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Procurement, Handling and Transplantation of Cells, Tissues and Organs Act[1]

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Amended by the following acts

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20.02.2019	RT I, 13.03.2019, 2	15.03.2019
15.12.2021	RT I, 03.01.2022, 2	13.01.2022
22.02.2023	RT I, 11.03.2023, 9	01.04.2023
20.06.2023	RT I, 06.07.2023, 6	01.01.2024

Chapter 1
GENERAL PROVISIONS

§ 1. Scope of application

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

(2) This Act applies to the cells, tissues and organs which are removed from a living or deceased human donor (hereinafter donor) and are or are not processed *in vitro* and which are intended for human use.
[RT I, 09.03.2017, 1 – entry into force 19.03.2017]

(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 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.

§ 2. Definitions

(1) For the purposes of this Act, the procurement of cells, tissues and organs means the process in the course of which cells, tissues and organs are made accessible for handling, transplantation, manufacture of advanced therapy medicinal products or making hospital-exemption medicinal products. The process of procurement of cells, tissues and organs for the purposes of this Act means above all the selection of a donor, removal of cells, tissues and organs and the coding, packaging, labelling and distribution of procured cells, tissues and organs to the handler, transplanter, manufacturer of advanced therapy medicinal products or maker of hospital-exemption medicinal products.

[RT I, 03.01.2022, 2 – entry into force 13.01.2022]

(2) For the purposes of this Act, the handling of cells, tissues and organs means the description, coding, labelling, testing, preservation and processing of cells, tissues and organs and the packaging, labelling, storage, release and distribution of handled cells, tissues and organs to the transplanter, manufacturer of advanced therapy medicinal products or maker of hospital-exemption medicinal products.
[RT I, 03.01.2022, 2 – entry into force 13.01.2022]

(3) 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 for therapeutic purposes.
[RT I, 09.03.2017, 1 – entry into force 19.03.2017]

(4) For the purposes of this Act, cells mean individual human cells or a collection of human cells when not bound by any form of connective tissue.

(5) For the purposes of this Act, tissues mean all constituent parts of the human body formed by cells.

(6) For the purposes of this Act, an organ means a differentiated 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 after removal from the human body. An organ also means a part of an organ if the functioning thereof in the human body is used for the same purpose as a complete organ and it maintains its structure and vascularisation after removal from the human body.

(7) Donation means the voluntary donating of cells, tissues and organs for transplantation, manufacture of advanced therapy medicinal products or making hospital-exemption medicinal products.
[RT I, 03.01.2022, 2 – entry into force 13.01.2022]

(8) A donor means a person from whom cells, tissues or organs are removed for transplantation, manufacture of advanced therapy medicinal products or making hospital-exemption medicinal products.
[RT I, 03.01.2022, 2 – entry into force 13.01.2022]

(9) A recipient means a person to whom the cells, tissues or organs removed from a donor are transplanted.

(10) For the purposes of this Act, a procurer means a special medical care provider to whom an activity licence has been issued for the procurement of cells, tissues and organs.

(11) For the purposes of this Act, a handler means a legal person in private law to whom an activity licence has been issued for the handling of cells or tissues. Organs may be handled by a special medical care provider to whom an activity licence has been issued for the handling of organs.

(12) For the purposes of this Act, a transplanter means a special medical care provider who engages in the transplantation of cells, tissues or organs.

(13) For the purposes of this Act, human use means the use of cells, tissues and organs on or in a human recipient or *in vitro*.
[RT I, 09.03.2017, 1 – entry into force 19.03.2017]

(14) For the purposes of this Act, a third country supplier outside the European Union and the European Economic Area means the procurer or handler of cells and tissues founded in a third country outside the European Union and the European Economic Area or another person responsible for the export of such cells and tissues to the European Union and the European Economic Area, which the person supplies to the importing procurer of the handler of cells and tissues. A third country supplier may perform one or many operations outside the European Union and the European Economic Area relating to the donation, procurement, study, processing, preservation, storage and distribution of cells and tissues imported to the European Union and the European Economic Area.
[RT I, 09.03.2017, 1 – entry into force 19.03.2017]

§ 3. Seeking financial gain

The donation of cells, tissues and organs is voluntary and offering reward or seeking financial gain for the donation is prohibited, except in the cases provided for in the Artificial Insemination and Embryo Protection Act.

§ 4. Protection of personal data

The personal data of donors and recipients shall be processed according to the Personal Data Protection Act and Regulation (EU) 2016/679 of the European Parliament and of the Council on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 04.05.2016, p. 1–88) and the data may be disclosed only to the procurer, handler, transplanter and to the person who needs the data for the performance of his or her duties arising from the law.
[RT I, 13.03.2019, 2 – entry into force 15.03.2019]

Chapter 2
ORGANISATION OF PROCUREMENT, HANDLING AND TRANSPLANTATION OF CELLS, TISSUE AND ORGANS

§ 5. Transplantation infrastructure

(1) The transplantation infrastructure means the national system of procurement, handling and transplantation of cells, tissues and organs, the purpose of which is to ensure the procurement, handling and transplantation of cells, tissues and organs according to the established legislation .

(2) The transplantation infrastructure shall be composed of:
1) transplantation council;
2) national transplantation agency;
3) transplantation centres;
4) the procurers and handlers of cells, tissues and organs;
5) Estonian Health Insurance Fund;
[RT I, 11.03.2023, 9 – entry into force 01.04.2023]
6) State Agency of Medicines;
7) Health Board;
8) Ministry of Social Affairs.

§ 6. Transplantation council

(1) The transplantation council is an independent advisory committee formed by the minister in charge of the policy sector, the members of which are the procurers, handlers and transplanters of cells, tissues and organs and the representatives of the Estonian Health Insurance Fund, the Health Board, the State Agency of Medicines, the Ministry of Social Affairs, the representative organisations of patients and the relevant professional organisations.
[RT I, 11.03.2023, 9 – entry into force 01.04.2023]

(2) The function of the transplantation council is to submit proposals to the relevant organisations:
1) to determine and update the national need for the procurement, handling and transplantation of cells, tissues and organs;
2) to establish the strategic goals for the procurement, handling and transplantation of cells, tissues and organs;
3) to finance the procurement, handling and transplantation of cells, tissues and organs;
4) to promote the awareness on the donation of cells, tissues and organs.

