible risks have been explained to that person and their informed consent or, in the case of a person not having the capacity to consent, the appropriate authorization has been obtained.

Art. 3

1. The donor referred to in Article 2 consents freely and in writing beforehand to the removal, after having been appropriately informed by a doctor, before the removal, of the possible consequences thereof, in particular medical, social, psychological, as well as the benefit that the donation presents for the recipient. In addition, he is informed of the right to receive independent information on the risks of the removal from a doctor with appropriate experience and not involved in the removal of this organ or the subsequent stages of the transplant. The donor subject can freely withdraw their consent at any time.

Art. 5

Article 4 of the law is completed in fine by the following sentence: “Appropriate medical follow-up is offered to the donor.”

Art. 6

Article 5 of the law is replaced as follows:

“Art. 5

1. The sampling operations referred to in Article 2 are subject to the approval of a committee of three experts, appointed by the Minister of Health in his or her attributions, hereinafter the Minister, including at least one doctor, proposed by the Medical College, and someone

with legal expertise. This committee ensures that the legal conditions are respected and, in particular, if the donor's consent has been given without any pressure.

2. If the removal is carried out in application of paragraph (2) of Article 2, the donor must, after the approval referred to in paragraph (1) of this article, express his consent to the president of the district court competent in function of his domicile, or before the magistrate that the president delegates for this purpose."

Art. 7

An article 13bis is introduced following article 13 of the law, worded as follows:

"Art. 13bis: In the context of the removal, the human body should be treated withrespect, and all reasonable steps should be taken to restore the appearance of the body."

Art. 8

Articles 14 to 16 of the law are replaced by the following articles:

1. Organ samples, characterizations and transplants can only be carried out in hospitals that have the following equipment and services:
    - An intensive care unit or intensive care;
    - A medical imaging service with a facility for arteriography or with a computerized axial tomography;
    - A neurology department with an electroencephalograph or suitable equipment for the search for evoked potentials;
    - A biochemical and bacteriological analysis laboratory;
    - An operating theatre equipped with the equipment necessary for carrying out organ harvesting.

    These establishments must also provide proof of an organization and functioning, such as to ensure that the operations involved in the withdrawals are carried out according to the rules of the art.
2. All the equipment and services necessary for the samples must be located on the same site of the hospital, apart from the biochemical and bacteriological analysis laboratory.
3. A list of the hospitals that comply with the conditions provided in paragraphs 1 and 2 is drawn up by the Minister.

Art. 15

Any removal, characterization, transport, and transplantation of organs covered by this law can only occur within the framework of a national coordination service for these operations.

This service will guarantee patients' fair access to transplantation services and will ensure the allocation of organs removed according to transparent and duly justified rules, taking particular account of medical criteria. It will organize the collection and registration of the information necessary to ensure the traceability of these organs and will register patients awaiting a transplant on an official waiting list.

The Minister may approve a non-profit private law body to perform the function of the national coordination service referred to in paragraph 1. With the Minister's agreement, this service may collaborate with an international body to achieve the objectives sought in the preceding paragraph.

A Grand-Ducal regulation determines the organization and working methods of the national coordination service. This same regulation can fix, if necessary, the modalities of the collaboration, of which question above, of this service with an international organization.

Art. 15 *bis*

1. All the organs obtained and the donors are subject to characterization; the Grand-Ducal regulation determines the information to be requested.
2. If, after a risk-benefit analysis in a particular case, including in a life-threatening emergency, it appears that the expected benefits for the recipient outweigh the risks arising from incomplete donor information, transplantation of an organ may be considered, even if all the information required by paragraph 1 is not available.

Art. 15 *ter*

1. The Health Department sets up a system to report, examine, record, and transmit the necessary relevant information concerning serious adverse incidents likely to affect the quality and safety of organs that could be attributed to the monitoring, characterization, procurement, storage, or transport of organs, as well as any severe adverse reactions observed during or after transplantation that could berelated to these activities.
2. The establishments authorized based on Article 14 and the national coordination service provided for in Article 15 are required to notify the Health Department:
    a. Any serious adverse event or reaction;
    b. Management measure for serious adverse events and reactions.

