Official Journal of the European Communities 2005 No 169 item 1411

LAW of 1 July 2005

Removal, storage and transplantation of cells, tissues and organs [1)]

Based on OJ EU of 2020, item 2134

Chapter 1

Article 1.1. The law sets the rules for:

1) the removal, storage, transplantation and human use of cells, including hematopoietic cells of the bone marrow, peripheral blood and umbilical cord blood, tissues and organs of a living donor or corpse.
2) the analysis, development and distribution of human cells and tissues.
3) the donation, removal, collection, testing and circulation of tissues intended for the manufacture of advanced therapy medicinal products as proposed under the ordinance (EC) No 1394/2007 of the European Parliament and of the Council of the European Union of 13 November 2007 on advanced therapy medicinal products, changing the Directive 2001/83/EC and 726/2004. (OJ L 324, 10.12.2007, p. 121, as amended 2[)]).

[1)] This law implements the provisions of the following European Union directives:

1) Directive 2004/23/EC of the European Parliament and of the Council of the European Union of 31 March 2004 on the establishment of quality and safety standards for the donation, removal, testing, processing, storage, and distribution of human tissues and cells (OJ L 102, 07.04.2004, p. 48, OJ L 188, 18.07.2009, p. 14 and OJ L 7, 13.01.2015, p. 5/2) – OJ EU Polish Special Edition, Ch. 15, Volume 8, p. 291);

2) Commission Directive (EU) 2015/565 of 8 April 2015 amending Directive 2006/86/EC as regards certain technical requirements for the coding of human tissues and cells (OJ EU L 93, 09.04.2015, p. 43);

3) Commission Directive (EU) 2015/566 of 8 April 2015 on the implementation of 2004/23/EC as regards the procedures to verify the equivalent quality and safety standards of imported tissues and cells (OJ EU L 93, 09.04.2015, p. 56).

[2)] The amendments to this ordinance were published in OJ EU L 87, 31.03.2009, p. 174 and OJ EU L 348, 31.12.2010, p. 1.

2. The provisions of the Act shall not apply to:

1) the removal, transplantation of reproductive cells, gonads, embryonic tissues and reproductive organs or parts thereof.
2) the removal, storage and distribution of blood for the purpose of transfusion, separation of its components or transformation into medicinal products.
3) the autologous removal and transplantation and autologous removal of cells and tissues during the same surgical procedure, in which the cells and tissues taken are not processed, tested, sterilized or stored.

3. For permits, referred to in the law, in the context of unregulated matters, the provisions of the Code of Administrative Procedure shall apply

Article 2. 1. The terms used in the law mean:

[1)] assignment – selection of the transplant receiver from the national list of people waiting for transplantation;

[2)] donation authorization – to obtain legal consent for the collection of donor cells, tissues and organs;

[3)] institute of tissues and cells - organizational unit operating in the removal, processing, sterilization, storage, distribution, circulation, importation, exportation of tissues and cells or import activities of tissues and cells; that institute may also procure or test tissues and cells after meeting the requirements of the law;

4) a tissue and cell institution engaged in import activities – an institute of tissues and cells which is also part of the contract with a supplier from a third country, referred to in Article 31a, concluded for the purpose of bringing tissues or cells originating in a third country and intended for use for transplantation or human use;

5) transplant receiver - a person to whom cells, tissues or organs have been transplanted, or a person to whom tissues or cells have been applied;
6) the expiration date of tissues or cells - the date by which tissues, or cells can be transplanted or used in humans;
7) donor – living donor, human corpse or any other living or deceased person from which cells, tissues or organs are taken;
8) donation - donation of cells, tissues or organs intended for transplantation or use in human beings;
9) placing into circulation – transfer of tissues or cells to another body for further processing, storage or sterilization;
10) supplier of a country and third countries – a tissue and cell institute or another entity established in a third country, from which the institution which manages the import activity of the Republic of Poland imports tissues or cells;
11) distribution – transport and delivery of tissues, cells or organs intended for transplantation or human use;
12) import activity – the import activity of an institution of tissues and cells intended for transplantation or human use in the territory of the Republic of Poland by a third-country supplier based on a license referred to in Article 26, paragraph 2;
13) final label - the label affixed by a tissue and cell institute to a container that comes into direct contact with tissues or cells, distributed or placed in circulation, which includes at least the marking of the donation identification sequence;
14) Code of the Europe Institute of tissues and cells - a unique identifier for tissue and cell institutions in the Member States of the European Union, accredited, appointed, authorized or licensed, consisting of the ISO code of the country concerned and the number of the institute of tissues and cells as defined in the European compendium of tissue and cell institutes;
15) European compendium of tissue and cell institutes – a register of all tissue and cell institutions which have been accredited, appointed, authorized by the competent authority of a Member State of the European Union, containing information on these tissue and cell institutions;
16) European compendium of processed tissues and cells – a register of all types of tissues and cells authorized in the Member States of the European Union and their codes for tissues and cells within coding systems (EUTC, ISBT 128 and Eurocode);
17) storage – reception of tissues and cells for processing, sterilization, storage, distribution or circulation purposes;
18) adverse serious event – an unforeseen event relating to the removal, processing, analysis, storage, distribution, circulation, import, transplantation of cells, tissues or organs or the human use of cells or tissues which may lead to the transmission of an infectious disease, which may cause

deterioration of health conditions, the need or prolongation of hospital stay, personal physical injury, disability, inability for work, danger of life or death;

19) severe adverse reaction – an unforeseen reaction in the donor or receiver's body, the collection, processing, testing, storage, distribution, circulation, import, export, transplantation of cells, tissues or organs or the use in human of cells or tissues, which involves the transmission of an infectious disease which causes deterioration of health, the need or prolongation of hospital stay, body injury, inability for work, danger of life or death;
20) Single European Code – unique identifier used for tissues and cells distributed within the Member States of the European Union, consisting of a sequence of identification of donations and identification sequences of tissues and cells; for the distribution of tissues or cells in the Member States of the European Union, it's used the abbreviation "SEC';
21) Single import – the single introduction of certain tissues or cells into the territory of the Republic of Poland for transplantation or use in the intended receiver, carried out by a tissue and cell institute, coming from a supplier from third countries;
22) tissue and cell code – identifier for a specific type of tissue or cell consisting of an identifier of the tissue and cell coding system indicating the coding system used by the institute of tissues and cells ("E" for EUTC, "A" for ISBT 128, "B" for Eurocode) and number of tissue and cells expected for a certain type of tissue or cell in a given coding system;
23) cell – a single cell or group of cells unrelated to each other with intercellular substance;
24) storage – the use of chemical reagents, the alteration of environmental conditions or other measures taken during the process in order to prevent or delay the degradation of cells, tissues or organs;
25) coordination of sampling, transplantation or supply and human use - provisions for the organization, supervision and documentation of donor identification and qualification processes, authorization to removal, conservation, assignment, distribution and transplantation of cells, tissues and organs or the human use of cells or tissues, including the method of transferring, transporting and receiving cells, tissues or organs in a health care unit as defined in Article 4 of the Law of 15 April 2011 on medical activities (Official Journal of 2020, Articles 295, 567 and 1493) or institutes of tissues and cells and their delivery to the receiver;
26) coordinator of removal, transplant or removal and human use- authorized and trained person which organize the coordination of removal and transplantation or coordination of removal and human use;
27) acceptance criteria – quantitative and qualitative limits adopted, their fields of application or other established indicators of controlled parameters, based on which it is decided to consider the effect of a given activity acceptable;