§ 7. National transplantation agency

(1) Performance of the functions of national transplantation agency shall be ensured by the Estonian Health Insurance Fund who may enter into an administrative contract with a transplantation centre therefor, based on the conditions provided for in the Administrative Co-operation Act.
[RT I, 11.03.2023, 9 – entry into force 01.04.2023]

(2) The national transplantation agency shall perform the following functions:
1) organises the subsequent observation of the medical status of live organ donors;
2) [Repealed – RT I, 28.12.2017, 4 – entry into force 01.01.2020]
3) [Repealed – RT I, 28.12.2017, 4 – entry into force 01.01.2020]
4) [Repealed – RT I, 28.12.2017, 4 – entry into force 01.01.2020]
5) organises activities, the purpose of which is to notify of the importance of the donation of cells, tissues and organs;
[RT I, 28.12.2017, 4 – entry into force 01.01.2020]
6) carries out audits over the donation of cells, tissues and organs and establishes the reasons for non-donation;
7) organises the development of quality and safety instructions for the procurement, handling and transplantation of cells, tissues and organs;
8) [Repealed – RT I, 28.12.2017, 4 – entry into force 01.01.2020]
9) [Repealed – RT I, 28.12.2017, 4 – entry into force 01.01.2020]

(3) [Repealed – RT I, 28.12.2017, 4 – entry into force 01.01.2020]

§ 8. Transplantation centre

(1) A transplantation centre is Tartu University Hospital, provided that an activity licence has been issued thereto for the procurement, handling and transplantation of organs.
[RT I, 28.12.2017, 4 – entry into force 01.01.2020]

(1^1) The transplantation centre shall perform the following functions:
1) organises the traceability and biovigilance of the procurement, handling and transplantation of organs;
2) maintains the organ transplant waiting lists;
3) organises the distribution and international exchange of organs to be transplanted and enters into contracts therefor with the relevant organisations of the European Union and third countries;
4) organises the communication concerning the procurement, handling and transplantation of cells, tissues and organs with the procurers, handlers, transplanters and the State Agency of Medicines.
[RT I, 28.12.2017, 4 – entry into force 01.01.2020]

(1^2) The transplantation centre shall ensure the 24-hour performance of functions specified in clauses 1–3 of subsection 1^1 of this section.
[RT I, 28.12.2017, 4 – entry into force 01.01.2020]

(2) [Repealed – RT I, 28.12.2017, 4 – entry into force 01.01.2020]

Chapter 3
PROCUREMENT, HANDLING AND TRANSPLANTATION OF CELLS, TISSUES AND ORGANS

Subchapter 1
Selection of Donor

§ 9. Notification obligation of potential deceased donor

(1) Regional and central hospitals shall be required to establish the death and notify the transplantation centre of a potential deceased donor.
[RT I, 28.12.2017, 4 – entry into force 01.01.2020]

(2) A person is a potential deceased donor if the person's death has been started to be established pursuant to the procedure provided for in § 16 of this Act.

§ 10. Selection of donor

(1) A donor may be a person whom the doctor has declared, based on the person's state of health and the requirements provided for in this Act, to be medically suitable for the donation of cells, tissues or organs for transplantation to another person, manufacture of advanced therapy medicinal products or for making hospital-exemption medicinal products.
[RT I, 03.01.2022, 2 – entry into force 13.01.2022]

(2) The criteria for the selection of cell, tissue and organ donors and the list of circumstances precluding the donation of cells, tissues and organs shall be established by a regulation of the minister in charge of the policy sector.

(3) The procurer shall ensure that the laboratory testing specified in the regulation established under subsection 5 of this section is carried out on the donor upon the donation of cells, tissues or organ.

(4) Upon donation of an organ, laboratory testing shall be carried out on a donor in a laboratory accredited by an international accreditation institution to ascertain the tissue compatibility.

(5) 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 in charge of the policy sector.

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

(7) 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.

Subchapter 2
Living Donor

§ 11. Conditions for removal of cells, tissues and organ from living donor

(1) Cells, tissues or an organ may be removed from a living donor if:
1) the donor has granted his or her consent for the removal of cells, tissues or an organ;

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 of cells, tissues or an organ is not higher than the risk implied by any other surgical operation of the same degree of complexity;
3) the purpose of removal of the organ is its transplantation for therapeutic purposes into a person with whom the donor has a genetic or emotional connection;
4) the donor has received psychological counselling before the removal of an organ.

(2) With the 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 person specified in clause 3 of subsection 1 of this section.

(3) In the case specified in subsection 2 of this section, the medical history of the living donor shall contain a written explanation concerning the circumstances which prevented the transplantation to the person specified in clause 3 of subsection 1 of this section.

§ 12. Consent of living donor

(1) For the purposes of this Act, the consent of a living donor means the consent granted by a donor for the removal of cells, tissues or an organ. The consent of a person with restricted active legal capacity shall be granted by his or her legal representative based on the requirements provided for in § 13 of this Act.

(2) Consent for the removal of cells, tissues or an organs shall be given by the persons specified in subsection 1 of this section expressly in writing for a specific donation.

(3) Consent granted by the persons specified in subsection 1 of this section is valid if they have been provided with information beforehand in writing or in a format which can be reproduced in writing:
1) as to the purpose and nature of the removal of cells, tissues or an organ;
2) as to the consequences and risks of the removal of cells, tissues or an organ;
3) as to the tests performed before the removal of cells, tissues or organ and the results thereof;
4) as to the registration and protection of the donor's personal data;
5) as to the purpose of transplantation and potential efficiency factors of the donated cells, tissues or an organ, manufacture of advanced therapy medicinal products or making hospital-exemption medicinal products;
[RT I, 03.01.2022, 2 – entry into force 13.01.2022]
6) as to the safety measures applied for the protection of the life and health of a donor.

(4) A consent may be withdrawn at any time until the removal of cells, tissues or an organ.

§ 13. Persons with restricted active legal capacity as living 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 removed;
2) there is no compatible donor available who has active legal capacity;
3) the recipient is the sibling, child or biological parent of the person with restricted active legal capacity;
4) consent of the legal representative of the donor and permission of a court for removal of cells, tissues or organ has been obtained, and
5) the person with restricted active legal capacity does not object to the removal and transplantation.

