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Handling and Transplantation of Cells, Tissues and Organs Act¹

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Chapter 1 GENERAL PROVISIONS

[RT I 2008, 25, 163 - entry into force 01.01.2009]

§ 1. Scope of application

(1) This Act establishes the conditions and procedure for the handling and transplantation of cells, tissues and organs of human origin, the procedure for supervision and liability.

(2) This Act applies to the cells, tissues and organs which are removed from a living or deceased donor (hereinafter donor) and are or are not processed *in vitro* and which come into immediate contact with a human organism by way of topical or systemic transplantation or in any other manner.

(3) This Act does not regulate:

1) the transplantation of gametes and embryos within the meaning of the Artificial Insemination and Embryo Protection Act;

- 2) the handling of blood products within the meaning of the Blood Act;
- 3) the transplantation of cells, tissues and organs taken from a person to the person in the course of one surgical procedure;
- 4) the use of cells, tissues and organs in scientific research if used for purposes other than medical use on human beings.

(4) The provisions of the Administrative Procedure Act apply to the administrative proceedings prescribed in this Act, taking account of the specifications provided for in this Act.
[RT I 2008, 25, 163 - entry into force 01.01.2009]

§ 2. Definitions

(1) For the purposes of this Act, the handling of cells, tissues and organs means the procurement of cells, tissues and organs, including removal for transplantation purposes, coding, labelling, testing, preservation, processing, packaging, storage, release and distribution.

(2) For the purposes of this Act, the transplantation of cells, tissues and organs means the implantation of cells, tissues and organs removed from a donor into another person (hereinafter recipient) for therapeutic purposes.
[RT I 2008, 25, 163 - entry into force 01.01.2009]

§ 3. Seeking financial gain

Offering reward and seeking financial gain for the donation of cells, tissues and organs is prohibited, except in the cases provided for in the Artificial Insemination and Embryo Protection Act.
[RT I 2008, 25, 163 - entry into force 01.01.2009]

Chapter 1¹

HANDLING AND TRANSPLANTATION OF CELLS, TISSUES AND ORGANS

[RT I 2008, 25, 163 - entry into force 01.01.2009]

§ 4. Handler and transplanter of cells, tissues and organs

(1) Special medical care providers who hold an activity licence for the handling of cells, tissues and organs which is issued on the basis of this Act (hereinafter handler) have the right to handle cells, tissues and organs.

(2) Special medical care providers who hold an activity licence for the provision of specialised medical care which is issued on the basis of the Health Services Organisation Act have the right to transplant cells, tissues and organs.
[RT I 2008, 25, 163 - entry into force 01.01.2009]

§ 4¹. Activity licence for handling of cells, tissues and organs

(1) An activity licence for the handling of cells, tissues and organs (hereinafter activity licence) shall be issued for the handling of cells, tissues and organs.

(2) An activity licence grants the handler the right to operate under the conditions and pursuant to the procedure provided by this Act and legislation established on the basis thereof within a specified period of time in the area of activity, place of business and under the conditions set out in the activity licence. The activity licence is not transferable.
[RT I 2008, 25, 163 - entry into force 01.01.2009]

§ 4². Obligations of handlers

- (1) A handler is required to:
- 1) guarantee the existence of conditions for the handling of cells, tissues and organs in compliance with this Act and legislation established on the basis thereof and with the requirements of other legislation regulating the handling of cells, tissues and organs;
 - 2) guarantee that the competent person, and in the absence thereof, his or her substitute, has necessary conditions and means for performing his or her duties;
 - 3) guarantee that cells, tissues and organs are handled taking account of the developments in the area of science and technology;
 - 4) guarantee that cells, tissues and organs are distributed, under the conditions and pursuant to the procedure provided by this Act and legislation established on the basis thereof, only to persons with the right to handle or transplant such cells, tissues and organs;
 - 5) maintain records on the handling of cells, tissues and organs and submit a report thereon to the State Agency of Medicines once a year;

6) guarantee the quality of cells, tissues and organs and that their purposeful use is effective and safe for the recipient.

(2) In order to ensure the safety and quality of cells, tissues and organs, the handler shall develop a quality assurance system. The applied quality assurance system must be fully documented and continuously monitored in all its stages. In order to apply the quality assurance system, the necessary resources, such as competent personnel, suitable facilities, equipment and means must be ensured.

[RT I 2008, 25, 163 - entry into force 01.01.2009]

§ 4³. Issue and renewal of activity licence

The State Agency of Medicines shall decide on the issue of or refusal to issue an activity licence or the renewal of or refusal to renew an activity licence.