28) critical moment - a phase of the process with a potential impact on the quality and safety of cells, tissues or organs;
29) emergency - any unforeseen situation in which there is no solution other than the urgent importation of tissues or cells from a third country into the territory of the Republic of Poland for immediate transplantation or application into a known receiver whose health, in the event of non-compliance with such imports, would be seriously threatened;
30) organ – a distinct and essential part of the human body, constructed by various tissues, able to maintain its structure, blood supply and the possibility of performing autonomous physiological functions; an organ is also understood as part of an organ if it can be used in the human body for the same purpose as the entire organ;
31) unique donation number - single number of a specific donation of tissues and cells allocated according to the system for allocating these numbers in force in a Member State of the European Union;
32) division number – a number that uniquely distinguishes and identifies tissues and cells with the same donation number and the same code as the tissue and cell originating in the same tissue and cell establishment;
33) third countries - countries other than the Member States of the European Union;
34) removal – activities by which cells, tissues or organs are obtained for diagnostic, therapeutic, scientific or research purposes, educational activities;
35) storage – the maintenance of cells, tissues or organs under properly controlled conditions until transplantation or human use;
36) transplantation – a process aimed at restoring certain bodily functions by transferring a cell, tissue or organ from the donor to the receiving body;
37) treatment – all activities of preparation, storage and packaging of tissues or cells intended for use in transplantation or human use;
38) imports – imports into the territory of the Republic of Poland of:
    a. organs intended for transplantation;
    b. tissues or cells originating in the Member States of the European Union for transplantation or human use;
    c. imported tissues or cells in the context of an emergency;
39) sequence of identification of donations - first part of the Single European Code consisting of a European code for tissue and cell institutes and a single donation number;
40) tissue and cell identification sequence – second part of the Single European Code consisting of a tissue and cell code, a division number and an expiration date of tissues or cells;

41) standard operating procedures – written instructions describing the conduct of specific processes, including the materials and methods used and the expected results of these processes.
42) sterilization – use of chemical reagents, biological agents and physical agents, in order to dispose of biological pathogens in cells and tissues.
43) EUTC coding system – tissue and cell coding system developed by the European Commission and consisting of a register of all types of cell tissues authorized in the Member States of the European Union and their respective tissue and cells and cell codes.
44) quality assurance system – the organizational structure, procedures, processes and resources that directly or indirectly influence the high quality of maintenance of cells, tissues or organs.
45) testing – carrying out tests to ensure the suitability of cells, tissues or organs for transplantation or cells or tissues for human use.
46) tissue - any component of the human body formed by cells.
47) validation of the process - a documented action to demonstrate that a process carried out within the established range of parameters works effectively, can be repeated and meets the established acceptance criteria.
48) foreign removal organization – an organization in which the removal of tissues or cells of a donor has been carried out, with its registered office outside the territory of the Republic of Poland.
49) intended receiver – a known potential receiver for which tissues or cells are intended, including from a third country.
50) human use – use of tissues or cells on the body or body of the receiver and extracorporeal use of tissues or cells.
51) allogenic use – use of tissues or cells taken from one person in another person.
52) autologous use – use of tissues or cells in the same person.
53) living donor - the person from whom cells, tissues or organs are collected.

2. Whenever the law refers to the Member States of the European Union, the Member States of the European Free Trade Association (EFTA) – party to the Agreement on the European Economic Area – shall also be included.

Article 3. 1. For the donation of cells, tissues or organs taken, a donor may not accept or may not be solicited at least a payment or any other pecuniary or personal benefit.

2. The cost of removing, storing, processing, sterilizing, distributing, transplanting cells, tissues or organs and human use of cells or tissues taken from the donor shall not constitute a payment and shall not constitute a financial or personal gain within the meaning of paragraph 1.

3. The costs of taking cells, tissues and organs shall include the costs of:

1) coordination of the removal.

2) medical examinations and opinions based on them.

3) identification of the potential donor.

4) qualification of potential donor.

5) finding of irreversible and permanent termination of brain function (cerebral death) or irreversible cardiac arrest prior to organ sampling, as defined in the Law of 5 December 1996 on the professions of doctor and dentist (Official Journal of 2020, Articles 514, 567, 1291 and 1493).

6) hospitalization of a potential donor, from the determination of an irreversible and permanent termination of brain function to the removal of organs, including activities consisting in supporting the functions of the organs.

7) laboratory tests before the removal of cells, tissues or organs.

8) tests to verify the organs suitable for transplantation, upon donation by the donor.

9) procedures for the collection of donations of cells or tissues.

10) tests to qualify cells or tissues suitable for transplantation or human use, after removal from a donor.

11) finding organs, considering the costs incurred by the health care provider when:

a. an organ or organs have been taken;

(b) an organ or organs taken have been transplanted.

4. For the collection of bone marrow, hematopoietic cells of peripheral blood and umbilical cord blood, in addition to the costs referred to in paragraph 3, points from 1) to 4), 7) and 9), the costs shall be included:

1) the transport of the potential donor to the health facility where the removal of bone marrow and hematopoietic cells of peripheral blood will be carried out, and the potential donor or donor of that health facility;
2) the permanence of the donor in a health facility for the collection of bone marrow and hematopoietic cells of peripheral blood;
3) the preservation and treatment of bone marrow, peripheral blood hematopoietic cells and umbilical cord;
4) the transport of the bone marrow taken and treated, blood cells and peripheral blood and umbilical cord blood to the health facility where the transplant will take place;

5) the costs incurred by the bone marrow donor center in relation to the supply of bone marrow, hematopoietic cells of peripheral blood and umbilical cord blood.

5. The costs of taking cells or tissues from human corpses, in addition to points 1 to 4, 7, 9 and 10 shall include the costs of:

1) transport of cells or tissues from a medical establishment or medical establishment in the department of pathological anatomy of a medical higher education institution and an entity in which scientific and training activities are carried out in the field of medical sciences, by a federation of providers of the higher education system involved in scientific activities in the field of medical sciences, by a research institute, referred to in Article 3 of the Law of 30 April 2010 on research institutes and centers (Official Journal of 2020, item 1383) and a funeral home enterprise and a room for autopsies of the tissue and cell institute.

2) human resources, materials and organizational resources necessary for the removal of cells or tissues;

3) testing, processing, storage, sterilization, storage and distribution of cells or tissues.

6. The costs of taking from a living donor of regenerating cells or tissues other than the marrow, hematopoietic cells of peripheral blood and umbilical cord blood, in addition to the costs referred to in paragraph 3, points from 1) to 4), 7) and 9), shall include the costs of:

1) the transport of the potential donor to the health facility where the removal will be carried out, or to the nursing institution where the transplant is to be carried out and a potential donor or donor of such entities;

2) the permanence of the potential donor in the medical facility relating to the removal;

3) the storage and processing of cells or tissues taken;

4) the transport from the medical structure of the cells or tissues taken from the institute of tissues and cells;

5) the culture of cells or tissues taken;

6) the transport of cells or tissues taken to a medical facility where the transplant is to be performed.

7. The costs of organ collection by a living donor, in addition to the costs specified in points 1 to 4, 7 and 11 of paragraph 3 shall include the costs of:

1) transport of a potential living donor to the health facility where the removal is to take place or to the health facility where the transplant is to be carried out and the potential living donor or living donor of such entities;

2) preparation of a potential living donor for removal;

3) transport of the collected organ to the health facility where the transplant will take place;

4) treatment of a living donor after organ removal surgery.

8. The cost of transplantation of organs, marrow, hematopoietic cells of peripheral blood and umbilical cord includes the costs for:

1) the coordination of transplantation;

2) the transport of the potential receiver to the health facility where the transplant is to be carried out;

3) the identification and qualification of the potential receiver for transplantation;

4) the operation of the transplant procedure;

5) post-transplant treatment, for a period to be determined by the provisions of publicly funded health services.