(3) A county court shall decide on the grant of court permission provided for in clause 4 of subsection 2 of this section in proceedings on petition at the request of the legal representative of the donor or the procurer performing the removal of a cells or tissues, verifying that the person with restricted active legal capacity does not object to the removal and transplantation of cells or tissues.

§ 14. Rights and obligations of living donors

(1) A living donor has the rights and obligations of a patient as provided for in the Law of Obligations Act.

(2) A living donor has the right to:
1) obtain relevant information regarding the removal, handling and transplantation of cells, tissues or organ, manufacture of advanced therapy medicinal products or making hospital-exemption medicinal products from a qualified person who is able to provide information appropriately by using definitions which are understandable to the living donor;
[RT I, 03.01.2022, 2 – entry into force 13.01.2022]
2) obtain information regarding the risks arising from the donation of cells, tissues or organ;
3) receive information on his or her state of health, on the results of the tests conducted on his or her cells, tissues and organ, and the suitability for treatment of the cells, tissues and organ donated by him or her

accompanied by explanations understandable to the living donor and the measures applied for the protection of his or her health;
4) receive treatment arising from the state of health after removal of an organ regardless of being covered by health insurance;
5) the protection of personal data according to the Personal Data Protection Act.

(3) A living donor is required to:
1) submit his or her personal data and contact information to the procurer;
2) disclose all information and circumstances to the procurer which, to the donor's best understanding are relevant to the donation of cells, tissues or organs;
3) inform the procurer of circumstances, to his or her best understanding, which have 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 of the donated cells, tissues or organs for transplantation, manufacture of advanced therapy medicinal products or making hospital-exemption medicinal products;
[RT I, 03.01.2022, 2 – entry into force 13.01.2022]
4) confirm the correctness of the submitted information by his or her signature.

Subchapter 3
Deceased Donor

§ 15. Conditions for removal of cells, tissues and organs from deceased donor

(1) Cells, tissues or organs may be removed from a deceased donor if:
1) the death of the person has been established pursuant to the procedure provided for in § 16 of this Act;
2) during lifetime, the deceased donor had expressed a wish to donate cells, tissues or organs after his or her death according to the provisions of § 17 of this Act, or if no information is available that the person had objected to it.

(2) The removal of cells, tissues or organs must not impede the conduct of forensic medical examination of a deceased person who died a violent death.

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

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

(5) The standard format for statements on the removal of cells, tissues or organs from a deceased donor shall be established in the rules for procurement and handling of cells, tissues and organs established under subsection 3 of § 22 of this Act.

§ 16. Establishment 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 established by a committee of doctors with at least two members, who shall prepare a statement on the establishment of death.

(2) The death of a person shall not be established by a doctor who directly participates in the removal or transplantation 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.

(3) The conditions and procedure for the establishment of death of a person and the standard format for statements on the establishment of death shall be established by a regulation of the minister in charge of the policy sector.

§ 17. Declaration of intention of deceased donor expressed during his or her lifetime

(1) A person may express his or her intention to donate cells, tissues or organs for transplantation after death by confirming it through the health information system or in another clearly expressed manner.

(2) The procurer of cells, tissues and organs shall verify in the health information system the declaration of intention of a deceased person expressed during his or her lifetime to donate cells, tissues or organs for transplantation.

(3) If no information is available in the health information system on the declaration of intention of a deceased person expressed during his or her lifetime or if the deceased person had not expressed his or her intention in any other manner to donate his or her cells, tissues and organs for transplantation purposes, the procurer of cells, tissues and organs shall be required, if possible, to ascertain the declaration of intention of the deceased person expressed during his or her lifetime from the following persons in the following order:
1) spouse, registered spouse or cohabitee of the deceased person;

[RT I, 06.07.2023, 6 – entry into force 01.01.2024]
2) adult child of the deceased person;
3) parent of the deceased person;
4) adult sibling of the deceased person;
5) grandparent of the deceased person;
6) emotionally close person or another person with active legal capacity if the persons listed above are absent or unavailable.

(4) Other persons may not prohibit the removal of cells, tissues or organs if the deceased person has consented with the removal and transplantation in his or her lifetime. Other persons may not allow the removal of cells, tissue or organs if the deceased person has refused from the removal for transplantation during his or her lifetime.

§ 18. Person with restricted active legal capacity as deceased donor

(1) The consent of a deceased person with restricted active legal capacity for the removal of cells, tissues or organs shall be asked from the following persons in the following order:
1) the spouse, registered partner or cohabitee of the deceased person;
[RT I, 06.07.2023, 6 – entry into force 01.01.2024]
2) adult child of the deceased person;
3) parent of the deceased person;
4) adult sibling of the deceased person;
5) grandparent of the deceased person;
6) emotionally close person or another person with active legal capacity if the persons listed above are absent or unavailable.

(2) The consent of a person specified in subsection 1 of this section for the removal of cells, tissues and organs must be clearly expressed. The consent shall be documented by a health care professional.

(3) The consent of a person specified in subsection 1 of this section is valid if he or she has been previously provided with the information specified in clauses 1, 4 and 5 of subsection 4 of § 12 of this Act.

Subchapter 4
Recipient

§ 19. Recipient's consent

(1) For the purposes of this Act, recipient's consent means the consent of the recipient or, in the cases provided for in the law, the consent of his or her legal representative which must be in written form, clearly expressed and for a specific donation.

(2) The recipient having granted his or her consent or, in the cases provided for in the law, his or her legal representative, may withdraw the consent at any time until the transplantation of cells, tissues or an organ.

(3) The consent granted by a person specified in subsection 1 of this section is valid if he or she has been provided with appropriate information beforehand as to the purpose and nature of the transplantation of cells, tissues or organs as well as on the potential risks and consequences thereof.

(4) The transplantation of cells, tissues or an organ into a recipient with restricted active legal capacity is allowed with the consent of the legal representative of the recipient. If the decision of the legal representative clearly damages the interests of the recipient, the health care provider may not comply with it.

(5) 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 an organ, or if other circumstances prevent the obtaining of consent from the legal representative of the recipient, the transplantation of cells, tissues or an organ 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.

(6) In the cases specified in subsection 4 and 5 of this section, the medical history of the recipient shall contain an explanation on how the decision of the legal representative of the recipient clearly damages the interests of the recipient as well as the circumstances which prevented the obtaining of consent, and a justification of the necessity of transplantation of cells, tissues or an organ to the recipient.

