

REPUBLIC OF LITHUANIA
LAW ON DONATION AND TRANSPLANTATION
OF HUMAN TISSUES, CELLS AND ORGANS

19 November 1996 No I-1626

Vilnius

(As last amended on 12 May 2016 – No XII-2344)

CHAPTER I
GENERAL PROVISIONS

Article 1. Purpose and scope of the Law

1. The purpose of this Law shall be to ensure and develop the safety and quality of the process of donation and transplantation of human tissues, cells and organs.

2. This Law shall lay down the conditions and procedure of the process of donation and transplantation of human tissues, cells and organs.

3. The provisions of this Law regulating donation, procurement and testing of human tissues and cells shall apply to human tissues and cells used to manufacture medicinal products for human use, and the provisions of the Law of the Republic of Lithuania on Pharmacy and Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ 2007 L 324, p.121) shall regulate the processing, preservation, storage and distribution of such human tissues and cells.

4. This Law shall not regulate the procurement or testing of human tissues, cells and organs in the cases of anatomical pathology, forensic medical and biomedical research of human beings; human tissues and cells which are used as an autologous graft within the same surgical procedure and without being subjected to any banking process; donation of sperm, eggs, embryos and embryonic stem cells, foetal tissues or cells (except the amniotic membrane after the birth); the process of donation and transplantation of blood or blood components (except haematopoietic peripheral blood, umbilical-cord (blood) and bone-marrow stem cells.

5. This Law shall implement the legal acts of the European Union listed in the Annex to this Law.

Article 2. Definitions

1. Traceability means the ability at each stage in the chain from donation to transplantation to locate and identify the tissue, cell, organ, donor, recipient and all relevant information relating to materials coming into contact with that tissue, cell, organ.

2. Tissue means all constituent parts of the human body formed by cells.

3. Tissue bank means a health care institution providing services related to procurement, processing, preservation, storage and distribution of human tissues and cells, as well as performing other functions laid down by legal acts.

4. Processing of tissues, cells or organs (hereinafter: '**processing**') means the preparation, manipulation and packaging of tissues, cells or organs.

5. Donation of tissues, cells or organs (hereinafter: '**donation**') means donating for transplantation human tissues, cells or organs voluntarily and without return consideration.

6. Testing of tissues, cells or organs (hereinafter: '**testing**') means the evaluation of suitability of human tissues, cells or organs for transplantation.

7. Preservation of tissues, cells or organs (hereinafter: '**preservation**') means the use of chemical agents, alterations in environmental conditions or other means to prevent or retard biological or physical deterioration of tissues, cells or organs.

8. Human application means the use of tissues or cells on or in a human recipient and the use of organs in a human recipient.

9. Procurement of tissues, cells or organs (hereinafter: '**procurement**') means the procurement of tissues, cells or organs during surgery and other procedures in the prescribed manner.

10. Selection of tissues, cells or organs (hereinafter: '**selection**') means proper distribution of donated tissues, cells or organs to recipients on the basis of medical and other criteria and requirements for the selection of a donor and recipient pair, as approved by the Minister of Health.

11. Distribution (allocation) of tissues, cells or organs (hereinafter: '**distribution (allocation)**') means transportation and delivery of tissues, cells or organs intended for human applications to a health care institution.

12. Disposal of tissues, cells or organs (hereinafter: '**disposal**') means the destruction of a tissue, cell or organ where it is not used for transplantation (or after transplant rejection).

13. Transplantation of tissues, cells or organs (hereinafter: '**transplantation**') means transferring tissues, cells or organs to recipients for therapeutic purposes.

14. Donor means a person who donates tissues, cells or organs for transplantation, whether donation occurs during lifetime or after death.

15. Process of donation and transplantation means a process which is aimed at ensuring proper procurement of human tissues, cells or organs and transplantation into a recipient and which consists of the interrelated stages of donation, procurement, testing, processing, preservation, storage, selection, distribution (allocation) and transplantation.