9. Reimbursement of the costs referred to in paragraph 3, points 6), 7) and 11), letter a) shall be reimbursed by the Transplantation Organization and Coordination Center "Poltransplant" or by the National Fund in accordance with the provisions on publicly funded health care benefits. The reimbursement is made based on an invoice issued by the health facility which made the removal of the body.

10. The costs referred to in paragraph 3, points 8) and 11) letter b) shall be reimbursed by the health facility to which the transplantation organ was delivered, based on an invoice issued by the health facility which took the organ.

11. Reimbursement of the costs referred to in point 9 of paragraph 3 and paragraphs 5 and 6 shall be reimbursed by the institution of tissues and cells on the basis of an invoice issued by the body referred to in Article 36, paragraph 1), points 1) and 3), which has received cells or tissues.

12. The health structure of the expenditure defined:

1. in paragraph 3, headings 1 to 5, it shall be carried out by the National Fund;

2. in paragraphs 4, 7 and 8, it shall be carried out by the National Fund or the Minister for Health – under a health contract concluded based on public-funded health care ordinance.

13. The expenditure referred to in paragraph 3, point 10) shall be the operating expenses of a tissue and cell institution.

14. The Minister of Health shall establish, by means of an ordinance, a detailed method for determining the costs of the activities of sampling, storage, treatment, sterilization and distribution of cells, tissues, taking into account the procedures necessary for carrying out such activities.

Chapter 2

Removal of cells, tissues or organs from human corpses

Article 4. 1. Cells, tissues and organs may be taken from human corpses after the determination of death as defined in the Law of 5 December 1996 on the professions of doctor and dentist for diagnostic, therapeutic, medical, scientific and educational activities.

2. Cells, tissues or organs of human corpses may also be taken during the autopsy carried out based on separate provisions.

Article 5. 1.The removal of cells, tissues or organs from human corpses by transplantation or removal of cells or tissues for human use may be carried out if the deceased has not objected during his life.

2. In the case of an underage person or other person who does not have full legal capacity, the objection may be raised by a legal representative during their life.

3. In the case of a child over the age of sixteen, the objection may also be expressed by the minor.

4. The provisions of paragraphs 1 to 3 shall not apply in the case of the removal of cells, tissues and organs in order to identify the cause of death during autopsy.

Article 6. 1. The objection shall be expressed in the form of:

1) inclusion in the central register of objections to the removal of cells, tissues and organs from human corpses;

2) a written declaration bearing an autograph signature;

3) an oral statement issued in the presence of at least two witnesses, confirmed by them in writing.

2. The provisions of paragraph 1 shall also apply to the objection expressed by the legal representation.

3. Opposition by a legal representative or a person referred to in Article 5, paragraph 3) shall influence the others.

4. The opposition may be withdrawn at any time on the forms referred to in paragraph 1

Article 7. 1. In order to register, store and share an entry referred to in Article 6, paragraph 1), point 1) and to request the deletion of the entry of objections, a central register of objections to the collection of cells, tissues and organs known as the 'central register of objections' shall be established.

2. The entry or cancellation of an objection in the central register of objections shall be notified immediately by registered mail to the person to whom it relates or to that person's legal representative.

3. The central register of objections shall contain the following details of the person registered:

1) first and last name;

2) date and place of birth;

3) social security number, if any;

4) address and place of residence;

5) the date and place where the objection or removal was drawn up;

6) the date on which the objection was received or the date on which the application for cancellation of the objection was received.

4. In the case referred to in Article 5, paragraph 2), the central register of objections shall also include the data referred to in paragraphs 3, points from 1) to 3) relating to the legal representative.

5. The data referred to in paragraphs 3 and 4 shall be kept for a period of 5 years, from the date of the death of the person concerned and, after the date of its expiry, it shall be destroyed in such a way as to make it impossible to identify that person.

6. Information on the possible registration of a person's activity in the central register of objections shall be provided as soon as a doctor or person authorized by them requests it with the intention of removal.

7. The central register of objections shall be kept by the Transplantation Organization and Coordination Center "Poltransplant".

7a. The Transplantation Organization and Coordination Center "Poltransplant" makes the data contained in the central register of objections available to the health information system referred to in the Law of 28 April 2011 on the Health Information System (Official Journal of 2020, item 702, 1493 and 1875).

8. The Minister for Health, in agreement with the Minister of Justice, shall, by means of an order, keep the central register of objections and the procedures for entry in that register, taking into account the possibility of keeping that register in electronic form.

Article 8. 1. If there is a reasonable suspicion that the death occurred as a result of a crime, the removal of cells, tissues and organs may be carried out after the competent public prosecutor has indicated that they do not object to the intention to remove cells, tissues and organs and, where proceedings are conducted against a minor – the position of the family court shall be required.

2. The Minister of Justice, in agreement with the Minister for Health, shall determine, by means of an order, the manner and procedures by which the information or positions referred to in paragraph 1 are obtained, taking into account in particular the need to take evidence and how to deal with urgent cases.

Article 9. 1. (repealed)

2. (repealed)

3. (repealed)

4. (repealed)

5. (repealed)

6. During procedures related to cell collection and transplantation, the tissues or organs of a deceased person may not be attended by the doctors referred to in Article 10, paragraph 1) a) and b) of Directive 91/414/EEC; Article 43a (5) of the Law of 5 December 1996 on the professions of doctor and dentist, which led to a permanent irreversible cessation of brain activity (brain death).

Article 9a, 1. (repealed)

2. During proceedings relating to the collection and transplantation of cells, tissues or organs of a deceased person, the doctors referred to in Article 10, paragraph 1) a) and b) of Directive 91/414/EEC; Article 43a (6) of the Law of 5 December 1996 on the professions of doctor and dentist, which resulted in an irreversible cardiac arrest in that person before organ donation, may not be present.

3. (repealed)

Article 9b. During the procedures relating to the removal and transplantation of cells, tissues or organs of a deceased person, the doctor who declared that person's death shall not be present.

Article 10. Before the removal of cells, tissues or organs from a deceased person, a doctor or a person authorized by them must

1) verify the existence of an objection expressed in the form referred to in Article 6, paragraph 1), point 1).

2) determine the existence of an objection expressed in the form referred to in Article 6, paragraph 1) points 1), 2) and 3) based on the information or documents available.

Article 11. The doctor who removes cells, tissues or organs from human cadavers shall ensure that the cadaver is given a suitable appearance.

Chapter 3

Removal of cells, tissues or organs from living donors

Article 12. 1. Cells, tissues or organs for transplantation or cells, tissues or organs for use in another person may be taken from a living donor, under the following conditions:

1) the removal shall be for the benefit of a relative in a direct line, a sibling, an adopted person or spouse and, except for Article 13, to another person, where special personal reasons so justify;

2) regarding the removal of bone marrow or other regenerating cells or tissues, sampling may be carried out or even for the benefit of a person other than that and mentioned in point 1;

3) the suitability for the removal and transplantation of cells, tissues or organs or the human use of cells or tissues from a specific donor shall be determined by doctors who take and transplant them or use them in a known receiver on the basis of the current state of medical knowledge;

4) the removal shall be preceded by the necessary medical examinations to determine whether the risk of surgery does not exceed the limits laid down and accepted for this type of treatment and will not significantly compromise the health of the donor;

5) the donor candidate shall be informed in detail, before giving his written consent, of the nature of the operation, of the risks associated with this procedure and of the foreseeable consequences for his health by the doctor performing the procedure and by another doctor who is not directly involved in the collection and transplantation of cells, tissues or organs or in the use of cells or tissues in humans;

6) a pregnant woman may be applied only for the donation of cells and tissues; the risks referred to in points 4 and 5 are determined again for the child, with the participation of a gynecologist, obstetrician and a neonatologist;

7) the donor candidate has full legal capacity and has voluntarily given the doctor written informed consent to the removal of cells, tissues or organs for transplantation or cells or tissues for transplantation into a known receiver; the obligation to determine the receiver of the transplant refers to the removal of the bone marrow or other regenerating cells and tissues;

8) the donor candidate was notified before giving their consent of the consequences for the receiver of the removal of cells, tissues or organs associated with the last stage of the receiver's preparation for transplantation or human use;

9) the receiving candidate was informed of the risks associated with the removal of cells, tissues or organs and the possible consequences for the donor's state of health, and agreed to accept the cells, tissues or organ of that donor; the obligation to consent to transplantation from a particular donor does not apply to the marrow or other regenerating cells and tissues.

