

ACT No. CLIV OF 1997 ON HEALTH¹
(Hungary)

Chapter XI

ORGAN AND TISSUE TRANSPLANTATION

Section 202

For the purpose of this Chapter:

- a) *tissue*: any part of the human body with the exclusion of the following:
 - aa) sperm and ovum
 - ab) embryo and fetus
 - ac) blood and blood component;
- b) *organ*: any part of the human body composed of tissues of specialized structure, which, if removed entirely, cannot be renewed by the body,
- c) *organ and tissue transplantation*: the removal of an organ or a tissue from one person and its transplantation to another live person,
- d) *donor*: a person who donates an organ or tissue for grafting into another person's body, or one from whom an organ or tissue is taken, after his death, for grafting into another person's body,
- e) *recipient*: the person into whose body an organ or a tissue is transplanted that has been removed from another person's body,
- f) *brain death*: entire, permanent, and irreversible cessation of functions of the brain, including the brain stem,
- g) *death*: beginning of irreversible autolysis of the organism due to entire cessation of respiration, circulation and brain functions.

Section 203

- (1) Primarily organs and tissues removed from cadaver donors should be used for transplantation.
- (2)
- (3) Organ and tissue transplants from live or cadaver donors that are steadily storable and may be transplanted shall be stored in organ and tissue banks.
- (4)
- (5) The minister shall stipulate the detailed regulations governing organ and tissue transplantation in a decree.

Removal of organs and tissues from live donors

Section 204

- (1) Organs and tissues removed from the body of live donors, with the exceptions as in Subsection (2), must be subjected to histopathological study.
- (2) No histopathological study shall be required if:
 - a) the removal is done for the purpose of transplantation into another person's body,
 - b) the removal is done in order to perform a special diagnostic examination, and
 - c) in the case of particular organs or tissues as specified by the decree of the minister.

¹ Excerpt from the Law in effect as of 1 June 2010.

Section 205

- (1) Removal of transplants from a live donor for transplantation to another person shall be restricted to the following organs or tissues:
 - a) one of a paired organ whose removal will not result in severe and permanent disability,
 - b) a part of an organ (organ segment) whose removal will not greatly alter physiological functions,
 - c) renewable tissues.
- (2) In case of Paragraph b) of Subsection (1) the regulations governing organ transplantation shall be applied.

Section 206

- (1) Organs and tissues, with the exception of Subsection (5), may only be donated by a person with legal capacity.
- (2) Donation of organs from a person with legal capacity shall be allowed only if the donor is:
 - a) a lineal kin of the recipient,
 - b) a sibling of a lineal kin of the recipient,
 - c) a sibling of the recipient,
 - d) a lineal kin of a sibling of the recipient.
- (3) Donation of an organ may be possible in exceptional cases, when the stipulations as in Subsection (2) are not met. In this case the joint request of donor and recipient shall be considered by a hospital ethics committee. The hospital ethics committee shall give consent to the removal of the organ only after it has established that a close emotional relationship exists between the donor and the recipient, and the donation has taken place without consideration in return, force, duress, coercion or deception.
- (4) Detainees may become organ donors only in cases as in Subsection (2).
- (5) Bone marrow, hematopoietic primordial cells or other renewable tissues – in exceptional cases – may be taken for transplantation from the body of a person with restricted or no disposing capacities provided that the following requirements are met:
 - a) a suitable donor with full disposing capacity is not available,
 - b) the recipient is the donor's sibling,
 - c) the donation is very likely life-saving for the recipient,
 - d) the consent of the legal representative has been approved by the hospital ethics committee,
 - e) the hospital ethics committee prior to making its decision in accordance with Paragraph d), shall give the person with restricted or no disposing capacities a hearing – provided that the health status or age of the patient does not exclude it – and ascertain that the he/she has agreed to the intervention without force, duress, coercion or deception.

Section 207

- (1) Donation of organs and tissues shall only take place without consideration given in return.
- (2) The donors shall be eligible for recompense of loss of income related to the donation, and of his justified costs incurred in connection with making his statement of donation and with travelling, which are not reimbursed under his social insurance coverage. Furthermore, additional shipping costs, arising from the transfer to the institute enacting the donor collection, shall also be reimbursed. These expenses shall be paid by the institution responsible for handling the health insurance fund, who is reimbursed from the state budget.
- (3) The disbursement of the justified fee to the donor arising from the justified medical and related technical services in connection with the transplantation can not be considered as the offset of the donation in subsection (1).

Section 208

Before a transplant procedure of an organ or tissue is undertaken, the physician to remove and transplant the organ or tissue must document that the donor meets the conditions for organ or tissue transplant, there is no medical contraindication of the transplant, furthermore that the transplant is justified for the recipient, the conditions for the procedure are met and that the organ is suitable for transplantation.

Section 209

(1) Before the removal of an organ or tissue is undertaken, the donor must be fully informed, verbally and in writing, and beyond the general rules as in Section 13, of all important circumstances related to the procedure, with special regard to the possible short-term and long-term consequences of organ or tissue removal, or the loss of an organ, and to the mandatory postmortem that must be performed on a donor after death. The information of the donor shall be done by a physician who is not involved directly in the transplantation procedure.

(2) The donor's consent to an organ donation shall be incorporated in a public deed. Such public deed must contain, beyond the general requirements of a consent, the donor's declaration stating that the donation has taken place without force, duress, coercion or deception and that he gives consent to autopsy following his death.