16. Donor characterisation means the collection of the relevant information on the characteristics of the donor needed to evaluate his/her suitability for organ donation, in order to undertake a proper risk assessment and minimise the risks for the recipient, and optimise the distribution (allocation) of tissues, cells or organs.

17. Cell means the basic structural unit of a living human organism, not bound by any form of connective tissue.

18. Organ means a part of the human body, formed by different tissues, that maintains its structure, vascularisation and capacity to develop physiological functions with an important level of autonomy. 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.

19. Organ characterisation means the collection of the relevant information on the characteristics of the organ needed to evaluate its suitability, in order to undertake a proper risk assessment and minimise the risks for the recipient, and optimise organ selection.

20. Serious adverse reaction means an unintended response, including communicable diseases, in the living donor or in the recipient that is associated with the procurement or human application of tissues, cells or organs where such response is life-threatening, disabling, incapacitating, fatal or results in, or prolongs, morbidity or hospitalisation.

21. Serious adverse event means any undesired and unexpected occurrence associated with the procurement, testing, processing, storage, selection, distribution (allocation) and transplantation of tissues, cells and organs that might lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions for patients or which might result in, or prolong, morbidity or hospitalisation.

22. Paired donation means the exchange of donor organs suitable for transplantation between two pairs where an organ of the donor of one mutually incompatible pair related by marriage or by blood, is suitable for the recipient of the other mutually incompatible pair related by marriage or by blood, while an organ of the donor of the second pair is suitable for the recipient of the first pair.

23. Recipient means a patient who needs transplantation of a tissue(s), cells or an organ(s) and whose name is entered on the Register of Donors and Recipients of Human Tissues, Cells and Organs in accordance with the procedure laid down by legal acts.

24. Regenerating tissue means the tissue of a living person which, after being injured or a part of it removed, restores by itself.

25. Foreign entity means a legal person or its branch registered in a foreign state in compliance with its legal acts and carrying out there the activities with human tissues, cells and organs.

CHAPTER II

PRINCIPLES AND PROCEDURE OF IMPLEMENTATION OF THE PROCESS OF DONATION AND TRANSPLANTATION OF HUMAN TISSUES, CELLS AND/OR ORGANS

Article 3. Principles of the process of donation and transplantation of human tissues, cells and organs

The process of donation and transplantation of human tissues, cells and organs shall be performed according to the principles of volunteering, non-payment, anonymity, confidentiality, respect for human dignity, more expected therapeutic benefit than a potential risk to donor's or recipient's health.

Article 4. Procedure of implementation of the process of donation and transplantation of human tissues, cells and/or organs

A legally capable person who expresses in accordance with the procedure laid down by the Minister of Health his consent to donate his tissues, cells or organs for transplantation may be a donor. Minors may be donors of regenerating tissues and cells in accordance with the procedure laid down in Article 6(5) of this Law.

Every legally capable person shall enjoy the right to express in accordance with the procedure laid down by the Minister of Health the objection to transplantation of his tissues or organs after his death.

3. Before giving consent, a person must be familiarised in accordance with the procedure laid down by the Minister of Health with donation conditions and procedure and informed about a possibility to any time change his decision to give his tissues, cells or organs.

4. It shall be prohibited to procure tissues, cells or organs from a legally incapable adult donor or an adult donor with limited legal capacity.

5. It shall be prohibited to procure non-regenerative tissues and organs of a living minor.

Article 5. Procedure and conditions of implementation of the process of donation and transplantation of tissues and organs of a deceased donor

1. Tissues and organs of a deceased donor may be transplanted into a recipient only for therapeutic purposes.

2. It shall be permitted to procure and give for transplantation the tissues and/or organs of a deceased person who, while alive, did not express his will in accordance with the procedure laid down in Article 4(1) and (2) of this Law, if his relatives give consent to the donation of the deceased person's tissues and/or organs in accordance with the procedure laid down by the Minister of Health. It shall be prohibited to procure and use for transplantation the tissues or organs of a deceased person without his relatives' consent, except the case provided for in paragraph 4 of this Article.