2. In the event of imminent danger of loss of life, and this danger can only be avoided by carrying out a bone marrow transplant or hematopoietic cells of peripheral blood, the donor could even be a minor if this does not result in a predictable impairment for the donor organism.

3. The removal of the bone marrow or hematopoietic cells of peripheral blood in a minor who does not have full legal capacity may be carried out with the consent of the legal representative after obtaining the consent of the court of the competent protection court at the place of residence of the donor candidate. If the bone marrow donor is a minor but over the age of thirteen, his consent is also required.

4. At the request of the legal representatives of the donor candidate, the court shall listen to the minor and consult an experienced psychologist and, in the case of a child over the age of sixteen, also at his request. The application shall be accompanied by a medical certificate certifying that the removal of the marrow shall not lead to any foreseeable compromise of the donor organism.

5. The application referred to in paragraph 4 shall be examined within 7 days.

6. The Minister of Health shall establish, by means of an ordinance, the health requirements to be met by the donor candidate, the list of medical examinations and diagnostic tests to which the candidate should be subjected for the donation of cells, tissues or organs, and contraindications to the donation of tissues or organs, taking into account the state of health of the living donor.

Article 13. 1. The removal of cells, tissues or organs from a living donor for the benefit of a person who is not a direct relative, in-law, adopt or spouse, shall require the consent of the district court competent for the place where the donor resides, issued in non-procedural proceedings, after requesting and hearing the opinion of the Ethics Committee of the National Transplant Council.

2. Paragraph 1 shall not apply to the removal of bone marrow and other regenerating tissues or tissues.

3. The court shall initiate proceedings at the request of the donor candidate. The application must be accompanied by:

1) the written consent of the receiver to the collection of cells, tissues or organs from that donor;

2) the opinion of the Ethics Committee of the National Transplant Council;

3) the decision of the head of the medical team to carry out the transplant on the legitimacy and purpose of the procedure.

4. The application referred to in paragraph 3 shall be submitted within 7 days.

Article 14. Proceedings in cases referred to in Articles 12, paragraph 3 and 13 shall be exempt from procedural costs

Article 15. 1. In order to monitor and assess the health status of the donor and from which the organ was taken for transplantation, a central register of organ donors shall be established, hereafter referred to as the 'Register of Living Donors'.

2. The following data shall be included in the register of living donors:

1) name and surname of the living donor;

2) the date and place of birth of the living donor;

3) the address of the place of residence of the living donor;

4) the social security number of the living donor, if any;

5) the date and place of removal;

6) the organ which has been taken;

7) the name and address of the health facility in which the removal was made;

8) the name of the doctor who made the sampling;

9) other relevant medical information.

3. The data referred to in paragraph 2 shall be made available to the Minister for Health;

4. The data referred to in paragraph 2 shall be made available to the Minister for Education and the National Council of Transplant.

5. The register of living donors shall be established by the Transplantation Organization and Coordination Center “Poltransplant”.

Article 16. 1. In order to permit the transplantation or human use of bone marrow, hematopoietic cells of peripheral blood and umbilical cord blood from unrelated donors, a central register of compatible bone marrow blood and umbilical cord blood shall be established, hereafter referred to as the 'bone marrow and umbilical cord blood register'.

1. The bone marrow and umbilical cord blood register is a database of potential allogenic bone marrow donors, hematopoietic peripheral blood cells and umbilical cord blood.

2. The bone marrow and umbilical cord blood register shall consist of two parts:

1) register of potential donors of bone marrow and peripheral blood hematopoietic cells;

2) umbilical cord blood register.

3. The register referred to in paragraph 2, point 1) shall contain the following information concerning a potential bone marrow and peripheral blood hematopoietic cells donor:

1) first and last name;

2) date and place of birth;

3) the address of the place of residence;

4) social security number, if any;

5) information on tissue compatibility antigens;

6) the indication of the entity which has carried out the tissue compatibility antigen test;

7) other relevant medical information.

4. The register referred to in paragraph 2, point 2) shall contain the following particulars:

1) determination of the blood sample of the umbilical cord taken;

2) the date and place of removal;

3) information on tissue compatibility antigens;

4) an indication of the institute of tissues and cells in which the sample is stored;

5) other relevant medical information.

5. The data referred to in paragraphs 3 and 4 shall be provided by the bone marrow and umbilical cord blood register to the medicals staff of the foundations referred to in Article16a, paragraph 1) or by the institutes of tissues and cells.

6.(expired) [3)]

7. The bone marrow and umbilical cord blood register shall be kept by the Transplantation Organization and Coordination Center "Poltransplant".

8. The Minister for Health shall determine, by means of an order, how to keep the records referred to in paragraph 1, taking into account the need for quality and safety of sampling, transplantation and human use and the possibility of keeping a register in electronic form.

[3)] As of 29 July 2014, based on the judgment of the Constitutional Court of 22 July 2014. Ref. Law K-25/13 (Official Journal, item 1000).

Article 16a. 1. Allogenic bone marrow and peripheral blood hematopoietic cells may be carried out by health facilities or foundations, hereafter referred to as "bone marrow donation centers", after receiving the authorization of the Minister for Health.

2. The tasks of the bone marrow donation centers shall include in particular:

1) the acquisition of potential donors of allogenic bone marrow and peripheral blood hematopoietic cells;

2) the tests of tissue compatibility antigens or the commission of these tests to appropriate bodies;

3) the storage of the data referred to in paragraph 8 and their updating, considering the possibility of storing them in electronic form;

4) the organization of assistance to bone marrow donors and peripheral blood hematopoietic cells;

5) the rapid transmission of data on potential donors of bone marrow and peripheral blood hematopoietic cells to the bone marrow and umbilical cord blood register;

6) make available to national or foreign institutions responsible for the transplant of bone marrow and peripheral blood hematopoietic cells for bone marrow transplantation and peripheral blood cells;

7) cooperation with other bone marrow and peripheral blood hematopoietic cells donation and transplantation centers.

3. Substantial control of the activities of bone marrow donation centers shall be exercised by the national consultant in hematology in consultation with the consultant in clinical immunology.

4. The tasks referred to in paragraph 2 shall be carried out by people who have medical, biological or biotechnological training and have received training referred to in Article 40a, paragraph 1)

5. The task referred to in paragraph 2, paragraph 2) shall also be financed from the funds of the Transplant Organization and Coordination Centre “Poltransplant” based on a contract.

6. The Bone Marrow Donation Centre shall conclude a written agreement on medical examinations and tissue compatibility antigens which it does not carry out with the person whose activity affects the quality and safety of the bone marrow or hematopoietic cells of peripheral blood. The provisions of Article 31, paragraphs 2) and 3) shall apply by analogy.

