

LAW ON THE REMOVAL AND TRANSPLANTATION OF ORGANS AND TISSUES FOR MEDICAL TREATMENT

I. GENERAL PROVISIONS

Article 1

This Act regulates the conditions for the removal of organs and tissues from a living or deceased person (hereinafter referred to as the donor) for the purpose of transplantation for treatment of a second person (hereinafter referred to as the recipient).

The provisions of this Act do not apply to the procurement of blood and blood components, with the exception of the procurement of haematopoietic stem cells for allogeneic transplantation.

The removal and transplantation of testicles, ovaries, embryos and the use of sperm and ova shall be regulated by a special law.

Article 2

The removal and transplantation of organs and tissues for medical treatment may only be carried out in accordance with the terms and conditions laid down in this Law.

Removal and transplantation of organs and tissues may be carried out only in the absence of any other treatment of comparable effectiveness, provided that it does not entail excessive risks for both the living donor and the recipient and that the necessary medical investigations are carried out in advance, in accordance with professional rules, in order to predict with a high degree of certainty the safety of the donor and the recipient and the success of the procedure.

Article 3

The removal of organs and tissues from a deceased person shall be carried out with due respect for the deceased and his family.

The organs and tissues of the deceased shall be subject to the regulations of the medical profession.

The principle of equal access to treatment must be applied. If it is not possible to find a suitable recipient for transplantation in the Republic of Slovenia, it may be donated to a foreign legal entity with which there is mutual cooperation in the exchange of organs and tissues.

Article 4

No remuneration or other pecuniary benefit may be given or received for the removal of organs and tissues.

Nevertheless, this prohibition shall not apply to payment for medical and technical services relating to removal and transplantation. It is permitted to compensate the donor for loss of earnings and other costs associated with the donation of the organ or tissue. The donor is entitled to free treatment after the procedure and/or appropriate compensation in the event of serious unforeseen damage to his health as a direct result of the organ removal.

Article 5

Information on the donor and the recipient shall constitute professional confidentiality. Information on the deceased donor shall not be disclosed to the recipient and information on the recipient shall not be disclosed to the family of the deceased donor.

The recipient's physician shall be authorised to have access to the donor's health data if necessary for the purpose of medical examinations.

Article 6

A transplantation may be performed only with the written consent of the recipient prior to the procedure. The consent must represent the expression of the recipient's free will, based on an adequate explanation of the nature, purpose and course of the procedure, the likelihood of success and the most common risks.

In the case of a minor without full legal capacity or an adult deprived of full legal capacity by a court order, the consent referred to in the previous paragraph shall be established by the legal representative.

Notwithstanding the consent of the legal representative, the intervention may not be carried out if the person referred to in the preceding paragraph expressly objects, only if he is able to understand the meaning of his statement.

II. REMOVAL OF ORGANS AND TISSUES FROM A LIVING DONOR

Article 7

The removal of organs and tissues from a living donor shall be authorised with the written consent of the donor and only where the risk to his health is medically acceptable. The risk must not outweigh the expected benefit for the recipient.

Article 8

As a general rule, only regenerating tissues may be retrieved from a living donor.

Notwithstanding the provision in the previous paragraph, a single kidney or part of a liver may be removed from a living donor for transplantation into a person to whom the donor is genetically, familiarly, or emotionally related, if the deceased donor organ cannot be obtained within a reasonable time or if the use of the living donor organ provides a significantly better therapeutic option than other forms of replacement therapy for end-stage renal or liver failure.

Procurement in accordance with the previous paragraph is subject to prior approval by the Transplantation Ethics Committee.

Article 9

Organs and tissues may only be removed from a person who has reached the age of majority, provided that he or she is competent to stand trial.

By way of derogation from the preceding paragraph, regenerating tissues may also be removed from a person under the age of eighteen or from a person who is not competent to stand trial, where the transplant is to be carried out in the brother or sister of that person.

The approval of the Ethics Committee for Transplantation shall be required for procurement under the preceding paragraph.

By way of derogation from the provisions of paragraphs 1 and 2 of this Article, haematopoietic stem cells collected from the severed umbilical cord of a child born alive may be collected and stored. The collected cells may later be used for related or unrelated transplants.