Art. 15 *quarter*

The national coordination service referred to in Article 15 shall record the activities of collection or transplantation establishments, record the aggregated numbers of living and deceased donors, and the types and quantities of organs obtained and transplanted or disposed of.

The national coordination service draws up and makes public an annual report on the activities referred to in paragraph 1. It establishes and maintains an up-to-date list of procurement establishments and transplantation establishments.

Art. 15 *quinquies*

The health personnel involved in the chain from donation to transplantation or organ disposal have the skills, qualifications and training determined by the Grand-Ducal regulation.

Art. 15 *sexies*

For organ exchanges with another member state of the European Union, a Grand-Ducal regulation establishes:

a) Procedures for the transmission of information relating to the characterization of organs and donors under Article 15 *bis*;
b) Procedures for the transmission of the information necessary to ensure the traceability of organs, per Article 15, paragraph 2;
c) Procedures for ensuring the notification of any serious adverse incident or reaction, in accordance with Article *15b.*

Art. 16

Without prejudice to the reimbursement of lost income and all costs that may arise from the organ removals referred to in this law, the transfer of any organ must be free. Anyone who makes or accepts payment in contravention of the rule set out in the preceding paragraph is liable to the penalties provided for in Article 18.

It is punished by the same penalties:

- The act of aiding promotes obtaining an organ against payment thereof or of ceding such an organ of another person's body against payment.
- Any measure making public the need for or the availability of organs, which is intended to offer or seek financial gain or comparable advantage.

The Minister of Health, Luxembourg Palace, June 25, 2015.

Lydia Mutsch **Henri**

Grand-Ducal Regulation of October 6, 2009, amending the Grand-Ducal Regulation of January 24, 1984, relating to the national coordination service for kidney removal.

Amending Act

Type: Grand-Ducal regulation

Signature: 06/10/2009

Publication: 10/16/2009

Memorial: A204

Author: Health

Main subjects: medical service

Secondary topics: organ donation

Permalink ELI: http://data.legilux.public.lu/eli/etat/leg/rgd/2009/10/06/n3/jo

We Henri, Grand Duke of Luxembourg, Duke of Nassau,

Considering the law of November 25, 1982, regulating the collection of substances of human origin, and in particular its article 15;

Having regard to the opinion of the Medical College;

Our Council of State heard;

On the report of Our Minister of Health and after deliberation of the Government in Council;

Repealed:

Art. I

The title of the Grand-Ducal regulation of January 24, 1984, relating to the national coordination service for kidney collection is amended as follow: “Grand-Ducal regulation relating to the national coordination service for organ harvesting.”

Art. II

The terms “kidneys” and used in the provisions of the aforementioned Grand-Ducal Regulation of January 24, 1984, are replaced by the term “organs”.

Art. III

Article 3 of the aforementioned Grand-Ducal Regulation of January 24, 1984, is replaced by the following text:

Art. 3

The association must be able to ensure availability, at any time of the day and night:

- A team of doctors able to take a sample and comprising an anesthesiologist, a surgeon or a urologist as well as a doctor specialist in internal medicine with knowledge in immunoallergology; the surgeon or urologist must be able to rely on experience in organ harvesting;
- A team of coordinators responsible for receiving calls signalling the existence of a candidate donor, ensuring, if necessary, consultation with the European organ bank referred to in article 5 below, and make the preparations required for the sample.

Art. IV

Our Minister of Health is responsible for executing these regulations, which will be published in the Memorial.

The Minister of Health, Luxembourg Palace, October 6, 2009.

Mars Di Bartolomeo **Henri**

Grand-Ducal Regulation of December 3, 2009, determining the procedures to be followed to ascertain death for the purpose of removal.