Subchapter 5

Procurer, Handler and Transplanter

§ 20. Obligations of handlers and procurers

(1) Handlers and procurers shall be required to:
1) guarantee the existence of conditions for the procurement and 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 procurement and handling of cells, tissues and organs;
2) guarantee that the person responsible for procurement or 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 the procurement and handling of cells, tissues and organs comply with the internationally recognised or scientifically justified procedures, including the updating of procurement and handling procedures according to the development 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 thereof or with the right to manufacture advanced therapy medicinal products or make hospital-exemption medicinal products;
[RT I, 03.01.2022, 2 – entry into force 13.01.2022]
5) guarantee that the cells, tissues and organs intended for transplantation, manufacture of advanced therapy medicinal products or making hospital-exemption medicinal products are of high quality and as safe as possible.
[RT I, 03.01.2022, 2 – entry into force 13.01.2022]

(2) Procurers and handlers shall maintain records on the procurement, handling and transplantation of cells and tissues and shall submit a report concerning the previous year to the State Agency of Medicines by 1 April each year. The State Agency of Medicines shall prepare and publish a consolidated report by 1 May of the calendar year.

(3) Procurers and handlers shall maintain records on the procurement, handling and transplantation of organs and shall submit a report concerning the previous year to the transplantation centre by 1 April each year. The transplantation centre shall prepare and publish a consolidated report by 1 May of the calendar year.
[RT I, 28.12.2017, 4 – entry into force 01.01.2020]

(4) The minister in charge of the policy sector shall establish, by a regulation, the requirements for the preparation of reports on the procurement, handling and transplantation of cells, tissues and organs and the composition of data.

§ 21. Obligations of transplanters

(1) Transplanters shall be required to:
1) guarantee the existence of conditions for the transplantation 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 transplantation of cells, tissues and organs;
2) guarantee that the transplantation of cells, tissues and organs complies with the development of science and technology;
3) guarantee that cells, tissues and organs are transplanted only on the conditions and pursuant to the procedure provided for in this Act and in the legislation established on the basis thereof;
4) guarantee that the cells, tissues and organs to be transplanted are of high quality and that their purposeful use is safe for the recipient.

(2) Transplanters shall maintain records on the transplantation of organs and shall submit a report concerning the previous year to the transplantation centre by 1 April each year. The transplantation centre shall prepare and publish a consolidated report by 1 May of the calendar year.
[RT I, 28.12.2017, 4 – entry into force 01.01.2020]

(3) The minister in charge of the policy sector shall establish, by a regulation, the requirements for preparation of reports on the transplantation of organs and the composition of data.

Subchapter 6
Requirements for Procurement, Handling and Transplantation of Cells, Tissues and Organs

§ 22. Conditions for procurement and handling of cells, tissues and organs

(1) In order to ensure the safety and quality of cells, tissues and organs, the procurer and handler shall develop a quality assurance system which complies with the good practices of the European Union. The applied quality assurance system must be fully documented and continuously monitored in all its stages.

(2) In order to apply the quality assurance system, the necessary resources, such as competent personnel, suitable facilities, equipment and means must be ensured by the procurer and handler.

(3) The minister in charge of the policy sector shall establish, by a regulation, the rules for the procurement and handling of cells, tissues and organs which provides for the requirements for the:
1) document management of procurers and handlers;
2) personnel of procurers and handlers;
3) procurement and handling facilities;
4) equipment and materials used upon procurement and handling;
5) procurement and handling procedures;
6) quality assurance upon procurement and handling;
7) biovigilance and withdrawal;
8) communication between procurers, handlers, transplanters, manufacturers of advanced therapy medicinal products or makers of hospital-exemption medicinal products;
[RT I, 03.01.2022, 2 – entry into force 13.01.2022]
9) traceability;
10) settlement of disputes having arisen upon procurement, handling or transplantation.
11) list of documents necessary for the application for the issue of an import certificate, composition of data and format of the import certificate.
[RT I, 09.03.2017, 1 – entry into force 19.03.2017]

(4) The procurer and handler shall preserve the necessary documents to ensure the traceability of cells, tissues and organs for 30 years and the documents reflecting the safety and quality for ten years after the clinical use or destruction of cells, tissues and organs.
[RT I, 13.03.2019, 2 – entry into force 15.03.2019]

§ 23. Competent person and person responsible for procurement

(1) A competent person is a natural person designated by the handler, who is responsible for the handling of a type of cells, tissues and organs and who shall ensure that the cells, tissues or organs intended for transplantation into recipient, manufacture of advanced therapy medicinal products or making hospital-exemption medicinal products have been handled according to the requirements of the legislation and the instructions established by the handler and they are as safe as possible for the recipient.
[RT I, 03.01.2022, 2 – entry into force 13.01.2022]

(2) A person responsible for procurement is a natural person designated by the procurer who shall ensure the compliance of the entire process of procurement of cells, tissues and organs with the requirements provided for in this Act.

(3) A person may be designated as a competent person or a person responsible for procurement by one handler or procurer at a time.

(4) The substitute for a competent person or a person responsible for procurement must comply with the requirements established for a competent person or a person responsible for procurement.

§ 24. Qualification requirements for competent person and person responsible for procurement

(1) The competent person designated by the handler of cells or tissues shall have an academic degree in medicine, biology or in a specialty related to biology acquired in a university or a corresponding foreign qualification and at least two years of work experience in the field of handling cells and tissues.

(2) A person responsible for the procurement or cells or tissues shall have an education acquired in a university or an institution of professional higher education in medicine, biology, nursing or midwifery or a corresponding foreign qualification and work experience in the field of procurement of cells and tissues or a special training ensured by the procurer.

(3) A competent person designated by the handler of organs must have completed the residency curriculum in full or acquired the specialty of a medical specialist or a corresponding foreign qualification and at least two years of work experience in the field of handling of organs.

(4) A person responsible for the procurement of organs must have completed the residency curriculum in full or acquired the specialty of a medical specialist or a corresponding foreign qualification.

§ 25. Conditions for transplantation of cells, tissues and organs

(1) 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.

(2) Cells, tissues and an organ may be transplanted into a recipient with the consent of the recipient.