Procedures for the collection, storage and use of haematopoietic stem cells are subject to regulations issued by the Minister of Health.

Article 10

The donor's consent relates exclusively to the planned procedure. It must be given in writing and must constitute the expression of the donor's free will, based on an adequate explanation of the nature, purpose and course of the procedure, the likelihood of success and the most common risks. The explanation must not be such as to suggest the donor.

The person concerned must be informed of his rights and of the protection guaranteed by this law, in particular the right to an independent consultation on the risks to his health with a doctor who will not be involved in the removal or transplantation of the organ and who is not the recipient's personal physician.

Consent may only be given by a person of full age who is competent to stand trial. Consent may be made conditional on the transplant being performed on a specific person.

Consent may be withdrawn by the donor up to the time of the procedure.

Article 11

In the case of a minor or a person of full age who is not competent to stand trial, consent shall be given by the legal representative.

Where the minor is over 15 years of age and is competent to stand trial, his or her consent shall be required for the removal of an organ or tissue.

The removal of an organ or tissue from minors may only take place where it is not possible to find a donor capable of giving consent and only if the planned transplant is the only life-saving alternative for the recipient.

Under no circumstances may an organ or tissue be removed if the donor objects.

III. REMOVAL OF ORGANS AND TISSUES FROM A DECEASED PERSON

Article 12

Organs and tissues from a deceased person may be removed for transplantation into another person only after the donor's death has been established according to medical criteria and in accordance with the provisions of this Act.

Brain death is established by a Committee. The decision of the Committee members must be independent and unanimous. A report on the determination of death must be drawn up and signed by all members.

Committee members may not be doctors involved in the procurement or transplantation, nor may they be persons with an interest in or connection with the transplantation in question.

In the case of a person who has died as a result of cardiac arrest, death is established in accordance with the usual procedure. The doctor who determines death may not be involved in the procurement or transplantation.

Regulations on medical criteria, method, and procedure for the determination of brain death and the composition of the committee for the determination of death referred to in paragraph 2 of this Article, as well as regulations on the determination of death following a cardiac arrest referred to in the preceding paragraph, shall be issued by the Minister of Health.

Article 13

Organs and tissues of a deceased person may be removed for transplantation provided that the donor has given consent prior to death and that the written consent has been officially registered.

The written consent referred to in the previous paragraph must be given in the presence of an authorised person from the body or organisation responsible for activities in the field of organ and tissue donor research for transplantation purposes. Following the donor's consent, the written consent may also be formally recorded on the health card.

Based on the written consent referred to in paragraphs 1 and 2 of this Article, an organ or tissue may be removed from the donor at the time of death, subject to notification of the donor's next of kin.

The authorities or organisations referred to in paragraph 2 of this Article, the procedures for the written consent of the donor, the methods of recording the written consent, the procedures for protecting the confidentiality of the donor's information and the procedure for withdrawing the donor's consent shall be established by regulations issued by the Minister of Health.

Article 14

The removal of an organ or tissue from a deceased person for the purpose of transplantation may also take place in the case of a holder of a Special Donor Card issued by the Slovenian Red Cross or an organisation authorised by the Minister of Health.

On the basis of the Donor Card referred to in the previous paragraph, an organ or tissue may be removed for transplantation from the holder at the time of death, provided that the close relatives of the deceased are informed and if they do not expressly object to the removal after being informed.

The donor card, the authorities and organisations authorised to issue cards and the procedure enabling the removal of organs and tissues from the deceased for transplantation purposes on the basis of the donor card shall be laid down by provisions of the Minister of Health.

Article 15

Organs and tissues of a deceased person who is a citizen of the Republic of Slovenia and/or a resident of the Republic of Slovenia may be removed for transplantation purposes even if the person has not expressly consented to the removal, provided that he or she has not expressly denied it. If there is conflicting information on the deceased's position on donation, the donation may not be performed.

Notwithstanding the previous paragraph, the removal of organs and tissues from a deceased person will not be carried out if a family member objects. If a person is willing, they will be informed of the planned removal and will be able to exercise their right to refuse. This person will be given a reasonable time to accept or refuse.