Unmodified basic act

Type: Grand-Ducal regulation

Signature: 03/12/2009

Art. 2

1. In the presence of primary or secondary brain injury, the following clinical signs should be checked individually to conclude that the brain has failed completely:
    a. Complete absence of consciousness;
    b. Pupils in bilateral mydriasis, unresponsive to light;
    c. Absence of oculo-cephalic reflexes;
    d. Absence of corneal reflexes;
    e. Absence of brain reaction to painful, acoustic, and visual stimuli;
    f. Absence of cough and oropharyngeal reflexes;
    g. The total absence of respiratory activity, demonstrated by an apnea test.
2. To conclude that the brain failure is irreversible and to establish the diagnosis of death, the clinical evaluations referred to in paragraph (1) must be repeated after an observation of at least six hours in adults and children over two years old, and twenty-four hours in children under two years old.
3. When the origin of the total lack of consciousness is unknown when thereis suspicion of intoxication or hypothermia, as well as when the patient's condition is likely to be explained by pathological metabolic parameters or by taking drugs that depress the nervous system, the procedure for determining the irreversibility of the brain failure is suspended. The observation referred to in paragraph (2) does not begin until after the origin of the total lack of consciousness has been determined or, where applicable, after the causes as mentioned above suspected to be at its head ceased to produce theireffect.
4. The repetition of clinical evaluations as well as the observation period, referred to in paragraph (2) above, may be replaced by one or more of the following technical examinations:
    a. Electroencephalogram;

b. Evoked potentials;
c. Cerebral arteriography;
d. Transcranial Doppler ultrasound;
e. Computed axial tomography with the injection of a contrast medium;
f. Single-photon emission tomography.

5. The clinical evaluation provided for in paragraph (1) must be supplemented by at least one of the technical examinations referred to in the preceding paragraph when, in the event of craniofacial trauma, an adequate clinical examination of the brainstem reflexes is not possible.
6. Physicians called upon to ascertain death carry out clinical evaluations and apply the criteria for interpreting technical examinations referred to in paragraph (4) in accordance with the data acquired by science.
7. One of the two physicians called upon to certify death under this article must be a physician specializing in neurology or neurosurgery.

Art. 3

1. In the case of:
   - A cardiac arrest occurring without any medical aid and proving immediately or secondarily irreversible;
   - Cardiac arrest that occurred in the presence of an emergency worker and persisted after an attempt at resuscitation (cardiac massage and artificial respiration);
   - An irreversible cardiac arrest occurring after planned discontinuation of treatment decided upon extensivedestruction of the brain;
   - An irreversible cardiac arrest occurred during a state ofprimary encephalic death during the patient's treatment in intensive care.

   The declaration of death can only be established if the following three clinicalcriteria are simultaneously present:
   - Complete absence of consciousness and spontaneous motoractivity;
   - Absence of all brainstem reflexes;
   - The total absence of spontaneous ventilation.
2. To conclude that the cardio-circulatory arrest is irreversible, whatever the cause, and to establish the diagnosis of death, the clinical evaluations referred to in paragraph (1) must be carried out after an observation of a minimum duration of five minutes of a complete cardio-circulatory and respiratory arrest, in normothermic conditions, and with electro-cartographic and capnography recording. In the cases referred to in the first and second indent of paragraph (1), the procedures leading to the declaration of death may not begin until after cardiopulmonary resuscitation lasting a minimum of thirty minutes.
   When the cardio-circulatory arrest was preceded by cardiopulmonary resuscitation, the observation referred to in the first paragraph does not beginuntil the attempt at cardio-pulmonary resuscitation is considered unsuccessful.
   Cardiopulmonary resuscitation is considered unsuccessful if, practised according to guidelines, it has at no time re-established spontaneous heart activity within an interval of thirty minutes and in the absence of any reversible cause, and all the clinical signs listed in paragraph (1) are present. If spontaneous cardiac activity momentarily resumes under the effect of resuscitation, the thirty-minute resuscitation duration is reset at the end of this episode of spontaneous cardiac activity.
   In children under two years of age and people with hypothermia, i.e. with a core temperature below 34.5 ° C, resuscitation measures should be performed for forty-five minutes before

considering cardiopulmonary resuscitation as unsuccessful. In people with initial hypothermia, the core temperature must be raised to 34.5 ° C before a diagnosis of death can be made. Regarding people likely to be intoxicated, it is at the attending physician's discretion to decide how long the resuscitation measures should be continued while respecting the minimum duration of thirty minutes.