(3) An organ may be transplanted into a recipient who has been registered on the organ transplant waiting list pursuant to the procedure provided for in this Act.

Chapter 4
ACTIVITY LICENCE

§ 26. Activity licence obligation

(1) Based on this Act, an activity licence must be present for:
1) the procurement of cells, tissues and organs;
2) the handling of cells, tissues and organs.

(2) An activity licence for the provision of special medical care must also be issued on the basis of the Health Services Organisation Act to the person who simultaneously applies for an activity licence for the procurement and handling of cells, tissues and organs.

(3) An activity licence for the provision of special medical care must be issued on the basis of the Health Services Organisation Act to a health care provider for the transplantation of cells, tissues and organs. An activity licence for the provision of special medical care, with the appropriate secondary condition, must be issued to a manager of regional hospital who transplants organs.

(4) An activity licence grants the right to commence and perform economic activities in the place of business specified in the activity licence.

(5) Activity licences for the procurement and handling of cells, tissues and organs shall be registered in the register of activity licences of the State Agency of Medicines on the basis of subsection 1 of § 39 of the Medicinal Products Act.

(6) The State Agency of Medicines shall enter the data on the activity licence for the procurement or handling of cells and tissues in the EU Tissue Establishments Registry founded by the European Commission where all the activity licences issued by the EU Member States for the handling and procurement of cells and tissues are entered. The State Agency of Medicines shall also enter in the EU Tissue Establishments Registry the data specified in the 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), and in Annex VIII to the Commission Directive (EU) 2015/565 amending directive 2006/86/EC as regards certain technical requirements for the coding of human cells and tissues (OJT L 93, 09.04.2015, p 43–55), and in case of changes in the data, shall update the data according to Article 10b (2) d–f of Directive (EU) 2015/565 amending directive 2006/86/EC as regards certain technical requirements for the coding of human cells and tissues (OJ L 93, 09.04.2015, p 43–55) without undue delay but not later than after ten working days.
[RT I, 09.03.2017, 1 – entry into force 19.03.2017, implemented since 29 April 2017]

(7) A unique identification number shall be given in the EU Tissue Establishments Registry to the holder of an activity licence for the handling or procurement of cells and tissues. The State Agency of Medicines shall enter the unique identification number in the register of activity licences of the State Agency of Medicines.
[RT I, 09.03.2017, 1 – entry into force. 19.03.2017, implemented since 29 April 2017]

(8) If the holder of an activity licence for the procurement or handling of cells and tissues wishes to import cells and tissues from a third country outside the European Union or the European Economic Area, the data and documents, the composition and format of which has been provided for in the rules for the procurement and handling of cells, tissues and organs established under subsection 3 of § 22 of this Act, shall be submitted additionally upon application for an import certificate.
[RT I, 09.03.2017, 1 – entry into force 19.03.2017, implemented since 29 April 2017]

§ 27. Application for activity licence

(1) The State Agency of Medicines shall decide the issue or refusal to issue an activity licence for the procurement of cells, tissues and organs or for the handling of cells, tissues and organs (hereinafter the activity licence) within 60 days after the submission of an application.

(2) In addition to the data provided for in the General Part of the Economic Activities Code Act, an application for activity licence shall set out the following data and documents:
1) documents certifying the right of use of the facilities;
2) layout and description of facilities of the place of business;
3) organisation chart reflecting the composition and structure of the staff;
4) in case a quality manager is present, his or her name, personal identification code, a copy of a document certifying qualification, a copy of an identity document and, if necessary, a copy of a document certifying a change of name and data on professional work experience and training;
5) movement plans of the staff and materials;

6) the procedure for cleaning, maintenance and sterilisation of the facilities and equipment;
7) description of the procedure for the procurement of cells, tissues and organs, including the procedure for the selection of donors and the laboratory testing carried out on donors;
8) the list of third parties performing contract works and the description of the content of contract works;
9) contract entered into with a laboratory accredited by an international accreditation institution in which necessary laboratory testing is carried out on a living donor to ascertain tissue compatibility;
10) description of the biovigilance system;
11) description of the organisation of waste management.

(3) In addition to the data provided for in the General Part of the Economic Activities Code Act and the provisions of subsection 2 of this section, an application for activity licence for the handling of cells, tissues and organs shall separately set out the following data and documents for each type of cell, tissue or organ:
1) description of the handler's quality system;
2) description of the handler's document management system;
3) the name of the competent person of the handler, his or her personal identification code, a copy of a document certifying qualification, a copy of an identity document and a copy of a document certifying change of name, if necessary, data on professional work experience and training and the areas of responsibility and the procedure for substitution;
4) simplified plan and description of the ventilation system of the handling facilities and types of filters;
5) simplified plan and description of the water system of the handling facilities and quality classes of water;
6) the list of equipment used in the handling process and quality control and the purpose of each equipment;
7) the plan and short description of the procurement and handling procedure;
8) the description of critical equipment and materials used upon handling;
9) description of the procedure for the release of cells, tissues and organs;
10) critical quality requirements for the cells, tissues and organs to be procured and handled;
11) a copy of radiation practice licence if radiation is involved in handling.

(4) In addition to the data provided for in the General Part of the Economic Activities Code Act and the provisions of subsection 2 of this section, an application for the activity licence for the procurement of cells, tissues and organs shall set out the name of the person responsible for procurement, his or her personal identification code, a copy of a document certifying qualification, a copy of an identity document and a copy of a document certifying change of name, if necessary, data on professional work experience and training and the areas of responsibility and the procedure for substitution.

§ 28. Subject of review of activity licence

An activity licence shall be granted if the applicant complies with the requirements provided for in this Act and the legislation established on the basis thereof and other legislation regulating the procurement, handling and transplantation of cells, tissues and organs.

§ 29. Secondary conditions of activity licence

The following secondary conditions may be added to an activity licence:
1) particular type of cell, tissue or organ allowed upon procurement or handling;
2) particular type of handling operation allowed upon handling;
3) additional requirements for the measures applied upon procurement or handling;
4) additional requirements for the health protection measures applied upon commencement and termination of activities.

§ 30. Specifications for revocation of activity licence

Upon revocation of an activity licence in part or in full or upon prohibition of economic activities, the State Agency of Medicines may set a term and conditions for the holder of an activity licence for the sale or destruction of the procured and handled materials and submission of reports.