3. In the case provided for in paragraph 2 of this Article, the deceased person's relatives shall be asked for the consent in the following order of priority: the spouse, adult children (adopted children), parents (adoptive parents), brothers (sisters). If the consent is given by one of the above-mentioned persons in the order of priority, the consent of the other relatives of the deceased shall not be asked for. If the objection is expressed by one of the above-mentioned persons in the order of priority, it shall be prohibited to procure and give for transplantation the deceased person's tissues or organs.

4. If a deceased person, while alive, did not express his will in accordance with the procedure laid down in Article 4(1) and (2) of this Law regarding the donation of tissues and/or organs and did not have the relatives specified in paragraph 3 of this Article, the decision to give the deceased person's tissues or organs for transplantation shall, in accordance with the procedure laid down by the Minister of Health, be taken by a consultation of the doctors of a health care institution six hours after the establishment of the fact of death of the above-mentioned person. The consultation of the doctors shall comprise a representative of the medical ethics commission of the health care institution, the doctor who treated the deceased person and the head or any other representative of the administration of the department where the person was treated.

5. In the presence of the conditions stipulated in paragraph 4 of this Article, the persons who are interested, due to any reasons, in the transplantation of the above-mentioned person's tissues or organs shall not have the right to take part in taking the decision on procurement of the above-mentioned person's tissues or organs for transplantation.

6. The procedure for establishing the moment and fact of death shall be laid down in the Law of the Republic of Lithuania on the Establishment of Death of a Human Being, and on Critical Conditions, and in other legal acts.

7. Before procuring the tissues or organs of a deceased donor for transplantation all data necessary for donor and his organs characterisation to be made must be collected in accordance with the procedure laid down by the Minister of Health.

8. The Register of Donors and Recipients of Human Tissues, Cells and Organs shall record as recipients of the deceased donor's tissues or organs only the persons covered by the mandatory health insurance as well as the persons to whom this Law must apply pursuant to the regulations of the coordination of social security systems of the European Union.

9. The procedure for implementing the process of donation and transplantation of the tissues or organs of a deceased donor in a health care institution shall be laid down by the Minister of Health.

Article 6. Procedure and conditions of implementation of the process of donation and transplantation of tissues, cells and/or organs of a living donor

Tissues, cells or organs of a living donor may be given for transplantation only for the treatment of a patient.

A living legally capable donor may donate non-regenerative tissues or organs for transplantation, provided that all of the following conditions are satisfied (except the cases of donation of the amniotic membrane after the birth, bone and muscle tissues):

1) the donor signs the consent of the form set out by the Minister of Health to donate his non-regenerative tissues or organs for transplantation;

2) non-regenerative tissues or organs are transplanted only into the donor's spouse or a recipient related to the donor by blood, or in the paired donation manner.

3. A living legally capable donor may donate non-regenerative tissues or organs for transplantation as paired donation, provided that all of the following conditions are satisfied:

1) the donor signs the consent of the form set out by the Minister of Health to donate his non-regenerative tissues or organs for transplantation;

2) a mutually incompatible pair consists of the spouses or persons closely related by blood;

3) a tissue or an organ of the donor of one mutually incompatible pair is suitable for the recipient of the other mutually incompatible pair, while a tissue or an organ of the donor of the second pair is suitable for the recipient of the first pair.

4. The amniotic membrane after the birth or bone and muscle tissues of a living legally capable donor may be procured and donated for transplantation, provided that all of the following conditions are satisfied:

1) the donor signs the consent of the form set out by the Minister of Health to donate his non-regenerative tissues for transplantation;

2) tissues are procured in accordance with the procedure laid down in paragraph 9 of this Article.

5. Regenerating tissues and cells of a living minor may be procured and donated for transplantation, provided that all of the following conditions are satisfied:

1) there suitable adult donors of regenerating tissues and cells are available;

2) before a minor reaches the age of 18, his parents (adoptive parents) or guardians, curators (except the persons who acquire full legal capacity before they reach the age of 18) sign the consent to donate the minor's regenerating tissues and cells for donation and transplantation;

3) a minor over 14 years of age sign the consent to donate his own regenerating tissues and cells for transplantation;

4) the tissues and cells are transplanted with the aim of treating a close relative of the donor.