(3) The donor's consent to a tissue donation shall be incorporated in a private deed having full probative force.

(4) The donor is at liberty to withdraw his consent any time until the removal of the organ or tissue without any formal restrictions. Even in case of a valid consent the physician must terminate the organ or tissue donation procedure if during the course of such procedure a situation has arisen that will endanger the donor's life or impair his health.

(5) The recipient shall be informed of all significant circumstances in connection with the procedure, pursuant to the general rules (Section 13), and especially of the following:

- a) the risks for the donor's health involved in organ donation,
- b) the requirement of mandatory post-mortem after his death,
- c) the origin of the organ or tissue to be transplanted into his body .

(6) The consent of the recipient to the transplant must be committed to paper.

Section 210

If the donor sustains impairment to his health or bodily harm as a result of organ or tissue donation, excluding the harm inherent in the loss of an organ or tissue, becomes disabled or dies, and provided that it cannot be imputed to the healthcare worker carrying out the procedure, he or his dependent relatives shall be eligible to recompense by the state for all the damages that are not reimbursed under his social insurance coverage.

Removal of organs or tissues from cadaver donors

Section 211

(1) Organs or tissues may only be removed from cadaver donors if the deceased did not make a declaration opposing donation during his lifetime. A person with legal capacity may make a declaration in writing (in a public deed or private deed having full probative force), or verbally at his attending physician in case of inability to, or significant difficulty in making a written declaration. A person with restricted legal capacity may make an opposition

declaration without his legal representative's involvement. Such opposition declaration may be made on behalf of a person with no legal capacity by his legal representative.

(2) The attending physician must establish within the time available for organ or tissue removal if an opposition declaration has been left by the deceased.

(3) If no written opposition declaration is found or forwarded to the attending physician within the time available for transplant removal, its absence should be presumed.

(4) If the deceased is under age and no opposition declaration can be found, the organ or tissue removal procedure may be initiated only after the written consent of the legal representative of the deceased has been obtained.

Section 212

(1) Organ or tissue removal may be commenced only after members of a committee of three physicians (hereinafter: committee) have determined brain death, by their independent and corroborating judgment, pursuant to the provisions in the decree of the minister.

(2) The members of the committee shall be physicians who possess special medical knowledge and practice, have undergone special training and have been appointed by the head of the medical institution.

(3) Physicians who are involved in organ or tissue removal or transplant, or in the treatment of the recipient shall not be members of the committee.

(4) The committee shall place on record the results of clinical and instrumental investigations and the probable cause of death.

(5) Once brain death is established, mechanical ventilation and artificial maintenance of other bodily functions shall only be justified if undertaken in order to maintain the functional capacity of organs or tissues for transplantation.

Section 213

Organs or tissues removed from the deceased but not transplanted shall be subjected to histopathological study.

Section 214

Organs or tissues may be removed for transplantation from victims of crimes, unless otherwise provided by separate piece of legislation and pursuant to the provisions as in Section 211, provided the prior written consent of the investigating authority has been obtained. In this case changes caused by the procedure must be documented in detail.

Organ or tissue implantation

Section 215

(1) Patients in whose cases organ or tissue transplantation is medically justified shall be put on a national waiting list maintained separately by type of organ and tissue. Entry into the waiting list shall be initiated by the medical institution establishing indication for organ or tissue transplantation.

(2) The patient shall be kept informed of all significant circumstances in connection with his name being put onto the waiting list.

(3) Recipients shall be selected from the waiting list exclusively on the basis of professional rules.

(4) The health authority shall exercise professional control over how individuals are put onto, and selected from the waiting list, and shall investigate patient complaints.

Chapter XVII

INTERNATIONAL PROVISIONS

Section 243

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(5) When a non-citizen dies within the borders of the Republic of Hungary

- a) an autopsy shall be performed at the request of a member of the immediate family of the deceased,
- b) a coroner's post mortem shall be performed if the death occurred under exceptional circumstances.

In the course of these autopsies, organs and tissues shall be removed only to determine the cause and circumstances of death.

(6) Organs and tissue shall be transported from the Republic of Hungary to another country or from another country to the Republic of Hungary only

- a) for transplant,
- b) for treatment of the patient transporting the organ or tissue,
- c) for diagnostic purposes or
- d) for research

if this is made possible by an international agreement or covenant. Another condition for transporting an organ to another country under Paragraph a), is that there shall be no suitable recipient within the borders of the Republic of Hungary. This condition may not be applied if an organ has been transported to and transplanted within the Republic of Hungary, and in return to this donation an organ of the same type is transported abroad, under an international treaty or agreement. The return obligation starts when the organ is transplanted within the Republic of Hungary, and ends as soon as the organ offered in return is accepted and transplanted abroad.

(7) The prerequisite for the validity of a contract concerning the transport of organs or tissue, other than blood and blood products, to another country or from another country to Hungary, other than when said contract is in the form of an interstate or intergovernmental agreement or covenant, is the agreement of the public health authority. The public health authority shall deny the agreement if it can be determined that the contract involves profiting. There is no legal recourse against a decision of the public health authority. The public health authority shall keep a registry of said contracts or agreements, other than interstate or intergovernmental agreements or covenants, which shall be reported to it by the Hungarian party to said contracts or agreements.

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(11) The disbursement of the fee of the justified medical and related technical services in connection with the transplantation can not be considered as profit in subsection (7).