Chapter 5
ORGAN TRANSPLANT WAITING LIST

§ 31. Obligations of manager of organ transplant waiting list

(1) For the purpose of this Act, an organ transplant waiting list (hereinafter the waiting list) means a list of persons, accompanied by their health data, who are waiting for an organ transplantation due to medical indications. The waiting list is maintained nationally by organs to be transplanted.

(2) The waiting list manager is the transplantation centre.
[RT I, 28.12.2017, 4 – entry into force 01.01.2020]

(3) The waiting list manager shall establish the conditions of and procedure for the registration of persons on the waiting list based on the medical indications pursuant to the provisions of § 32 of this Act.

(4) The waiting list manager shall ensure that the persons registered on the waiting list comply with the conditions for registration on the waiting list specified in subsection 3 of this section.

(5) The waiting list manager shall publish on its website each year by 1 April the unpersonified statistical data for the previous calendar year concerning the maintenance of the waiting list.

§ 32. Registration on and removal from waiting list

(1) Estonian citizens residing in Estonia or foreigners residing in Estonia holding a residence permit of a long-term resident or citizens of the European Union holding a permanent right of residence may be registered on the waiting list.

(2) Citizens of another EU Member State, a country of the European Economic Area or a third country or persons without citizenship may also be registered on the waiting list on the condition that the waiting list manager shall be submitted a guarantee concerning the financing of the organ transplantation and a written confirmation by the person, bearing his or her handwritten signature, on the fact that he or she has not been registered on the organ transplant waiting list of another state. If a person is registered on the organ transplant waiting list of another state, he or she shall be required to notify the waiting list manager thereof immediately in writing.

(3) In case of recipients with similar compatibility for organ transplantation, the organ shall be transplanted:
1) as the first preference to the person specified in subsection 1 of this section who has been registered on the waiting list;
2) as the second preference to a citizen of another EU Member State or a country of the European Economic Area who has been registered on the waiting list;
3) as the third preference to a citizen of a third country or to a person without citizenship who has been registered on the waiting list.

(4) The equal treatment of persons must be ensured upon the registration of persons on the waiting list and the discrimination due to ethnical, religious, moral or other non-medical reasons is not allowed.

(5) A person may be registered on the waiting list of one waiting list manager only.

(6) The registration of a person on the waiting list and removal from the waiting list shall be decided by the waiting list manager based on the medical reasons on the proposal of the transplantation centre.

(7) The waiting list manager shall be required to notify a person, in a format which can be reproduced in writing, of the registration of the person on the waiting list and removal from the waiting list, except in case of death of the person registered on the waiting list.

Chapter 6
TRACEABILITY OF CELLS, TISSUES AND ORGANS AND BIOVIGILANCE

§ 33. Traceability of cells, tissues and organs

(1) Traceability means the possibility to identify cells, tissues and organs and to ascertain the location thereof during any step of the process from the procurement of cells, tissues and organs to distribution to the transplanter, manufacturer of advanced therapy medicinal products or holder of hospital-exemption authorisation or disposal thereof, including the possibility to ascertain the donor and the handler receiving, handling or storing the cells, tissues and organs or another agency, also the possibility to ascertain to whom the transplanter has transplanted the cells, tissues and organs. Traceability also covers the possibility to ascertain all the relevant information relating to the products, equipment, employees and materials which come into contact with the cells, tissues and organs.
[RT I, 03.01.2022, 2 – entry into force 13.01.2022]

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

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

(4) The requirements for the transmission of information between the procurer, handler, transplanter, transplantation centre and State Agency of Medicines in order to ensure the traceability of cells, tissues and organs shall be provided for in the rules for the procurement and handling of cells, tissues and organs established under subsection 3 of § 22 of this Act.
[RT I, 28.12.2017, 4 – entry into force 01.01.2020]

§ 34. Subsequent observation of living organ donors

(1) In order to maintain the health of a living organ donor at the best possible level and to ensure the quality of handling of the donated organ, the transplantation centre shall organise the observation of the state of health of a living organ donor until the end of his or her life.
[RT I, 28.12.2017, 4 – entry into force 01.01.2020]

(2) The national transplantation agency which has the duty to maintain confidentiality arising from the law shall have the right to process the personal data of a living organ donor in order to observe his or her state of health, including personal data of special categories and, if necessary, to make inquiries therefor to the appropriate state registers and databases.
[RT I, 13.03.2019, 2 – entry into force 15.03.2019]

§ 35. 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) For the purposes of this Act, a serious adverse reaction means an unintended response in the living donor or in the recipient which may be associated with any step of the process from the removal of cells, tissues or organs to the transplantation and which is fatal, life-threatening, disabling or incapacitating or which results in, or prolongs, hospitalisation or morbidity.

(3) For the purposes of this Act, a serious adverse event means an unwanted and unexpected event associated with any step of the process from the removal of cells, tissues or organs to the transplantation and which may lead to the transmission of infectious agents of communicable diseases, to death, be life-threatening for living donors or recipients, cause disability or incapacity or which may result in, or prolong, hospitalisation or morbidity.

(4) In the case of procurement and handling of gametes and embryos, a serious adverse event shall be deemed to be, in addition to the previous, an unwanted and unexpected event associated with any step of the process from the removal of gametes to the transplantation, the consequence of which is the formation of an unsuitable embryo, loss of biological material or transplantation thereof into a person not intended therefor and if the child born as a result of application of the gametes or embryo of a donor suffers from a serious or life-threatening genetic disease.

(5) The transplanter shall without undue delay notify the procurer or handler which issued to the transplanter the cells, tissues and organs transplanted into the recipient of any occurred serious adverse event or reaction.

(6) The procurer or handler shall without undue delay notify the State Agency of Medicines and the transplantation centre of serious adverse events and serious adverse reactions which have become evident upon the handling of cells, tissues and organs or after the handling.
[RT I, 28.12.2017, 4 – entry into force 01.01.2020]

(7) The procurers and handlers of cells, tissues and organs must have procedures prepared and in place which enable to assess the need to withdraw cells, tissues and organs immediately after a serious adverse event or reaction has been ascertained and, if possible, to withdraw the cells, tissues or organs.

(8) 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 provided for in the rules for the procurement and handling of cells, tissues and organs established under subsection 3 of § 22 of this Act.