[RT I 2008, 25, 163 - entry into force 01.01.2009]

§ 4⁴. Application for activity licence

(1) In order to receive or renew an activity licence, an applicant shall submit to the State Agency of Medicines an application and other necessary documents and information. Before submission of the application, the applicant shall pay a state fee.

(2) A list of documents and information to be submitted upon application for an activity licence shall be established by a regulation of the Minister of Social Affairs.

(3) An overview of handling operations at the place of business during the term of validity of the activity licence and the documents submitted upon application for the activity licence containing updated information or separate confirmation in writing for each document that the information contained in the document has not changed shall be appended to an application for renewal of an activity licence.

[RT I 2008, 25, 163 - entry into force 01.01.2009]

§ 4⁵. Decision to issue activity licence

(1) The State Agency of Medicines shall verify the information and documents submitted by the applicant. A decision to issue or refuse the issue of an activity licence shall be made by the State Agency of Medicines within two months after submission of the documents and information required pursuant to § 4⁴ of this Act.

(2) Prior to making a decision to issue or renew an activity licence, the State Agency of Medicines may request, and the applicant for the activity licence must provide explanations concerning the activities thereof, and the documents and information submitted thereby necessary for making the decision. The term for processing the application for issue or renewal of the activity licence is suspended until the requested explanations are submitted.

(3) Upon processing an application, the State Agency of Medicines has the right to verify the accuracy of information submitted upon application. Before issue or renewal of an activity licence, the State Agency of Medicines shall inspect, according to its competence, the conformity of the conditions, handling operations and if necessary, also of the personnel of a place of business to the established requirements.

(4) The decision to issue an activity licence shall set out the following:

- 1) the name, title and signature of the person who made the decision;
- 2) areas of activity;
- 3) the name, place of business and address of the handler;
- 4) the number of the activity licence and the date on which the decision is made;
- 5) the bases for making the decision;
- 6) the name of the competent person;
- 7) the special conditions;
- 8) the period of validity of the activity licence;
- 9) the procedure for contesting the decision.

(5) An activity licence may be issued subject to special conditions which:

- 1) restrict handling with certain cells, tissues or organs;
- 2) restrict handling by particular types of handling operations;
- 3) set additional requirements for the measures applied upon handling;
- 4) set additional requirements for the health protection measures applied upon commencement and termination of activities;
- 5) determine the date of commencement and termination of the activities.

[RT I 2008, 25, 163 - entry into force 01.01.2009]

§ 4⁶. Information entered on activity licence

The following information shall be entered on an activity licence:

- 1) areas of activity;
- 2) the name, place of business and address of the recipient of the activity licence;
- 3) the number of the activity licence and the date on which the decision is made;
- 4) the name of the competent person;
- 5) the special conditions;
- 6) the period of validity of the activity licence.

[RT I 2008, 25, 163 - entry into force 01.01.2009]

§ 4⁷. Refusal to issue or renew activity licence

(1) The State Agency of Medicines may refuse to issue or renew an activity licence if at least one of the following circumstances exists:

- 1) repeated or significant violations of the requirements provided by this Act or legislation established on the basis thereof have been discovered in the operation of the applicant for the activity licence;
- 2) the operation of the applicant for the activity licence does not meet the conditions of the activity licence;
- 3) the place of business of the applicant for the activity licence does not conform to the requirements provided by this Act or legislation established on the basis thereof;
- 4) the competent person fails to perform his or her duties;
- 5) the handler does not comply with the precept of the State Agency of Medicines by the prescribed date or to the prescribed extent;
- 6) the handler does not meet the requirements provided for in this Act.

(2) The State Agency of Medicines refuses to issue or renew an activity licence if at least one of the following circumstances exists:

- 1) the applicant does not meet the requirements provided by this Act or legislation established on the basis thereof;
- 2) documents or information required for obtaining an activity licence under this Act are not submitted;
- 3) the applicant has not paid the state fee;
- 4) the applicant has not submitted explanations pursuant to subsection 4⁵(2) of this Act;
- 5) the applicant has not eliminated the deficiencies which prevent the issue of the activity licence during the additional term;
- 6) inaccurate information was submitted upon application for the activity licence;
- 7) the applicant for the activity licence is declared bankrupt;
- 8) the applicant has been punished for operating without an activity licence in a field of activity for which an activity licence is required pursuant to this Act and the terms specified in § 25 of the Punishment Register Act have not expired;
- 9) a person formerly designated as the competent person by the handler whose activity licence has been revoked due to violations of the requirements provided for in this Act or legislation established on the basis thereof, is nominated for entry on the activity licence as the competent person, and less than two years have passed from the revocation of the activity licence.