3. Doctors called upon to ascertain death carry out clinical evaluations and apply the interpretation criteria referred to in paragraphs (1) and (2) in accordance with the data acquired by science.
4. One of the two physicians called upon to certify death under this article must be a physician specializing in anaesthesia-resuscitation or in cardiology and angiology.

Art. 4

As part of surgery to harvest organs from the body of a deceased person with a view to their transplantation into the body of another person, the medical data of the potential donor may be communicated to the national coordination service, referred to in article 15 of the law of November 25, 1982, regulating the removal of substances of human origin, and to European organ bank with which it collaborates.

The communication referred to in the preceding paragraph is limited to the medical data essential for carrying out the transplant project.

Supply of these data to the national coordination service can only be to a person subject to professional secrecy in the capacity as a doctor or member of one of the health professions covered by the amended law of March 26, 1992, on exercise and upgrading of certain health professions.

If necessary, the data is transmitted to the European organ bank through the care of the national coordination service. For these purposes, the information is de-identified through a reversible pseudonymization process, allowing the national coordination service to meet, if necessary, the requirements in terms of traceability.

If data transmission takes place through a computer network, secure transmission channels must be used.

Art. 5

The Grand-Ducal regulation of August 10, 1983, determining the procedures to be followed to ascertain death with a view to removal is repealed.

Art. 6

Our Minister of Health is responsible for the execution of these regulations, which will be published in the Memorial.

The Minister of Health, Luxembourg Palace, December 3, 2009.

Mars Di Bartolomeo **Henri**

Grand-Ducal Regulation of August 27, 2013, concerning the characterization, transport and exchange of organs intended for transplantation.

Unmodified basic act

Type: Grand-Ducal regulation

Signature: 08/27/2013

Publication: 03/09/2013

Effective date: 09/07/2013

Memorial: A159

Author: Health

Main subjects: medical service

Secondary topics: organ donation

Permalink ELI: http://data.legilux.public.lu/eli/etat/leg/rgd/2013/08/27/n1/jo

We Henri, Grand Duke of Luxembourg, Duke of Nassau,

Considering the amended law of November 25, 1982, regulating the sampling of substances of human origin;

Having regard to Directive 2010/53 / EU of the European Parliament and of the Council of July 7, 2010, relating to quality and safety standards for human organs intended for transplantation;

Having regard to the Commission implementing directive 2012/25 / EU of October 9, 2012, establishing information procedures for the exchange, between the Member States, of human organs intended for transplantation;

Having regard to the opinion of the Medical College;

Considering article 2, paragraph 1st of the law of July 12, 1996, on the reform of the State Council and considering that there is urgency;

On the report of Our Minister of Health and after deliberation of the Government in Council;

Repealed:

Art. 1

The information indicated in Annexe 1, Part A, is collected by the collection establishments for each organ donation.

The information indicated in Annexe 1, part B, constitutes a complementary set of data that must be collected in addition, according to the medical teams' decision, considering the availability of this information and the circumstances of the patient species.

Art. 2

The containers used for the transport of organs are labelled to show the following information:

a. The name of the procurement organization and the establishment where the procurement took place, including their address and telephone number;
b. The name of the recipient transplant centre, including its address and telephone number;
c. An indication that the container contains an organ, specifying the type of organ and mentioning, where appropriate, whether it is a right or left organ, as well as the words "FRAGILE";
d. Recommended transport conditions, including instructions for keeping the container at a suitable temperature and position.

The requirements referred to in paragraph 1 do not apply if the transport takes place within the same establishment.