Organs and tissues of a deceased person who is not a citizen of the Republic of Slovenia and/or not a resident of the Republic of Slovenia may be removed for transplantation if the person close to the deceased expressly gives consent.

Persons considered close to the deceased are the spouse or cohabiting partner, children of full age, parents and siblings, and those who were close to the deceased.

Article 16

Organs and tissues from a stillborn aborted foetus may be removed for transplantation provided the mother has given her consent after receiving full explanation of the purpose of the intended operation.

Embryonic tissues may be taken and used only after approval by the Medical Ethics Committee of the Ministry of Health following a proven need.

The doctor performing the termination of pregnancy shall not be involved in the procurement or transplantation and shall have no connection or interest in these procedures. The decision, procedures, timing, and other circumstances of the termination of pregnancy shall in no way depend on the harvesting.

Article 17

Organs and tissues of a deceased minor who has not acquired full legal capacity and/or an adult who has been deprived of legal capacity by a court order may be removed for transplantation only with the consent of the legal representative.

The consent of the legal representative shall not be required where a person referred to in the preceding paragraph is over 15 years of age and has during his or her lifetime consented to the removal, provided that he or she was capable of understanding the meaning of his or her statement.

Article 18

Where the circumstances leading up to the death indicate the need for a judicial autopsy, such an autopsy may be carried out only with the authorisation of the competent investigating judge.

IV. PROVISIONS/ORGANISATIONAL RULES

Article 19

Only in public health facilities authorised by the Minister of Health may organ and tissue removal and transplantation and preservation be carried out.

Notwithstanding the preceding paragraph, transplantation of skin, bones, veins and corneas may be carried out by Slovenian or foreign legal or natural persons performing a public service in the health sector on the basis of a concession, following authorisation by the Minister of Health.

The Institute for Organ and Tissue Transplantation of the Republic of Slovenia (called "Slovenia-Transplant") must be informed of any removal and transplantation of an organ or tissue.

The laboratory performing tissue typing and tissue compatibility testing for the Republic of Slovenia is designated by the Minister of Health.

The Minister of Health shall also determine the personnel, space, technical provisions for obtaining a permit to perform the activities referred to in paragraphs 1 and 2 of this Article.

Article 20

The Government hereby establishes the Institute for Organ and Tissue Transplantation of the Republic of Slovenia to perform the following tasks:

- coordination of activities of professional units of health institutions involved in identification of deceased donors, removal, transplantation and preservation of organs and tissues, tissue typing, and selection of donors and recipients on the territory of the Republic of Slovenia;
- maintenance of prescribed records;
- updating and maintaining the central information system for transplantation activities;
- updating the register of bone marrow donors;
- cooperation with related national and international systems in the field of transplantation;
- study of medical, legal, ethical, economic and social issues in the field of organ removal and transplantation;
- information on the importance of post-mortem organ donation for transplantation purposes; and
- other tasks in accordance with the act establishing the Institute.

The funds for the establishment and operation of the Institute for Organ and Tissue Transplantation of the Republic of Slovenia shall be provided from the state budget.

Article 21

The Minister of Health, upon the proposal of a health institution dealing with identification of deceased donors, removal, transplantation and preservation of organs and tissues, tissue typing, appoints a person to perform the duties of a hospital transplant coordinator.

The hospital transplant coordinator organises and coordinates the work within the health institution and is responsible for the relationship with the Institute for Organ and Tissue Transplantation of the Republic of Slovenia.

Article 22

The Minister of Health issues implementing regulations on the conditions and detailed procedures for carrying out organ and tissue removal and transplantation, establishing in particular:

- the order of waiting lists and immunogenetic and medical criteria for determining the order and selection of recipients;
- the procedure for notifying the death of persons eligible as donors;
- the immunogenetic criteria and tissue compatibility tests and medical conditions for selecting the most suitable recipient or donor;
- the way in which donors are screened for transplant-transmitted diseases;
- the operation of the register of potential bone marrow donors;
- the way in which organs and tissues intended for transplantation are stored and transported;
- the way in which donation and transplantation registers are kept;
- the arrangements for cooperation with foreign and related international organisations and the exchange of organs and tissues with other countries;
- the arrangements for protecting the personal data of donors and recipients;
- the composition, method of appointment and operating rules of the Transplantation Ethics Committee;
- the way in which transplant coordinators operate in health institutions;
- the conditions for the development and operation of the national unrelated donor bone marrow transplantation programme.