6. A living legally capable donor may donate his regenerating tissues and cells for transplantation only upon signing the consent in accordance with the procedure laid down by paragraph 9 of this Article.

7. A living donor (if a donor is a minor – his parents (adoptive parents) or guardians, curators until the person reaches the age of 18) must be informed about the potential consequences of the procurement of his tissues, cells or organs for his health. The Minister of Health shall set out the conditions when it is prohibited to procure tissues, cells or organs of a living donor.

8. Before the tissues, cells or organs of a living donor are procured for transplantation, information relevant to preparation of characterisations of a donor and its organs must be collected, as prescribed in the description of the Procedure and Conditions of Implementation of the Process of Donation and Transplantation of Tissues, Cells or Organs of a Living Donor approved by the Minister of Health.

9. The procedure for implementing the process of donation and transplantation of the tissues or organs of a living donor in a health care institution shall be laid down by the Minister of Health.

Article 7. Register of Donors and Recipients of Human Tissues, Cells and Organs

1. The Government of the Republic of Lithuania shall establish the Register of Donors and Recipients of Human Tissues, Cells and Organs (hereinafter: 'the Register') and approve its regulations.

2. The Register objects shall be as follows:

1) persons who have expressed their consent (objection) to donate after their death their tissues, cells or organs for transplantation;

2) living donors;

3) deceased donors;

4) recipients;

5) cases of procurement, transplantation or disposal of tissues, cells or organs.

3. The Register objects shall be recorded on the Register in accordance with the procedure laid down in the regulations of the Register of Donors and Recipients of Human Tissues, Cells and Organs (hereinafter: 'the regulations of the Register').

4. The manager of the Register shall be the Ministry of Health of the Republic of Lithuania (hereinafter: 'the Ministry of Health').

5. The administrator of the Register shall be the National Transplant Bureau under the Ministry of Health.

6. Register data suppliers and recipients shall be the subjects referred to in the regulations of the Register who supply in accordance with the procedure laid down by the regulations of the Register to the administrator of the Register, or receive from him, the data, information and documents specified in legal acts.

7. The rights and duties of Register data suppliers and recipients shall be governed by the Law of the Republic of Lithuania on Management of State Information Resources, the regulations of the Register and other legal acts.

8. The suppliers must ensure that the data, information and documents supplied by them would be recorded properly, submitted timely and correspond to the data of the associated registers.

9. The data contained in the Register shall be confidential and provided only in accordance with the procedure laid down by the Law of the Republic of Lithuania on Legal Protection of Personal Data and other legal acts.

10. Confidentiality of Register data shall be ensured by all natural and legal persons using the data of this Register.

11. Traceability of the data administered in the Register must be ensured.

CHAPTER III

STATE MANAGEMENT OF THE PROCESS OF DONATION AND TRANSPLANTATION OF HUMAN TISSUES, CELLS AND ORGANS

Article 8. Competence of subjects of the state management of the process of donation and transplantation of human tissues, cells and organs

1. The Ministry of Health shall shape state policy in the field of the process of donation and transplantation of human tissues, cells and organs, and shall organize, coordinate and control its implementation.

2. The National Transplant Bureau under the Ministry of Health shall, in accordance with the procedure laid down by this Law as well as other laws and legal acts, implement the state policy in the field of the process of donation and transplantation of human tissues, cells and organs and shall supervise the shaping and implementation of this policy.

3. The State Health Care Accreditation Agency under the Ministry of Health shall license establishments which intend to provide, in accordance with the procedure laid down by legal acts, services of the process of donation and transplantation of human tissues, cells and organs, and supervise the compliance with the licensing conditions.

4. The National Health Insurance Fund under the Ministry of Health shall, in accordance with the procedure laid down by legal acts, carry out reimbursement and supervision of the costs of the provided services of the process of donation and transplantation of human tissues, cells and organs.