(3) The issuer of activity licences shall notify an applicant for an activity licence of refusal to issue or renew the activity licence in writing within ten working days after the decision of refusal is made.

[RT I 2008, 25, 163 - entry into force 01.01.2009]

§ 4⁸. Validity of activity licence

(1) An activity licence shall be issued for a period of one to five years.

(2) If an applicant applies for an activity licence for the first time, the activity licence for the applicant shall be issued for a period of one to three years.

[RT I 2008, 25, 163 - entry into force 01.01.2009]

§ 4⁹. Change of data and alteration of data contained in activity licence

(1) The handler wishing to amend documents which are the bases for the issue of an activity licence, including changes which involve creation of new structural units or change or addition of the undertaking providing services related to handling to the handler, shall beforehand apply to the State Agency of Medicines for amendment of the activity licence, provide justification for the amendment, submit the documents required pursuant to § 4⁴ of this Act and pay the state fee.

(2) An application specified in subsection (1) of this section together with requisite documents shall be reviewed and the amendment decision shall be made within thirty days after receipt of the application. In exceptional cases, the State Agency of Medicines may extend such term to up to sixty days.

(3) Alteration of the data or conditions of an activity licence does not result in amendment of the term of validity of the activity licence.

[RT I 2008, 25, 163 - entry into force 01.01.2009]

§ 4¹⁰. Grounds and consequences of termination, revocation and suspension of activity licence

(1) An activity licence expires upon:

- 1) expiry of the term of validity of the activity licence;
- 2) dissolution or termination of the handler who is a legal person;
- 3) revocation of the activity licence.

(2) The State Agency of Medicines revokes an activity licence based on a written application to this effect of the handler.

(3) The State Agency of Medicines may revoke an activity licence in part or in full if one of the following circumstances exists:

- 1) the handler fails to perform the duties imposed on the holder by this Act;
- 2) the handler does not meet the requirements provided for in this Act;
- 3) significant or repeated violations of the requirements provided by this Act or legislation established on the basis thereof have been discovered at the place of business or in operation;
- 4) the place of business or operation does not meet the conditions of the activity licence;
- 5) incorrect information has been submitted upon application for the issue or renewal of the activity licence and such information is of material importance to the decision on whether to issue or renew the licence, or upon repeated failure to submit information required by the State Agency of Medicines by the prescribed term;
- 6) the handler does not comply with the precept of the State Agency of Medicines by the prescribed date or to the prescribed extent;
- 7) the competent person specified in the activity licence fails to perform the duties imposed on him or her on the basis of this Act;
- 8) circumstances become evident which, pursuant to this Act, constitute a basis for refusal to issue or renew an activity licence.

(4) If circumstances provided for in subsection (3) of this section become evident, the State Agency of Medicines may:

- 1) issue, before making the decision to revoke the activity licence, a precept to the handler, setting a reasonable term for elimination of the circumstances which constitute the basis for revocation of the licence;
- 2) suspend, based on a precept or without issue of a written precept, the activity licence in part or in full until the offence or its consequences are eliminated;
- 3) revoke the activity licence in part or in full and set the term and conditions for realisation or destruction of the handled materials and submission of reports.

(5) Suspension of an activity licence in part or in full is revoked by a decision of the State Agency of Medicines after elimination of an offence or the consequences thereof has been established in the process of checks conducted by the State Agency of Medicines, and the decision is communicated to the handler.

(6) The handler shall be notified of a decision to revoke an activity licence within ten working days after the decision is made.

(7) A decision to revoke an activity licence shall set out:

- 1) the name, place of business and address of the handler;
- 2) the number and date of issue of the activity licence;
- 3) the circumstances which caused the activity licence to be revoked and the bases for the revocation of the activity licence;
- 4) the date of the decision;
- 5) the name, title and signature of the person who made the decision.

(8) The period during which an activity licence is revoked does not extend the period of validity of the activity licence.

(9) Upon revocation of an activity licence before the date of expiry set out therein, the handler shall return the activity licence and copies thereof to the State Agency of Medicines within five working days after being notified of the decision on the revocation of the activity licence.

[RT I 2008, 25, 163 - entry into force 01.01.2009]

§ 4¹¹. Renewal of activity licence

(1) A handler shall apply for the renewal of an activity licence:

- 1) at least two months prior to the expiry of the activity licence;
- 2) upon handling of such cells, tissues or organs for the handling of which no activity licence has been issued to the handler previously;
- 3) if the place of business of the handler changes;
- 4) if the special conditions of the activity licence change.