Art. 3

The organs transported are accompanied by a report containing the characterization of the organ and donor under section 1.

Art. 4

For the purposes of the following articles:

a. "Member State of origin" means the Member State where the organ is obtained for the purpose of transplantation.
b. "Member State of destination" means the Member State to which the organ is sent for transplantation.
c. "National donor/recipient identification number" means the identification code assigned to a donor or a recipient under the identification system established at national level in application of article 15 *quater* of the amendedlaw of November 25, 1982, relating to organs intended for transplantation.
d. "Organ specification" means the anatomical description of anorgan, indicating:
    - Its type;
    - Where applicable, its position in the body;
    - If it is a whole organ or part of an organ with an indication of the lobe or segment of the organ concerned.
e. "National coordination service" means an approved service within the meaning of article 15, paragraph 3 of the amended law of November 25, 1982, relating to organs intended for transplantation.

Art. 5

1. Information transmitted in application of Articles 6 to 8 between competent authorities or delegated bodies, procurement organizations and/ortransplantation centres:
    a. Are communicated in writing, electronically or by fax;
    b. Are written in a language understood by both the sender and the addressee or, failing that, in a mutually agreed language or, failing that, in English;
    c. Are communicated as soon as possible;
    d. Are recorded and can be made available on request;
    e. Indicate the date and time of transmission;

f. Include the contact details of the person responsible for thetransmission;
g. Include the following reminder: “Contains personal information. Protect against unauthorized disclosure and access.”

2. In urgent cases, information may be exchanged verbally, within the framework of exchanges falling under Articles 6 and 8. A transmission follows these verbal contacts in writing in accordance with said articles.
3. The National Coordination Unit confirms the receipt of information pursuant to Articles 6 to 8 in accordance with the requirements of paragraph 1.

Art. 6

1. When an organ exchange is planned between Luxembourg and anotherMember State, the national coordination service transmits to the competent authorities or delegated bodies of the potential Member State of destination, before the exchange, the information collected for the characterization of the obtained bodies and the donor, as specified in section 1.
2. The information, which is not available in the initial transmission, is subsequently obtained and transmitted under paragraph 1, is communicated in good time to allow the medical decision-making:
    a. By the national coordination service to the competent authority or the delegated body of the Member State ofdestination, or
    b. Directly by the national coordination service at the transplantcentre.

Art. 7

1. The national coordination service informs the competent authority or thedelegated body of the Member State of destination:
    a. The specification of the organ;
    b. The national identification number of the donor;
    c. The date of obtaining;
    d. The name and contact details of the procurement centre.
2. The national coordination service informs the competent authority or the delegated body of the home Member State:
    a. The national identification number of the recipient or, if the organ has not been transplanted, its end use;
    b. The date of the transplantation, if possible;
    c. The name and contact details of the transplant centre.

Art. 8

1. The national coordination service, notified of an incident or severe adverse reaction that it suspects to be linked to an organ received from another Member State, immediately informs the competent authority or the delegated body of the home Member State and sends as soon as possible an initial report containing the information indicated in Annexe 2, to the extent that it is available.
2. The national coordination service immediately informs the competent authorities or delegated bodies of each Member State of destination concerned and sends each of them an initial report containing the information indicated in Annexe 2, whenever it is notified of an incident or severe adverse reaction that he suspects to be related to a donor whose organs have also been sent to other Member States.

3. If information becomes available after the initial report has been drawn up, it will be transmitted as soon as possible.
4. The national coordination service shall send to the competent authorities or delegated bodies of all the Member States of destination, within three monthsof the initial report transmitted in application of points (a) or (b), a joint final statement containing the information indicated in Annexe 3. The national coordination service sends all relevant information in good time to thecompetent authority or delegated body of the home Member State. The final report is drawn up after collecting the relevant information provided by all the Member States concerned.

Art. 9

Our Minister of Health is responsible for the execution of these regulations, which will be published in the Memorial.

The Minister of Health, Berg Castle, August 27, 2013.

Mars Di Bartolomeo **Henri**