7. The Bone Marrow Donation Centre shall conclude a written contract for the collection of potential donors of bone marrow or peripheral blood cells with authorized health care providers to carry out such activities.

8. The Bone Marrow Donation Centre for the performance of the task referred to in paragraph 2, point 1) shall collect data on potential bone marrow donors and peripheral blood hematopoietic cells, which shall include:

1) first and last name;

2) date and place of birth;

3) the address of the place of residence;

4) social security number, if any;

5) information on tissue compatibility antigens;

6) the indication of the entity which has carried out the tissue compatibility antigen test;

7) other relevant medical information.

9. Bone marrow donor shall keep records of potential donors of hematopoietic cells of peripheral blood for at least 30 years from the date of registration of a potential bone marrow donor and hematopoietic cells of peripheral blood in order to identify the potential donor of bone marrow and hematopoietic cells of peripheral blood.

10. The Minister for Health shall establish, by means of an order:

1) the arrangements for the organization of the bone marrow donation center;

2) how to obtain and test bone marrow donors and hematopoietic cells of peripheral blood;

3) procedures for testing tissue compatibility antigens or for commissioning such testing to competent entities;

4) how to manage the documentation of potential donors of bone marrow and hematopoietic cells of peripheral blood;

5) the arrangements for supplying bone marrow and hematopoietic cells of peripheral blood;

6) the conditions for the transport of samples for the analysis of potential donors of bone marrow and hematopoietic cells of peripheral blood;

7) the arrangements and conditions for organizing assistance to bone marrow donors or donors of peripheral blood cells;

8) the methods of transmitting the data referred to in paragraph 8 to the bone marrow and umbilical cord blood register;

9) the standard operating procedures in force at the Bone Marrow Donation Centre – considering the correct performance of the tasks referred to in paragraph 2, and the guarantee of the safety of donors and receivers.

Article 16b. 1. The Bone Marrow Donation Centre shall obtain the authorization referred to in Article 16a, paragraph 1) if it jointly fulfils the following conditions:

1) it is found in premises protected from data loss of potential bone marrow and hematopoietic cells of peripheral blood donors;

2) the head of the bone marrow donation center is a specialist doctor in clinical transplantation, clinical transfusion, hematology or oncology and pediatric hematology;

3) shall provide for and apply the standard operating procedures referred to in Article 16, paragraph 10), point 9);

4) hire people with the qualifications referred to in Article 16, paragraph 4);

2. The licenses referred to in Article 16a, paragraph 1), shall be issued by the Minister of Health, at the request of the National Centre for Tissue and Cell Institutes, after an opinion issued by the National Council of transplantation.

3. The authorization referred to in Article 16a, paragraph 1), shall be subject to the following conditions: the provisions of Article 26, paragraph 1), 2), 4) point 1), letter j) and points from 4 to 8 and paragraph 7 and Article 27, paragraphs from 1) to 5) shall apply.

Article 16c. 1. Health facilities carrying out organ transplantation or the use of bone marrow, peripheral blood hematopoietic cells and umbilical cord blood may operate as transplant-appropriate centers, hereinafter referred to as 'qualification centers'.

2. The tasks of the qualification center shall include in particular:

1) the registration of potential receivers reported by health facilities other than the health facilities referred to in paragraph 1 or dialysis centers;

2) confirmation of the notification of the potential receiver;

3) the collection of the data referred to in Article 17, paragraph 3).

3. At the qualification center, the Director of the health facility referred to in paragraph 1 shall designate a group of doctors responsible for the qualification of potential receivers of transplantation or human use, hereafter referred to as the "team".

4.The team shall consist of at least:

1) a specialist doctor in the field of clinical transplantation;

2) a specialist doctor in the field of surgery or pediatric surgery, or hematology or vascular or cardio surgeon surgery or clinical oncology or pediatric oncology and hematology or urology.

5. In addition, other medical professionals may be appointed for the composition of the team, as well as by a person appointed by the head of the health unit.

6. The work of the team shall be led by a specialist doctor in the field of clinical transplantation nominate by the head of the medical department referred to in paragraph 1

7. The team's tasks are:

1) the assessment of potential receivers pre-qualified by health facilities other than those referred to in paragraph 1 or by dialysis centers;

2) the qualification of a potential receiver for transplantation or application;

3) conducting specialized consultations with potential receivers in cases requiring further testing or verification;

4) the committee of specialized qualification tests, in particular:

a) typing of tissues;

b) antibody levels;

c) specialist research consultations and instrumental examinations.

8. The tasks referred to in paragraphs 2, 7, points 3) and 4c) shall be financed by the National Health Fund under a healthcare agreement, and the tasks referred to in paragraph 7, point 4) a) and (b) shall be

financed by the Transplantation Organization and Coordination Center "Poltransplant" on the basis of a contract.

9. Substantial supervision of the activities of centers qualifying potential receivers of organs and centers for the eligibility of potential receivers of bone marrow and umbilical cord blood cells shall be carried out by a national consultant for clinical transplantation to – national consultant on hematology.

10. The Minister for Health shall determine, by means of an ordinance, the operation of the eligible centers and the method of qualification of the potential receiving centers, taking into account the health safety of potential receivers and the proper performance of the tasks referred to in paragraph 2.

Article 17. 1. A receiver qualified for bone marrow, cell or organ transplantation shall be indicated on the national list of persons awaiting transplantation, hereafter referred to as "the list".

2. The data referred to in paragraph 3 shall be notified to the list by the doctor leading the team referred to in Article 16, paragraph 3).

3. The notification shall contain the following particulars:

1) the name of the potential receiver;

2) the date and place of birth of the potential receiver;

3) the address of the place of residence or the final address of the potential receiver;

4) the social security number of the potential receiver, if available;

5) medical diagnosis;

6) the blood group and Rh of the receiving potential;

7) the type of transplant envisaged;

8) urgency of transplantation according to the medical criteria currently in force for a given type of transplant;

9) the name, surname and place of practice of the profession of doctor notifying the report;

10) other significant medical information.

4. Inclusion in the list is a condition for receiving the transplant.

5. The potential receiver shall be selected based on the medical criteria laid down in the legislation adopted in accordance with paragraph 8.

6. The data referred to in paragraph 3 shall be made available to the Minister for Health and the National Transplant Council.

7. The list shall be kept by the Transplantation Organization and Coordination Center “Poltransplant”.

8. The Minister for Health shall, by means of an order:

1) the method and means of creating and keeping a list;

2) medical criteria and how to select a potential receiver;

3) how to inform potential receivers of the order of entry in the list – considering the current state of medical knowledge and the possibility of keeping a list in electronic form.

Article 18. 1. In order to monitor transplantation of cells, tissues and organs, a national transplant register shall be established, hereafter referred to as the "Transplant Register".

2. The following data shall be included in the transplant register:

1) the name and address of the transplant receiver;

2) the date and place of birth of the transplant receiver;

3) the social security number of the receiver of the transplant, if available;

4) the date of transplantation;

5) the type of transplanted cells, tissues or organs;

6) the name and address of the health facility where the transplant was carried out;

7) information on the survival of the receiver for a period of 3 to 12 months, after transplantation, and every 12 months until loss of transplantation or death of the transplant receiver.

3. The data referred to in paragraph 2 shall be provided by the health care provider currently treating the receiver of the transplant.

4. The data referred to in paragraph 2 shall be made available to the Minister for Health and the National Transplant Council.

5. The transplant registry is kept by the Transplantation Organization and Coordination Center "Poltransplant".

6. The Minister for Health shall determine, by means of an order, how to keep the records referred to in paragraph 1, considering the need to assess the results of transplantation and the possibility of keeping a register in electronic form.