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

Chapter 7
INTERNATIONAL EXCHANGE OF CELLS, TISSUES AND ORGANS

§ 36. Use of organ removed from donor in international exchange

[RT I, 09.03.2017, 1 – entry into force 19.03.2017]

The transplantation centre may enter into agreements for the exchange of organs removed from donors with the organ exchange organisations of the European Economic Area or third countries on the condition that it is possible to trace the organs intended for transplantation from the donor to the recipient and vice versa and that the organs comply with the quality requirements provided for in the rules of procurement and handling of cells, tissues and organs established under subsection 3 of § 22 of this Act.
[RT I, 28.12.2017, 4 – entry into force 01.01.2020]

§ 37. Maintenance of organ transplant waiting list upon joining international organ exchange organisation

(1) The persons registered on the national waiting list may be registered on the organ transplant waiting list maintained by the international organ exchange organisation according to the contract entered into with the international organ exchange organisation.

(2) If the waiting list is maintained by the international organ exchange organisation, the procedure for transmission of information related to the maintenance of the waiting list shall be provided for in the contract.

§ 38. Import and export of cells, tissues and organs

(1) The import and export of cells, tissues and organs shall take place on the conditions and pursuant to the procedure provided for in the Medicinal Products Act.

(1^1) The import of cells and tissues from third countries outside the European Union and the European Economic Area is only allowed based on the import certificate issued by the State Agency of Medicines. The list of documents, composition of data and format of documents necessary for the application for an import certificate, have been provided for in the rules for the procurement and handling of cells, tissues and organs established under subsection 3 of § 22 of this Act.
[RT I, 09.03.2017, 1 – entry into force 19.03.2017, implemented since 29 April 2017]

(1^2) In case of changes or a request to make changes in the data and documents forming the basis of the import certificate issued to the procurer or handler of cells and tissues, an application for the issue of a new certificate must be submitted, except in the cases provided for in subsection $1^3$of this section.
[RT I, 09.03.2017, 1 – entry into force 19.03.2017, implemented since 29 April 2017]

(1^3) The requirements of the import certificate may be deviated from if:
1) there is no other possibility to quickly import cells and tissues which are used immediately for a known recipient whose health would be in threat without such import;
2) specific type of cells or tissues are imported which are intended for the individual use of the handler or procurer and for a third country supplier outside the European Union and the European Economic Area for a recipient which was known before the import.
[RT I, 09.03.2017, 1 – entry into force 19.03.2017, implemented since 29 April 2017]

(1^4) In the cases specified in subsection $1^3$of this section specific type of cells and tissues are imported from third countries outside the European Union and the European Economic Area for the same recipient usually only once. Regular or recurrent import from a third country supplier is not deemed to be single import.
[RT I, 09.03.2017, 1 – entry into force 19.03.2017, implemented since 29 April 2017]

(1^5) The State Agency of Medicines shall issue the import certificate within 30 days after the submission of all the required data and documents.
[RT I, 09.03.2017, 1 – entry into force 19.03.2017, implemented since 29 April 2017]

(1^6) Upon exercising supervision, the State Agency of Medicines shall have the right to suspend the validity of an import certificate with an administrative act until compliance with the precept.
[RT I, 09.03.2017, 1 – entry into force 19.03.2017, implemented since 29 April 2017]

(1^7) The State Agency of Medicines shall revoke an import certificate if:
1) the holder of an activity licence has submitted an application for the revocation of certificate;
2) the validity of an import certificate of the holder of an activity licence has been suspended and the precept issued by the State Agency of Medicines has not been complied with regardless of the imposition of a coercive measure;
3) the activity licence expires.
[RT I, 09.03.2017, 1 – entry into force 19.03.2017, implemented since 29 April 2017]

(2) The handlers shall ensure the compliance of cells, tissues and organs to be imported and exported with the quality requirements provided for in the rules for procurement and handling of cells, tissues and organs established under subsection 3 of § 22 of this Act.

Chapter 8

FINANCING

§ 39. Financing of procurement, handling and transplantation of cells, tissues and organs

The procurement, handling and transplantation of cells, tissues and organs shall be financed by the recipient unless the payment obligation for health services is assumed by the Estonian Health Insurance Fund.
[RT I, 11.03.2023, 9 – entry into force 01.04.2023]

§ 40. Compensation of expenses by Estonian Health Insurance Fund
[RT I, 11.03.2023, 9 – entry into force 01.04.2023]

(1) The Estonian Health Insurance Fund shall assume the obligation to pay a fee to the health care provider for the procurement and handling of cells, tissues and organs in the extent provided for in the Health Insurance Act if the donor and potential deceased donor is an insured person for the purposes of § 5 of the Health Insurance Act.
[RT I, 11.03.2023, 9 – entry into force 01.04.2023]

(2) The Estonian Health Insurance Fund shall assume the obligation to pay a fee to the health care provider for the transplantation of cells, tissues and organs in the extent provided for in the Health Insurance Act if the recipient is an insured person for the purposes of § 5 of the Health Insurance Act.
[RT I, 11.03.2023, 9 – entry into force 01.04.2023]

(3) Performance of functions of a national transplantation agency specified in subsection 2 of § 7 of this Act shall be financed from the budget of the Estonian Health Insurance Fund.
[RT I, 11.03.2023, 9 – entry into force 01.04.2023]

(4) Performance of functions of transplantation centre specified in subsection 1^1 of § 8 of this Act shall be financed from the budget of the Estonian Health Insurance Fund pursuant to the procedure provided for in the Health Insurance Act.
[RT I, 11.03.2023, 9 – entry into force 01.04.2023]

§ 41. Compensation of expenses of health services of persons not covered by health insurance
[RT I, 21.12.2018, 1 – entry into force 01.01.2020]

(1) The expenses of health services provided to a living donor not covered by health insurance which are connected with the procurement and handling of cells, tissues and organs and treatment due to a state of health having occurred after removal of an organ shall be paid for from the budget of the Estonian Health Insurance Fund on the bases, conditions and pursuant to the procedure provided for in the list of health services of the Estonian Health Insurance Fund.
[RT I, 11.03.2023, 9 – entry into force 01.04.2023]

(2) The expenses of health services provided to a deceased donor and potential deceased donor not covered by health insurance which are connected with the procurement and handling of cells, tissues and organs shall be paid for from the budget of the Estonian Health Insurance Fund on the bases, conditions and pursuant to the procedure provided for in the list of health services of the Estonian Health Insurance Fund.
[RT I, 11.03.2023, 9 – entry into force 01.04.2023]

(3) [Repealed – RT I, 28.12.2017, 4 – entry into force 01.01.2020]

Chapter 9
STATE SUPERVISION

§ 42. State supervision

(1) State supervision over compliance with this Act and the requirements of legislation established on the basis thereof shall be exercised by the State Agency of Medicines and the Health Board.