(2) Upon renewal of an activity licence, a new activity licence shall be issued pursuant to the procedure provided for in §§ 4⁴–4⁸ of this Act.

(3) Upon renewal of an activity licence, the applicant for the licence shall submit the documents and information required pursuant to § 4⁴ of this Act provided the documents and information are new for the State Agency of Medicines.

[RT I 2008, 25, 163 - entry into force 01.01.2009]

§ 4¹². Competent person

(1) For the purposes of this Act, a competent person is a person designated by the handler who complies with the requirements provided for in subsection (2) of this section.

(2) A competent person shall have the following qualifications:

1) an academic degree in medicine or biology or specialities relating to biology acquired in a university or a foreign qualification equal thereto;

2) at least two years of practical work experience in the field of handling cells, tissues and organs.

(3) The obligation of a competent person is to ensure that the handler handles cells, tissues and organs in accordance with the requirements established in this Act and on the basis thereof.

(4) The handler shall notify the State Agency of Medicines of designation of a competent person.

(5) A person may be designated as a competent person by one handler at a time.

(6) The substitute for a competent person must comply with the requirements set for competent persons. The substitute for a competent person shall be designated by the handler.

(7) The handler shall notify the State Agency of Medicines of substitution for a competent person.

[RT I 2008, 25, 163 - entry into force 01.01.2009]

§ 4¹³. Conditions for handling cells, tissues and organs

(1) The handling of cells, tissues and organs shall be carried out in compliance with good manufacturing practice valid within the European Union.

(2) The Minister of Social Affairs shall establish, by a regulation, the rules for the handling of cells, tissues and organs which provides for the requirements for the procurement, coding, labelling, testing, preservation, processing, packaging, storage, release, distribution and transportation of cells, tissues and organs and the requirements for the personnel, facilities, equipment and documentation and for the quality assurance system and settling of complaints.

[RT I 2008, 25, 163 - entry into force 01.01.2009]

§ 5. Medical preconditions for transplantation of cells, tissues or organs

Cells, tissues or organs may be transplanted if the medical investigations performed to the recipient and the results of such investigations give reason to expect successful transplantation, and improvement of the recipient's quality of life after transplantation.

[RT I 2008, 25, 163 - entry into force 01.01.2009]

§ 6. Informed consent

(1) For the purposes of this Act, informed consent is consent for removal or transplantation of cells, tissues or organs which is granted on a voluntary basis by the donor or recipient or, in cases provided by law, by their legal representatives.

(2) Consent granted by the persons specified in subsection (1) of this section is valid if they have been provided with appropriate information beforehand as to the purpose and nature of the removal or transplantation of cells, tissues or organs, as well as on its consequences and risks.

(3) Consent for the removal or transplantation of cells, tissues or organs shall be given by the persons specified in subsection (1) of this section expressly and specifically in writing.

(4) A person who has granted consent may freely withdraw it at any time until the performance of the transplantation.

[RT I 2008, 25, 163 - entry into force 01.01.2009]

§ 7. Conditions for transplantation of cells, tissues or organs into recipient

(1) The transplantation of cells, tissues or organs into a recipient is permitted only with the informed consent of the recipient.

(2) The transplantation of cells, tissues or organs into a recipient with restricted active legal capacity is permitted only with the informed consent of the legal representative of the recipient.

(3) If a recipient with active legal capacity is not able, because of his or her state of health, to express consent, or if the legal representative of a recipient with restricted active legal capacity refuses to grant consent for the transplantation of cells, tissues or organs, or if other circumstances prevent the obtaining of consent from the legal representative of the recipient, the transplantation of the cells, tissues or organs is permitted on the basis of a decision of a doctor on condition that transplantation is the only means of treatment that has the potential to be life-saving for the recipient.

(4) In the case specified in subsection (3) of this section, the medical history of the recipient shall contain a notation concerning the circumstances which prevented the obtaining of consent, and a justification of the necessity of transplantation of a cell, tissue or organ to the recipient.

[RT I 2008, 25, 163 - entry into force 01.01.2009]

§ 8. Protection of personal data

(1) The processing of personal data of living donors and recipients shall be carried out pursuant to the Personal Data Protection Act.

(2) The personal data of deceased donors shall be protected in the same manner as the personal data of living donors and recipients, and such data shall be disclosed only to the handler and the provider of specialised medical care performing transplantation and to persons who need such data for the performance of their duties arising from law.

[RT I 2008, 25, 163 - entry into force 01.01.2009]

Chapter 2 REMOVAL OF CELLS, TISSUES AND ORGANS FROM DONORS

[RT I 2008, 25, 163 - entry into force 01.01.2009]

§ 8¹. Donor

(1) A person declared suitable by a doctor arising from the state of health of the person and the requirements provided for in this Chapter may become a donor.