Article 19. 1. Personal data relating to a potential donor, donor, potential receiver and receiver shall be kept secret and shall be protected by the rules on professional secrecy and in the rules relating to medical records managed by medical entities.

2. Where the organ is to be taken from a living donor, the provision of paragraph 1 shall not apply to the disclosure of personal data relating to the donor and the receiver to those persons respectively.

Article 19a 1. The data controller kept in the registers referred to in Articles 7, 15, 16 and 18, and the list referred to in Article 17 shall be the Transplantation Organization and Coordination Center "Poltransplant".

2. The registers and list referred to in paragraph 1 shall be kept using information and communication systems.

3. The controller referred to in paragraph 1 may, in order to ensure the operation of the information and communication systems referred to in paragraph 2, entrust the processing of data to persons specializing in providing technical support for information and communication systems.

4. The persons referred to in paragraph 3 shall be required to create the conditions for organizational and technical provisions ensuring the protection of the data processed, in particular the protection of data against unauthorized access, illegal disclosure or acquisition and, as well as their modification, damage, destruction or loss. The data processed in the registers and in the list referred to in paragraph1 shall be subject to a high level of protection as provided for in the provisions issued pursuant to Article 39a of the Law of 29 August 1997 on the Protection of Personal Data (Official Journal of the European Communities 2016, item 922 and 2018, points 138 and 723)[4)]

5. The controller referred to in paragraph 1 may monitor the entity referred to in paragraph 3, as regards the implementation of the requirements referred to in paragraph 4, and as regards the purposes of entrusting the data processed in the registers referred to in paragraph 1.

6. The entity referred to in paragraph 3 may not entrust other entities with the processing of data collected in the registers and the list referred to in paragraph 1;

7. In the event of cessation of the processing of data collected in the registers referred to in Articles 7, 15, 16 and 18 and the list referred to in Article 17, the entity referred to in paragraph 3, in particular in relation to their liquidation, shall be involved in providing the data collected in those bodies, registers and list to the controller referred to in paragraph 1.

8. The subject referred to in paragraph 3 shall be obliged to keep confidential the information on the patient obtained in connection with the outsourcing of the data processing referred to in paragraph 3. These entities are bound to this secrecy even after the patient's death.

Chapter 4

Specific types of cells, tissue and organ collection and transplantation

Article 20, 1. Transplantation of cells, tissues or organs or human use of animal-derived cells or tissues is allowed.

2. The transplantation or use referred to in paragraph 1 shall be subject to the opinion of the National Council of Transplantation.

3. For the transplantation or use referred to in paragraph 1, the following provisions relating to medical experiments shall apply.

Article 21. Cells, tissues or organs may be taken for transplantation or may be obtained for use in patients from organs or parts thereof removed for reasons other than the removal of cells, tissues or organs, after obtaining permission for their use by a donor or his legal representative.

[4)] The Law was repealed as of 25 May 2018 with the exception of Articles 1, 2, 3(1), 4 to 7, 14 to 22, 23 to 28, Article 31 and Chapters 4, Amendments Nos 5 and 7, which remain in force with regard to the processing of personal data for the purpose of identifying, preventing, detecting and combating criminal offences, conducting proceedings in cases relating to such acts and the enforcement of judgments handed down therein, sanctions and coercive measures on which the services and bodies empowered to operate by the date of entry into force of the implementing provisions of Directive (EU) 2016/680 of the European Parliament and of the European Council , of 27 April 2016, relating to the protection of natural persons in relation to the

Chapter 5

Donation of cells, tissues and organs or parts thereof

Article 22. 1. Bone marrow or other regenerating cells and tissues donors are entitled to the title of transplant donor.

2. The badge and identity card confirming the title of transplant donor shall be released by the health facility which has taken the marrow or other regenerating cells or tissues.

3. A transplant donor who has donated bone marrow or other regenerating cells or tissues more than once and as an organ donor, is entitled to the title of Deserving Donor for Transplant.

4. The badge and identity card confirming the possession of the title of Deserving Donor for Transplant, is released by the Minister of Health at the request of the Transplantation Organization and Coordination Center "Poltransplant".

5. The releasing of identity cards and badges referred to in paragraph 2 and 4 shall be covered by the budget of the State of which the Minister for Health is competent.

6. The Minister of Health shall establish, by means of an order, the models of identity cards and badges, and the procedures for assigning the card "Donor for Transplant" and "Deserving Donor for Transplant" together with a way to document the number of donations for the purpose of assigning this card, taking into account the data taken from the Transplantation Organization and Coordination Center "Poltransplant" and promote the donation of tissues, cells and organs.

Article 23. 1. The Donor for Transplant and Deserving Transplant Donor have the right to out-of-service outpatient health care.

2. Bone marrow donors or peripheral blood hematopoietic cells and organ donors who have suffered personal injuries in connection with the sampling procedure shall be entitled to compensation under the provisions of the Civil Code.

---

processing of personal data by the competent authorities for the purpose of crime prevention, investigations, the detection of criminal proceedings and the execution of sanctions, on the free movement of such data and repealing Council Framework Decision 2008/977/JHA (OJ EU L 119, 04.05.2016, p. 89), pursuant to Article 175 of the Law of 10 May 2018 on the Protection of Personal Data (Official Journal heading 1000), which entered into force on 25 May 2018. The provisions of the law mentioned in the previous sentence have been repealed as of 6 February 2019, pursuant to Article 107 of the Law of 14 December 2018 on the protection of personal data processed in the field of

prevention and control (Official Journal of 2019, item 125), which entered into force on 6 February 2019.

Article 24. Entities which promote cells, tissues and organs donations, must inform the Minister for Health on the capacity of these activities.

Chapter 6

Tissues and cells institutions

Article 25 Tissue and cell institutions for transplantation or human use shall be established for the purpose of removal, process, sterilization, storage, distribution, or importation of tissues and cells intended for transplantation or human use.

Article 26. 1. A request for authorization to carry out activities referred to in Article 25 shall be submitted by the organizational unit, hereafter referred to as 'the applicant', to the National Centre for Tissues and Cells Institutions.

2. Authorization for the activity referred to in Article 25 shall be granted by the Minister of Health at the request of the National Centre for the Institutions of Tissues and Cells, after obtaining the opinion of the National Transplant Council, if the applicant fulfils the conditions laid down in paragraph 3. Authorizations for the activities and operations referred to in Article 25 shall be granted for a period of five years.

3. The applicant shall be authorized to carry out the activities referred to in Article 25 if they jointly fulfill the following conditions:

1) employ persons with appropriate qualifications, including a person responsible for complying with the provisions of this Law defined in the quality assurance system referred to in Article 29, hereafter referred to as the 'responsible person';

2) they have premises and facilities corresponding to the professional requirements and health provisions laid down in the provisions adopted pursuant to Article 27, paragraph 7);

3) they have a draft quality assurance system referred to in Article 29.

4. An application for authorization for the activity referred to in Article 25 shall contain:

1) data on the applicant:

a) the name or business name of the body in which the institute of tissues and cells is established, sand present;

b) the address or address of the registered office of the institution in which the tissue and cell institution is located, if any;

c) the postal address;

d) the identification of the organizational and legal form;

c) the Fiscal Identification Number (NIP);

f) the identification number in the official national register of national economic bodies (REGON);

g) the number in the national register of courts, if any;

h) the number of the register of bodies carrying out medical activities, if any;

i) a list of authorizations held by the Minister for Health referred to in paragraph 1, if any;

j) a description of the organizational structure;

2) the name of the responsible person to be contacted, the telephone number and e-mail address;

3) the address of the website of the institute of tissues and cells, if any;

4) information on the number of persons referred to in paragraph 3, point 1), their qualifications and areas of competence;

5) a list of the premises and structures referred to in paragraph 3, point 2);

6) the detailed scope of the activities referred to in Article 25, considering different types of tissues and cells;

7) a list of the entities referred to in Article 31, paragraph 1) to which the institute of tissues and cells, after being authorized to carrying out the activities referred to in Article 25, shall commission the activities and specify the activities to be commissioned;

8) the name of the responsible person.