V. DISPOSITION OF SENTENCE

Article 23

A fine of 500,000 to 5,000,000 thalers shall be imposed on a legal person who:

1. in violation of Article 16, paragraph 1 of this Law, takes organs and tissues of a dead aborted foetus for transplantation, without prior consent of the mother;
2. in violation of Article 16(2) of this Law, takes and uses foetal tissue without the approval of the Medical Ethics Committee of the Ministry of Health;
3. in violation of Articles 13 (1), 14 (2), 15 (2), and 17 (1), (2) and (3) of this Law, takes organs and tissues of a deceased person for transplantation purposes, in the absence of prior written consent, and/or if the next of kin expressly objects to the removal, and/or if a person close to the deceased objects to the removal, or if, in the case of a minor or a person of full age deprived of his/her legal capacity by a court order, the removal is not consented to by his/her legal guardian;
4. in violation of Section 19 (1) of this Law, performs a removal, transplantation and/or preservation of organs and tissues in the absence of authorisation from the Minister for Health
5. in breach of Article 19 (2), carries out skin, bone, blood vessel and cornea transplantation without authorisation from the Minister of Health.

A fine of 50,000 to 250,000 thalers shall be imposed on the head of a legal person for the offence referred to in items 1, 2, 3 and 4 of the preceding paragraphs.

A fine from 100,000 to 4,000,000 thalers shall be imposed for the offence referred to in item 4 of the first paragraph of this Article on a doctor who commits an offence in connection with the independent exercise of his activity.

A fine of 50,000 to 2,500,000 thalers shall be imposed for the offence referred to in point 5 of the first paragraph of this Article on a doctor who commits an offence in connection with the exercise of an independent activity.

VI. FINAL PROVISIONS

Article 24

The Minister of Health shall issue implementing regulations pursuant to this Act and establish an Ethics Committee for Transplantation within six months of the entry into force of this Act.

The Government of the Republic of Slovenia shall establish the Institute for Organ and Tissue Transplantation of the Republic of Slovenia ("Slovenia-Transplant") within six months of the entry into force of this Law.

Pending the issuance of the implementing regulations referred to in paragraph 1 of this Article, the Regulation on more detailed conditions for performing organ and tissue removal and transplantation (Official Gazette of the Republic of Slovenia, No 21/86) and the Regulation on more detailed medical criteria and the method for determining the occurrence of death of a person from whom organs and tissues may be removed for transplantation for the purpose of medical treatment (Official Gazette of the Republic of Slovenia, No 74/82) shall be applicable insofar as they do not contradict the provisions of this Act.

Article 25

On the date on which this Act enters into force, the Act on the Removal and Transplantation of Organs and Tissues for Medical Purposes (Official Gazette of the RSFSR, No 42/85) shall cease to apply and the Act on the Conditions of Exchange and Transfer of Organs and Tissues for Transplantation for Medical Purposes (Official Gazette of the RSFSR, Nos 43/82 and 18/88, Official Gazette of the RSFSR, No 63/94) shall cease to apply. (Official Gazette of the RSFSR, Nos 43/82 and 18/88, Official Gazette of the RS, No 63/94) ceases to apply and the Act on the Exchange and Transfer of Organs and Tissues for Medical Purposes (Official Gazette of the RSFSR, Nos 43/82 and 18/88, Official Gazette of the RS, No 63/94) ceases to apply.

Article 26

The Donor Card issued by the Slovenian Red Cross is considered a special document within the meaning of Article 14 of this Act even after the issuance of this Act.

Article 27

This Act shall enter into force on the 30th day following its publication in the Official Gazette of the Republic of Slovenia.

No 501-07/98-1/3

Ljubljana, 27 January 2000.

President of the National Assembly of the Republic of Slovenia

Janez Podobnik, Dr. med. l. r.