(2) The selection criteria for donors of cells, tissues and organs shall be established by a regulation of the Minister of Social Affairs.

(3) The handler shall ensure that laboratory testing is carried out upon donation of cells, tissues and organs.

(4) The list of laboratory testing compulsory for donors and the conditions and procedure for the testing shall be established by a regulation of the Minister of Social Affairs.

(5) If necessary, a doctor has the right to carry out supplementary testing to ascertain the suitability of a donor.

(6) In addition to the requirements provided for in this Act, the special requirements provided for in the Artificial Insemination and Embryo Protection Act apply to the donors of gametes.

[RT I 2008, 25, 163 - entry into force 01.01.2009]

§ 9. Conditions for removal of cells, tissues and organs from living donors

(1) Cells, tissues or organs may be removed from a living donor if:

- 1) an informed consent for the removal and transplantation of cells, tissues or organs has been granted by the living donor;
- 2) medical investigations performed on the living donor ascertain that the risk to the life or health of the living donor implied by the removal is not higher than the risk implied by any other surgical operation of the same degree of complexity;
- 3) the purpose of the removal of the organ is its transplantation for therapeutic purposes into the donor's descendant, spouse, cohabitee, parent, grandparent or their descendants;
- 4) there is no suitable organ available from a deceased person for transplantation within a reasonable period of time.

(2) With the informed consent of the living donor, a removed organ may be used for transplantation into another recipient if it is impossible to transplant the organ into the recipient specified in clause (1) 3) of this section.

§ 9¹. Rights and obligations of living donors

- (1) A living donor has the rights and obligations of a patient as provided by the Law of Obligations Act.
- (2) A living donor has the right to:
- 1) obtain relevant information regarding the handling and transplantation of cells, tissues or organs;
 - 2) obtain information regarding the dangers arising from the donation of cells, tissues or organs;
 - 3) decline from the donation of cells, tissues or organs at any time if he or she so decides;
 - 4) receive information on his or her state of health, on the results of the tests conducted on his or her cells, tissues and organs, and the suitability for treatment of the cells, tissues and organs donated by him or her;
 - 5) confidentiality of identity.
- (3) A living donor is required to:
- 1) submit his or her personal data and contact information to the handler;
 - 2) disclose all information and circumstances to the handler which, to the donor's best understanding are relevant to the donation of cells, tissues or organs;
 - 3) inform the handler of circumstances which become known to him or her after donation of cells, tissues or organs, and of any changes which occur in his or her state of health after donation which could affect the suitability for treatment of the donated cells, tissues or organs;
 - 4) confirm the correctness of the submitted information by his or her signature.
- [RT I 2008, 25, 163 - entry into force 01.01.2009]

§ 10. Persons with restricted active legal capacity as donors

- (1) Persons with restricted active legal capacity may not be living donors, except on the conditions provided for in subsection (2) of this section.
- (2) Persons with restricted active legal capacity may be living donors if:
- 1) regenerative cells or tissues are transplanted;
 - 2) there is no compatible donor available who has active legal capacity;
 - 3) the recipient is the donor's descendant, spouse, cohabitee, parent, grandparent or their descendants;
 - 4) consent of the legal representative of the donor and permission of a court for transplantation has been obtained;
 - 5) the potential donor does not object to transplantation.
- (3) A county court shall decide on the grant of court permission provided for in clause (2) 4) of this section in proceedings on petition at the request of the legal representative of the donor or the specialised medical care provider performing the removal of a cell or tissue from the donor.
- [RT I 2008, 25, 163 - entry into force 01.01.2009]

Chapter 3 REMOVAL OF CELLS, TISSUES AND ORGANS FROM DECEASED DONORS

[RT I 2008, 25, 163 - entry into force 01.01.2009]

§ 11. Conditions for removal of cells, tissues and organs from deceased donors

- (1) Cells, tissues or organs may be removed from a deceased donor if:
- 1) the death of the person has been certified pursuant to the procedure provided for in § 12 of this Act;
 - 2) during lifetime, the deceased donor had expressed a wish to donate cells, tissues or organs for transplantation after his or her death, or if no information is available that the person had objected to it;
 - 3) the removal of the cells, tissues or organs does not impede the conduct of forensic medical examination of a deceased person who died a violent death.
- (1¹) A person may express his or her wish to donate cells, tissues or organs for transplantation after his or her death and certify the fact by digital signature through the health information system.
- (2) If no information is available whether a deceased person, during his or her lifetime, had expressed an opinion on the post-mortem removal of cells, tissues and organs for transplantation purposes, the doctor who provided treatment to the deceased person during his or her lifetime is required, if possible, to ascertain through the descendants or ascendants, brothers, sisters, legal representative, spouse or cohabitee of the deceased person the opinion which the person held on the matter during his or her lifetime.
- (3) Other persons shall not prohibit the removal of cells, tissues or organs if the deceased person, during his or her lifetime, had consented to the removal or donation after his or her death. Other persons shall not permit the removal of cells, tissues or organs if the deceased person, during his or her lifetime, had refused to donate cells, tissues or organs after his or her death.