5. The application referred to in paragraph 1 shall be accompanied by:

1) a copy of the opinion of the competent national health inspector, certified by an authorized person to represent a tissue and cell institution, a copy of the opinion of the competent national health inspector in compliance with the requirements laid down in the provisions adopted pursuant to Article 27, paragraph 7);

2) a copy of the agreements concluded with tissue and cell supply organizations certified by an authorized person to represent a tissue and cell institute and copies of contracts concluded with the entities referred to in Article 31, paragraph 1);

3) the draft quality assurance system referred to in Article 29;

6. The application referred to in paragraph 1 relating to import activities shall also contain data:

1) as regards the tissues and cells to be imported:

a. a list of tissue or cell types;

b. the name of the tissues or cells or the name of the tissues or cells processed, in accordance with the European General List, if such a list has been drawn up,

c. the name of the third-country supplier for each type of tissue or cell;

2) as regards the definition of a list of activities to be carried out by the third-country supplier or the entity to which he has commissioned any activities, hereinafter referred to as 'subcontractors', before and during the transport of tissues or cells from the supplier of a third country to an applicant, including activities such as: removal, testing, processing, storage, broken down by type of tissue or cell and for states in whose territory each of these operations is to be carried out;

3) as regards the establishment of a list of activities to be carried out by the institute of tissues and cells after the tissues or cells have been delivered to it by a supplier from a Member State, including tests, treatments, storage, broken down by type of tissue and cell;

4) as regards suppliers from third countries:

a) the name (of the company);

b) the name of the responsible person;

c) the address of the registered office;

d) the postal address, if different from the address of the registered office;

e) a telephone number with an international code;

f) the emergency contact number, if different from the number referred to in e);

g) the e-mail addresses.

7. If the person responsible is temporarily replaced by another person, the tissues and cells institution shall immediately forward that person's name to the National Centre of tissues and cells Institutions and shall communicate the date of the beginning of that person’s duties.

8. The National Centre of Tissues and Cells institutions shall forward, within 10 days of the date on which the decision to grant a license to carry out the activities referred to in Article 25 has become final, to the European Compendium of Tissue and Cell Institutes, data on:

1) tissue and cell institutes:

a) the name (of the company);

b) national or international code;

c) the name (company) of the organism to which the tissue and cell institute is a member;

d) the address of the registered office;

c) contact details: e-mail address, telephone and fax number.

2) the licenses for the activity referred to in Article 25:

a) the name of the competent authority issuing the license;

b) the name of the national authority responsible for managing the European Compendium of Tissues and Cells institutes;

c) the procedures for carrying out inspections;

d) the name (company) of the license holder;

c) the types of tissues or cells for which a license has been granted;

f) the types of activity for which the license has been granted;

g) if the license is valid, revoked or if one has voluntarily ceased to carry out the activities for which the license was granted for the performance of the activities referred to in Article 25

- and on this basis assigns a European Code to the Institute of Tissues and Cells according to the Single European Code.

9. If a tissues and cells institute use more than one system to assign unique donation numbers, it will be assigned separate numbers for tissue and cell institutions corresponding to the number of allocation systems used.

10. For the assignment of a European Code to a tissues and cells institute within the meaning of paragraphs 8 or 9, the National Centre of Institutes of Tissues and Cells, within 7 days of its assignment, shall inform the Minister of Health.

11. Within 10 days of receiving the information referred to in paragraph 10, the Minister for Health shall issue to a certificate to the Institute of Tissues and Cells for the license to receive the work of the activities referred to in Article 25 on import duties.

12. The certificate referred to in paragraph 11 shall contain information on:

1) the number of the certificate;

2) the institutions of the tissues and cells in question carrying out import activities:

a) the name (company);

b) the European Code for Institutes of Tissues and Cells;

c) the address of the registered office;

d) the address of the site of receiver of tissues or cells for suppliers, where there is a difference from the address of the tissue and cell institute;

c) the telephone number;

f) the e-mail address,

g) the address of the website;

3) the scope of the import activity:

a) the type of imported tissues or cells;

b) the name of imported tissues or cells;

c) the conditions under which imports are subject, if any;

d) the third country in which the tissues or cells are taken;

c) the third country in which activities other than the removal of tissues or cells are carried out;

f) the name of the supplier and the third country from which the importation is to take place;

g) the Member State of the European Union in which the distribution will take place, if any;

4) licenses for the performance of the activities referred to in Article 25:

a) the license number;

b) the legal basis for the issue of the license;

c) the date of expiry of the license;

d) information on the number of licenses granted so far to the tissue and cell institute;

e) the name of the licensing authority;

f) the name of the official responsible for issuing the license;

g) the date of release of the license;

h) the signature of the official responsible for issuing the license and stamping the releasing authority.

13. The Minister for Health shall, by means of an order, establish a model of the certificate referred to in paragraph 11, taking into account the need to ensure the health safety of receivers and the equivalence of quality standards in force in the European Union.

Article 27. 1. The Institute of Tissues and Cells shall forthwith inform the National Centre for the Institutions of Tissues and Cells in the event of a change in the data referred to in Article 26, paragraphs 4) and 6) and shall submit, in the event of amendment, the documents referred to in Article 26, paragraph 5).

1a. A tissues and cells institute carrying out an import activity shall immediately inform the National Centre for Tissue and Cell Institutions of any partial or total removal or suspension of the act of the competent authority of a third country authorizing the export of tissues and cells held by the supplier of a third country.

1b. A tissue and cell institute carrying out an import activity shall immediately inform the National Centre for Tissue and Cell Institutes of any other decision that the competent authority of the country in which the supplier of third countries is established has undertaken in connection with an infringement by a supplier of third countries of which it may be detected and for the quality and safety of imported tissues and cells.

1c. A tissue and cell institute immediately informs the National Centre for Tissue and Cell Institutes of each import of tissues and cells into the territory of the Republic of Poland from a supplier from a third country within 7 days of the date on which the introduction was made.

1d. If the information referred to in paragraph 1 implies an amendment referred to in Article 26, paragraph 8), the National Centre for Tissue and Cell Institutes shall immediately transmit the modified data to the European Compendium of Tissue and Cell Institutes.

1e. A substantial change in the import activities of a tissue and cell institute, including the type of imported tissues or cells or suppliers from third countries, shall be required to obtain the authorization referred to in Article 26, paragraph 1) for the exercise of that activity.

1f. The Institute for Tissues and Cells shall immediately inform the Director of the National Centre for Institutes of Tissues and Cells of significant changes in import activity consisting of actions taken in third countries which could affect the quality and safety of imported tissues and cells. The Institute for Tissues and Cells may make this change after obtaining the written consent of the Director of the National Centre for the Institute of Tissues and Cells.

1g. If a tissue and cell institute operates in imports of tissues or cells from a supplier of a third country which is not covered by the license referred to in Article 26, paragraph 1), it shall not be considered as a substantial modification for the performance of import activities within the meaning of paragraph 1 and if the institution of tissues and cells carrying out the import activity is authorized to import the same type of tissues or cells as another supplier in a third country.