Article 9. National Bureau on Transplantation under the Ministry of Health

The National Bureau on Transplantation under the Ministry of Health shall:

- 1) coordinate and organize the process of donation and transplantation of human tissues, cells and organs from the procurement to the distribution (allocation);
- 2) in accordance with the procedure laid down by the Law of the Republic of Lithuania on Public Administration (hereinafter: 'the Law on Public Administration') exercise operational supervision of health care institutions providing services of the process of donation and transplantation;
- 3) form a positive public attitude towards donation;
- 4) fulfil the functions of the Register administrator in accordance with the procedure laid down by legal acts;
- 5) perform other functions assigned to it.

Article 10. Rights and duties of officials of the National Bureau on Transplantation under the Ministry of Health

1. When exercising operational supervision of health care institutions providing services of the process of donation and transplantation of human tissues, cells and organs, the officials of the National Bureau on Transplantation under the Ministry of Health shall act in compliance with the Law on Public Administration and have the right:

1) having produced a professional card and the order of the head of the National Bureau on Transplantation under the Ministry of Health or a person authorised by him, to enter the premises of the health care institutions under the operational supervision;

2) to request to produce or to seize temporarily (up to 30 days) the documents necessary for inspection and to obtain their copies, to receive other information necessary to carry out operational supervision actions from the health care institutions under the operational supervision;

3) to invite other healthcare professionals to participate in carrying out operational supervision actions;

4) to give binding instructions to persons authorised by the health care institutions under the operational supervision in order to ensure adequate implementation of the laws and other legal acts regulating donation, procurement, testing, processing, preservation, storage, distribution (allocation) and transplantation of human tissues, cells and organs, to demand from the persons authorised by the health care institutions under the operational supervision to address the circumstances and conditions preventing from carrying out operational supervision actions, to warn persons authorised by the health care institutions under the operational supervision regarding the established shortcomings and violations and to set time limits of their elimination (up to 60 days);

5) to draw up reports on administrative offences of law in accordance with the procedure laid down by legal acts;

Point 5 shall be repealed as of 1 January 2017.

6) to exercise other rights laid down by laws and other legal acts.

2. When carrying out operational supervision actions of health care institutions providing services of the process of donation and transplantation and having received information about a criminal act or any other violation of law, either in progress or already committed, the officials of the National Bureau on Transplantation under the Ministry of Health must notify this fact to law enforcement authorities and other competent bodies.

3. The Minister of Health shall lay down the order of operational supervision actions carried out by the National Bureau on Transplantation under the Ministry of Health.

CHAPTER IV

PROVISION OF SERVICES OF DONATION AND TRANSPLANTATION OF HUMAN TISSUES, CELLS AND ORGANS AND/OR SERVICES OF A TISSUE BANK

Article 11. Licensing of activities related to provision of services of donation and transplantation of human tissues, cells and organs and/or services of a tissue bank

Services of donation and transplantation of human tissues, cells and organs and/or services of a tissue bank may be provided only by legal persons which have obtained in accordance with the Law of the Republic of Lithuania on Healthcare Institutions (hereinafter: 'Law on Healthcare Institutions') an individual health care licence to carry out such activities.

Legal persons seeking to obtain an individual health care licence to carry out activities of a tissue bank must meet the requirements laid down in the Law on Healthcare Institutions for obtaining an individual health care licence as well as the following conditions:

1) equipped facilities, equipment and materials, used throughout the procedures of services of the tissue bank, are managed by the legal person's right of ownership or on any other legitimate grounds and meet the requirements for the provision of services of the tissue bank set out by the Minister of Health;

2) personnel of the legal person who are directly involved in the provision of services of the tissue bank have the qualification defined by the Minister of Health and have undergone the courses the training programmes of which are developed and the procedure of recognition of which is laid down by the Minister of Health;

3) organization and management of procurement, processing, preservation, storage and distribution of human tissues and cells meet the requirements of the provision of services of the tissue bank which are set out by the Minister of Health;

4) the set system of procurement, processing, preservation, storage and distribution of human tissues and cells ensures traceability.