(4) The removal of cells, tissues or organs from a deceased person who had died a violent death shall be approved by a forensic pathologist.

(5) The doctors who participate in the removal or transplantation of cells, tissues or organs from a deceased donor shall not be the same doctors who provided treatment to the deceased donor during his or her lifetime or who were members of the committee of doctors who certified his or her death.

(6) A doctor who removes cells, tissues or organs from a deceased donor shall prepare a statement on the removal of the cells, tissues or organs.

(7) The Minister of Social Affairs shall establish, by a regulation, the standard format for statements on the removal of cells, tissues or organs.

[RT I 2008, 25, 163 - entry into force 01.01.2009]

§ 12. Certification of death

(1) If cells, tissues or organs of a person will be used for transplantation after the death of the person, the death of the person shall be certified by a committee of doctors with at least two members, who shall prepare a statement on the certification of death.

(2) The standard format for statements on the certification of death shall be established by a regulation of the Minister of Social Affairs.

(3) The death of a person shall not be certified by a doctor who directly participates in the removal or transplantation procedures of cells, tissues or organs of the deceased person or a doctor whose obligations involve care of the possible recipients of the cells, tissues or organs of the deceased person.

(4) Death shall be certified pursuant to the Establishment of Cause of Death Act.

[RT I 2008, 25, 163 - entry into force 01.01.2009]

§ 13. Use of cells, tissues or organs removed from deceased donors in international exchange

(1) If suitable recipients for cells, tissues or organs removed from deceased donors cannot be found in Estonia, such cells, tissues and organs may be used in the international exchange of cells, tissues or organs.

(2) If an organ is sent into another state, the handler shall document the reasons why the organ cannot be used on Estonian recipients.

[RT I 2008, 25, 163 - entry into force 01.01.2009]

Chapter 3¹

TRACEABILITY OF HANDLING OF CELLS, TISSUES AND ORGANS AND BIOVIGILANCE

[RT I 2008, 25, 163 - entry into force 01.01.2009]

§ 13¹. Traceability of handling of cells, tissues and organs

(1) The handler shall ensure the traceability of cells, tissues or organs from the donor to the recipient and vice versa.

(2) A unique code shall be provided to donated organs and tissues and to cell donation.

(3) The handler shall preserve the information necessary to ensure traceability for at least thirty years as of transplantation of cells, tissues or organs into a recipient.

[RT I 2008, 25, 163 - entry into force 01.01.2009]

§ 13². Biovigilance

(1) Biovigilance means the provision of information concerning any serious adverse event associated with the handling of cells, tissues and organs and any serious adverse reaction occurring at the time or after transplantation of cells, tissues or organs into a recipient, and the procedure for establishing the reasons thereof.

(2) A serious adverse event means an unfavourable event associated with the handling of cells, tissues and organs which may cause the spread of infectious diseases, may endanger the life of a living donor or a recipient

or cause his or her death, require his or her extended hospitalisation, cause long-term loss of capacity for work or a severe or profound disability.

(3) A serious adverse reaction means an undesirable consequence associated with the transplantation of cells, tissues and organs, including the spread of infectious diseases which endangers the life of a living donor or a recipient or causes his or her death, requires his or her extended hospitalisation, causes long-term loss of capacity for work or a severe or profound disability.

(4) The health care provider shall inform the handler which issued the transplanted cells, tissues and organs to the recipient of any post-transplantation serious adverse reaction.

(5) The handler shall inform the State Agency of Medicines of serious adverse events and serious adverse reactions which have become evident upon handling of cells, tissues and organs or after the handling.

(6) The conditions and procedure for biovigilance and withdrawal applied in respect of cells, tissues and organs and the forms of giving notification of serious adverse events and serious adverse reactions shall be established by a regulation of the Minister of social Affairs.

(7) Cells, tissues and organs shall be withdrawn immediately after a serious adverse event has been ascertained.