(2) The State Agency of Medicines exercises supervision over compliance with the requirements for the procurement and handling of cells, tissues and organs provided for in this Act and legislation established on the basis thereof, including supervision over the quality and safety requirements of cells, tissues and organs.

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

(4) State supervision shall be exercised at least once in every two years.

(5) The State Agency of Medicines may inspect a third state supplier outside the European Union and the European Economic Area in connection with the importing activity of a holder of an activity licence for the handling and procurement of cells and tissues in Estonia in case of suspicion that the aforesaid supplier does not comply with the requirements established under this Act. An inspection can also be commenced upon the request of a Member State, European Commission, European Council or the European Medicines Agency.
[RT I, 09.03.2017, 1 – entry into force 19.03.2017]

§ 43. Special state supervision measures

For the execution of state supervision provided for in this Act, the law enforcement agency may apply the special state supervision measures provided for in §§ 30, 31, 32, 50, 51 and 52 of the Law Enforcement Act on the basis of and pursuant to the procedure provided for in the Law Enforcement Act.

§ 44. Limit of non-compliance levy

In the event of failure to comply with a precept, the upper limit of non-compliance levy imposed pursuant to the procedure provided for in the Substitutional Performance and Non-Compliance Levies Act shall be 9600 euros.
[RT I, 09.03.2017, 1 – entry into force 19.03.2017]

Chapter 10
REPORTING OBLIGATION

§ 45. 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 state supervision by 1 April 2016 and after that, once in every three years by the same term.

(2) If the State Agency of Medicines is notified of a serious adverse event or serious adverse reaction related with a donor whose organ was sent to another country of the European Economic Area or to a third country, the State Agency of Medicines shall immediately notify the competent authority of the relevant country thereof and shall, within three months as of the submission of the initial report, submit a report thereto which contains the data provided for in the rules for procurement and handling of cells, tissues and organs established under subsection 3 of § 22 of this Act.

(3) The transplantation centre shall submit to the European Commission a report regarding the activities related to the transplantation of organs and the acquired experiences by 1 August 2016 and after that, once in every three years by the same term.
[RT I, 28.12.2017, 4 – entry into force 01.01.2020]

Chapter 11
LIABILITY

§ 46. 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.

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

(1) Violation of the requirements for the procurement and 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 32 000 euros.
[RT I, 09.03.2017, 1 – entry into force 19.03.2017]

§ 48. Violation of requirements for transplantation of cells, tissues and organs

(1) Violation of the requirements for the transplantation 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 32 000 euros.
[RT I, 09.03.2017, 1 – entry into force 19.03.2017]

§ 49. Procedure

(1) [Repealed – RT I, 09.03.2017, 1 – entry into force 19.03.2017]

(2) Extra-judicial proceedings concerning the misdemeanour provided for in § 46 of this Act shall be conducted by the Police and Border Guard Board.
[RT I, 09.03.2017, 1 – entry into force 19.03.2017]

(3) Extra-judicial proceedings concerning the misdemeanour provided for in § 47 of this Act shall be conducted by the State Agency of Medicines.

(4) Extra-judicial proceedings concerning the misdemeanour provided for in § 48 of this Act shall be conducted by the Health Board.

Chapter 12
IMPLEMENTING PROVISIONS

§ 50. Implementation of activity licence obligation

(1) Activity licences issued for the handling, including procurement of cells, tissues and organs before the entry into force of this Act shall be valid.

(2) The procurers of cells, tissues and organs shall apply for an activity licence for the procurement of cells, tissues and organs no later than by 1 January 2016, except in the case provided for in subsection 1 of this section.

(3) Specialised medical care providers engaged in the transplantation of organs shall apply for an activity licence for the provision of specialised medical care no later than by 1 January 2016.

§ 50[1]. Implementation of subsections 6–8 of § 26 and subsections 1[1]–1[7] of § 38 of this Act

(1) The requirements established in subsections 6–8 of § 26 and subsections 1[1]–1[7] of § 38 shall be implemented since 29 April 2017.

(2) The holders of an activity licence for the handling or procurement of cells and tissues who import cells and tissues from third countries outside the European Union and the European Economic Area and to whom a respective activity licence has been issued before the implementation of subsection 1[1] of § 38 of this Act, shall submit an application with the data and documents necessary for the issue of an import certificate no later than by the term specified in subsection 1 of this section.
[RT I, 09.03.2017, 1 – entry into force 19.03.2017]

§ 51. - § 52. The amendment provisions of other Acts omitted from this translation.

§ 53. Repeal of Handling and Transplantation of Cells, Tissues and Organs Act

The Handling and Transplantation of Cells, Tissues and Organs Act shall be repealed.

§ 54. - § 59. The amendment provisions of other Acts omitted from this translation.

§ 60. Entry into force of Act

This Act enters into force on 1 March 2015.

[1]Directive 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) amended with Commission Directive 2012/39/EU amending Directive 2006/17/EC as regards certain technical requirements for the testing of human cells and tissues (OJ L 327, 27.11.2012, p 24–25); 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) amended with Commission Directive (EU) 2015/565 amending Directive 2006/86/EC as regards certain technical requirements for the coding of human tissues and cells (OJ L 93, 09.04.2015, p 43–55); Directive 2010/53/EU of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation (OJ L 207, 06.08.2010, p. 14–29); Commission implementing directive 2012/25/EU laying down information procedures for the exchange, between Member States, of human organs intended for transplantation (OJ L 275, 10.10.2012, p. 27–32); Commission Directive (EU) 2015/566 implementing

Directive 2004/23/EC as regards the procedures for verifying the equivalent standards of quality and safety of imported tissues and cells (OJ L 93, 09.04.2015, p 56–68). [RT I, 09.03.2017, 1 – entry into force 19.03.2017]