3. Suspension of an individual health care licence of services of donation and transplantation of human tissues, cells and organs and/or services of a tissue bank, revocation of the suspension of such a licence, grounds for, and time limits of, withdrawal of the licence shall be established in the Law on Healthcare Institutions.

4. The personnel of a legal person who are seeking to obtain an individual health care licence to provide services of donation and transplantation of human tissues, cells and organs and who are directly involved in the process of donation and transplantation must have the qualification defined by the Minister of Health and shall have undergone the courses the training

programmes of which are developed and the procedure of recognition of which is laid down by the Minister of Health.

Article 12. Reporting of serious adverse events and reactions

Health care institutions providing services of donation and transplantation of human tissues, cells and organs and/or services of a tissue bank must, in accordance with the procedure laid down by the Minister of Health, register, investigate and report to the National Bureau on Transplantation under the Ministry of Health on any serious adverse event and reaction.

CHAPTER V

PROHIBITION OF COMMERCIAL TRANSACTIONS

Article 13. Prohibition of commercial transactions

Tissues, cells and organs of a dead or living person may not be the subject of commercial transactions. It shall also be prohibited to advertise the need for, or availability of, human tissues, cells or organs where such advertising is with a view to seeking financial gain or comparable advantage.

CHAPTER VI

REIMBURSEMENT OF EXPENDITURE OF HEALTH CARE INSTITUTIONS

Article 14. Procedure for the reimbursement of expenses

Expenses incurred by health care institutions for the provided services of the process of donation and transplantation of human tissues, cells and organs shall be reimbursed from the budget of the Compulsory Health Insurance Fund or the state budget in accordance with the procedure laid down by legal acts.

CHAPTER VII

IMPORT AND EXPORT, AND EXCHANGE WITH FOREIGN ENTITIES, OF HUMAN TISSUES, CELLS AND ORGANS INTENDED FOR TRANSPLANTATION

Article 15. Import and export, and exchange with foreign entities, of human tissues, cells and organs intended for transplantation

1. Import and export of human organs intended for transplantation shall be carried out on the basis of contracts and agreements concluded with foreign entities, where such contracts and

agreements are concluded in accordance with the procedure laid down in paragraph 4 of this Article.

2. Import and export of human tissues, cells and organs intended for transplantation shall be carried out on the basis of contracts and agreements concluded with foreign entities, where such contracts and agreements are concluded in accordance with the procedure laid down in paragraph 4 of this Article, except the cases when certain human tissues or cells, which are needed urgently, are distributed directly to recipients and the one-off permits to import (export) such human tissues or cells are directly issued by the National Bureau on Transplantation under the Ministry of Health. The procedure for issuing one-off permits of the National Bureau on Transplantation under the Ministry of Health shall be laid down by the Minister of Health.

3. It shall be permitted to import human tissues, cells and organs intended for transplantation into the Republic of Lithuania, if the quality and safety requirements for import of human tissues, cells and organs imposed by a foreign entity supplying them meet the valid requirements of legal acts of Member States of the European Union and the Republic of Lithuania and if the traceability of imported tissues, cells and organs is guaranteed.

4. The Minister of Health shall lay down the procedure of import and export of human tissues, cells and organs intended for transplantation and issuing of one-off permits for direct distribution (allocation) of human tissues, cells or organs to recipients in case of urgent need.

CHAPTER VIII

FINAL PROVISIONS

Article 16. Liability

Persons in breach of the requirements of this Law shall be held liable according to the procedure established by means of laws of the Republic of Lithuania.

I promulgate this Law passed by the Seimas of the Republic of Lithuania.

PRESIDENT OF THE REPUBLIC

ALGIRDAS BRAZAUSKAS

Annex to
the Law of the Republic of Lithuania
on Donation and Transplantation of
Human Tissues, Cells and Organs

LEGAL ACTS OF THE EUROPEAN UNION IMPLEMENTED BY THIS LAW

1. Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (OJ 2004 L 102, p. 48-58).

2. Directive 2010/45/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 (OJ 2010 L 207, p. 14).