(8) Based on the information forwarded to the State Agency of Medicines, an annual consolidated report concerning the serious adverse events and the serious adverse reactions shall be prepared by the State Agency of Medicines.

[RT I 2008, 25, 163 - entry into force 01.01.2009]

§ 13³. Importation and exportation of cells, tissues and organs

(1) Cells, tissues and organs shall be imported and exported under the conditions and pursuant to the procedure provided for in the Medicinal Products Act.

(2) The handlers shall ensure the compliance of imported and exported cells, tissues and organs with the quality requirements set out in the rules for the handling of cells, tissues and organs established pursuant to § 4¹³ of this Act.

[RT I 2008, 25, 163 - entry into force 01.01.2009]

Chapter 4 FINANCING

§ 14. Financing of handling and transplantation

Handling and transplantation shall be financed by the recipient, unless the obligation to compensate for medical expenses is assumed by the Estonian Health Insurance Fund.

[RT I 2008, 25, 163 - entry into force 01.01.2009]

§ 15. Compensation of medical expenses out of national health insurance budget

(1) The Estonian Health Insurance Fund shall assume the obligation to compensate health care providers for the medical expenses incurred in connection with the handling and transplantation of cells, tissues and organs to recipients covered by health insurance.

(2) Living donors and recipients covered by health insurance shall be paid benefits for temporary incapacity for work by the Estonian Health Insurance Fund pursuant to the procedure provided in the Health Insurance Act.

[RT I 2008, 25, 163 - entry into force 01.01.2009]

Chapter 5 SUPERVISION AND REPORTING OBLIGATION

[RT I 2008, 25, 163 - entry into force 01.01.2009]

§ 16. Supervision over handling and transplantation of cells, tissues and organs

(1) The Health Care Board and the State Agency of Medicines exercise supervision over compliance with this Act pursuant to the provisions of the Administrative Procedure Act with the specifications arising from the Health Services Organisation Act and this Act.

[RT I 2009, 49, 331 - entry into force 01.01.2010]

(2) The State Agency of Medicines exercises supervision over compliance of the handlers of cells, tissues and organs with the requirements for the handling of cells, tissues and organs provided for in this Act and legislation

established on the basis thereof, with the exception of compliance with the requirements for the removal of cells, tissues and organs.

(3) The Health Care Board exercises supervision over compliance of the specialised medical care providers whose practice involves the removal and transplantation of cells, tissues and organs with the requirements for the removal and transplantation of cells, tissues and organs provided for in this Act and legislation established on the basis thereof.

[RT I 2009, 49, 331 - entry into force 01.01.2010]

§ 16¹. Rights and obligations of officials exercising supervision

(1) An official exercising supervision (hereinafter supervisory official) has the right, for performance of his or her duties, to:

- 1) check adherence with the requirements provided by this Act and legislation established on the basis thereof, including, if necessary, without giving prior notice;
- 2) take cells, organs, tissues or their samples for control analysis if necessary;
- 3) enter, for the exercise of supervision, the facilities being inspected;
- 4) obtain information necessary for the exercise of supervision from natural persons and representatives of legal persons, to examine relevant documents, and to obtain or make copies thereof or, if a misdemeanour is suspected, to take the documents with him or her;
- 5) make a proposal to the State Agency of Medicines, upon establishment of the violations specified in subsection 4¹⁰(3) of this Act, to suspend the validity of the activity licence in part or in full, or to revoke the activity licence;
- 6) submit proposals to the person being inspected in order to improve the activities thereof;
- 7) issue, within the limits of his or her rights, precepts to terminate a violation of the requirements of this Act or legislation established on the basis thereof or the conditions of an activity licence, to eliminate the consequences of the violation or to perform other acts.

(2) Supervisory officials are required to present identification for the performance of their duties.

(3) Supervisory officials are required to maintain the confidentiality of business secrets which become known to them unless keeping the secret is liable to pose a risk to the life or health of humans or animals, or to the environment.

[RT I 2008, 25, 163 - entry into force 01.01.2009]

§ 16². Precept of State Agency of Medicines and application of coercive measures

(1) A precept shall be issued in writing and shall contain the following information:

- 1) the name and position of the person who prepares the precept and the name and address of the supervisory agency;
- 2) the date and place of issue of the precept;
- 3) the name and seat of the recipient of the precept;
- 4) the circumstances which are the basis for the issue of the precept or a reference to the document in which the circumstances are set out, and reference to the legal grounds of the precept;
- 5) the conclusion of the precept in which the obligations of the obligated subject arising from the precept and the term for performance of the obligations are set out;
- 6) a reference to the possibility of administrative coercive measures being applied upon failure to comply with the precept;
- 7) the procedure and term for contesting the precept;
- 8) the signature of the person who prepares the precept.

(2) A precept shall be prepared in two original copies of which one shall remain with the person who prepares the precept and the other shall be given to the obligated subject. If it is necessary to inform a third party of the precept, a copy of the precept certified by the person who prepared the precept shall be delivered to the third party by post or by electronic means.

(3) Upon failure to comply with the precept, the supervisory agency has the right to impose penalty payment pursuant to the procedure provided for in the Substitutive Enforcement and Penalty Payment Act. The upper limit for a penalty payment is 1,600 euros.

[RT I 2010, 22, 108 - entry into force 01.01.2011]

§ 16³. Contestation of precept

(1) Upon disagreement with a precept of a supervisory official, the recipient of the precept has the right to file a written challenge with the head of the supervisory agency within ten working days as of the date on which the recipient of the precept became or should have become aware of the contested precept.

(2) The head of the supervisory agency shall review a challenge and make a decision within fourteen days as of the date on which the challenge is filed. The supervisory official against whose precept or act the challenge is filed shall not participate in the review of the challenge.

(3) The filing of a challenge shall not release the person who filed the challenge from the duty to comply with the precept. The head of the supervisory agency may suspend compliance with a contested precept if the circumstances specified in § 81 of the Administrative Procedure Act occur until a decision is made on the challenge.

(4) The head of the supervisory agency has the right to revoke, in part or in full, a precept which is contrary to this Act or legislation established on the basis thereof by a reasoned directive.
[RT I 2008, 25, 163 - entry into force 01.01.2009]

§ 16⁴. Reporting obligation

(1) The State Agency of Medicines shall submit to the European Commission a report regarding the handling of cells, tissues and organs and the results of supervision by 7 April 2009 and after that, once in every three years by the same due date.

(2) The State Agency of Medicines shall regularly maintain records on handlers and their activities.
[RT I 2008, 25, 163 - entry into force 01.01.2009]

Chapter 5¹ LIABILITY

[RT I 2002, 63, 387 - entry into force 01.09.2002]

§ 17. Derivation of financial gain for donation of cells, tissues and organs

Donation of cells, tissues and organs, if the donor or his or her legal representative has derived financial gain for it, is punishable by a fine of up to 300 fine units.
[RT I 2008, 25, 163 - entry into force 01.01.2009]

§ 17¹. Violation of requirements for handling of cells, tissues and organs

(1) Violation of the requirements for the handling of cells, tissues and organs is punishable by a fine of up to 300 fine units.

(2) The same act, if committed by a legal person, is punishable by a fine of up to 3,200 euros.
[RT I 2010, 22, 108 - entry into force 01.01.2011]

§ 17². Interference with exercise of state supervision

Interference with the exercise of state supervision, refusal to submit documents or information necessary for inspection or failure to submit these on time, submission of inaccurate information, or submission of documents or information such that it prevents the exercise of supervision, if committed by a legal person, is punishable by a fine of up to 3,200 euros.
[RT I 2010, 22, 108 - entry into force 01.01.2011]

§ 17³. Procedure

(1) The provisions of the General Part of the Penal Code and the Code of Misdemeanour Procedure apply to misdemeanours provided for in §§ 17-17² of this Act.
[RT I 2008, 25, 163 - entry into force 01.01.2009]

(2) Extra-judicial proceedings concerning the misdemeanours provided for in § 17 of this Act shall be conducted by police authorities.
[RT I 2009, 62, 405 - entry into force 01.01.2010]

(3) The State Agency of Medicines is the extra-judicial body which conducts proceedings in matters of misdemeanours provided for in §§ 17¹ and 17² of this Act.
[RT I 2008, 25, 163 - entry into force 01.01.2009]

§ 17⁴. Implementation of Act

Specialised medical care providers shall apply for an activity licence for the handling of cells, tissues and organs not later than by 1 April 2009.
[RT I 2008, 25, 163 - entry into force 01.01.2009]

Chapter 6

IMPLEMENTING PROVISION

§ 18. Entry into force of Act

This Act enters into force on the tenth day after publication in the *Riigi Teataja*, except for §§ 3 and 17 which enter into force simultaneously with the Penal Code.

¹Directive 2004/23/EC of the European Parliament and of the Council on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (OJ L 102, 7.04.2004, p. 48–58); Commission Directive 2006/17/EC implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells (OJ L 38, 9.02.2006, p. 40–52); Commission Directive 2006/86/EC implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells (OJ L 294, 25.10.2006, p. 32–50). [RT I 2008, 25, 163 – entered into force 01.01.2009]