2. The Minister of Health shall assess whether:

1) a tissue and cell institute applying for the authorization referred to in Article 26, paragraph 2) satisfies the conditions necessary to obtain it;

2) the entities referred to in Article 26, paragraph 4) point 7) shall, within the framework of the activities defined in the Agreement concluded with the Institute of Tissues and Cells, compare the requirements specified in the provisions adopted pursuant to paragraphs 6 and 7.

3. The assessment referred to in paragraph 2 shall be carried out on the basis of a report after the inspection carried out in order to determine whether a tissue and cell institution requesting the authorization referred to in Article 26, paragraph 2) fulfils the necessary conditions to obtain it.

4. The Minister of Health revokes the authorization if:

1) the institution of tissues and cells no longer fulfills the conditions necessary to obtain the license referred to in Article 26 paragraph 2);

2) the institute of tissues and cells makes it impossible to carry out the checks necessary to determine whether it meets the requirements for carrying out the tasks laid down by law;

3) the entities referred to in Article 26, paragraph 4), point 7) do not meet the requirements for tissue and cell institutions referred to in the Regulations issued pursuant to paragraph7 as regards the activities specified in the contract concluded with the tissue and cell institute;

4) persons employed in the institutions referred to in Article 26, paragraph 4), point 7) shall not comply with the requirements laid down in the provisions adopted pursuant to paragraph 6.

5. The granting, refusal and removal of a license referred to in Article 26, paragraph 2) shall be granted by an administrative decision. The decision to revoke the license shall be immediately enforced. This decision

specifies the procedures to transfer tissues and cells stored to other authorized tissues or cells institutes or centers.

6. The Minister of Health shall establish, by means of an ordinance, the qualifications required for persons employed in tissue and cell institutes directly engaged in the processing, storage, distribution or analysis of human tissues and cells, in order to ensure the safety of donors and receivers.

7. The Minister of Health shall establish, by means of an ordinance, the professional and health requirements for tissue and cell institutions, considering the scope of the activities carried out and considering the health safety of donors and receivers.

Article 28. 1. The head of the institute of tissues and cells shall appoint one responsible person.

2. The person referred to in paragraph 1 shall have at least:

1) a degree in the field of medical or biological sciences;

2) two years of professional experience gained in tissues and cells institutes or entities whose activities are related to the processing, storage, distribution, collection or experimentation of human tissues and cells.

3. The tasks of the person responsible shall include:

1) ensure compliance with:

a) requirements for the collection of human tissues and cells;

b) selection criteria for tissue and cell donors;

c) the carrying out of the laboratory tests necessary for the workers;

d) procedures for the collection of tissues and cells and their admission to an institute of tissues and cells;

e) requirements for the preparation of tissues and cells;

f) procedures for the processing, analysis, sterilization, storage and distribution of tissues and cells;

g) requirements for the direct distribution to the receiver of specific tissues and cells;

2) inform the National Centre for Tissues and Cells Institutes of any serious adverse event or adverse reaction;

3) carry out continuous monitoring of the compliance of tissues and cells institute staff with the quality assurance system;

4) transmit the necessary data to the register of tissues and cells institutes;

5) promote voluntary donation of tissues and cells.

Article 28a. The institute of tissues and cells shall be required to train employees whose activities affect the quality of cells and tissues and the safety of donors and receivers, including the responsible person, in accordance with the provisions of Article 40a, paragraph 1).

Article 29. 1. The Tissues and Cells Institute shall develop and implement a system to ensure quality, specifying in particular how to maintain the condition of tissues and cells between the donor and the receiver and all medical devices and materials directly in contact with these tissues and cells.

2. The quality assurance system shall include the following documents:

1) standard operating procedures;

2) guidelines;

3) procedural manuals;

4) signaling forms;

5) donor cards;

6) information on the destination of tissues or cells.

3. The Minister for Health shall, by means of an ordinance, lay down the requirements to be met by the quality assurance system referred to in paragraph 1, and in particular the requirements for the storage of tissues and cells, the recording of donor data and the need to establish standard procedures taking into account the documents referred to in paragraph 2.

Article 30 (repealed)

Article 31. 1. The Tissues and Cells Institute shall conclude a written cooperation agreement with an entity whose activities affect the quality and safety of tissues and cells processed in cooperation with this entity.

2. The Tissues and Cells Institute shall be obliged, before concluding the contract paragraph 1, to verify that the entity complies with the requirements laid down in the provisions adopted pursuant to Article 27, paragraphs 6) and 7), as laid down in the quality assurance system referred to in Article 29.

3. The Tissues and Cells Institute shall retain the agreements referred to in paragraph 1 for the purposes of the investigations referred to in Article 35

Article 31a. 1. The Tissues and Cells Institute carrying out import activities shall conclude a contract with a supplier from third countries on the import from a third country to the territory of the Republic of Poland of tissues or cells.

2. The agreement referred to in paragraph 1 shall contain:

1) data from the institute of tissues and cells carrying out the import activities referred to in Article 26, paragraph 8), point 1), the supplier of third countries concerned referred to in Article 26, paragraph 6), point 4) and the information of the subcontractors referred to in Article 26, paragraph 6), point 2), if any;

2) the power of the Minister of Health or a person acting under his authority to carry out checks on the supplier of a third country during the duration of the contract and within two years of its termination or completion of its implementation in terms of compliance with the requirements in a third country relating to the possibility of supplying tissues or cells in the territory of the Republic of Poland and as regards compliance with the quality and safety standards applied by the supplier of third countries with the requirements of Article 29;

3) the obligation on contracting parties to ensure compliance with the safety standards of imported tissues or cells intended for use in transplantation or human use, in accordance with the requirements laid down in Article 29

4) the identification of the subcontractor, if any, including:

a) the name (company);

b) organizational and legal form;

c) the address of the registered office;

d) a telephone number;

c) e-mail address;

5) the obligation on the supplier of third countries to communicate, within 14 days of the date of conclusion of the contract, to the Tissues and Cells Institute carrying out the import, written information on compliance with the requirements applicable in a third country relating to the possibility of supplying tissues and cells in the territory of the Republic of Poland;

6) the obligation on the supplier of third countries to inform immediately the supplier of a Tissues and Cells Institute carrying out import activities regarding:

a) changes in its activities relating to the total or partial removal or suspension of an export license for tissues or cells or other modifications which may affect the quality and safety of tissues or cells which have been or should be imported;

b) serious, suspected or real adverse events, or adverse reactions which may affect the quality and safety of tissues and cells which have been or should be imported;

7) the authorization of a Tissues and Cells Institute carrying out import activities to carry out regular checks with a supplier in third countries in relation to the quality and safety standards of imported tissues or cells intended for transplantation or human use, in accordance with the requirements of Article 29;

8) the conditions for the transport of tissues or cells;

9) the obligation on the third-country supplier or its subcontractor, if any, to keep records of tissues or cells donors by ensuring the protection of the donor's personal data from non-authorized processing and, for 30 years from the date of removal, and the identification of the entity to which donor data will be transferred in the event of cessation of the supplier's activity from a third country or its subcontractor, if any;

10) the obligation to the Tissues and Cells Institute who carries out the import activity and the suppliers from a third country of review the contract, referred to in paragraph 1, every six months, regarding the compliance with its provisions to the present law and acts implementing acts in terms of quality and security of trade of tissues or cells, and in case of onset, during the period of validity of legal status modifications that affect quality and safety standards, so that these rules are subject to a restriction on the further respect at the time of conclusion of the contract, the institute of tissues and cells and the suppliers from a third country are obliged to amend the content of the agreement with regard to quality and safety standards in good time;

11) the obligation on the third-country supplier to provide the Tissues and Cells Institute he carries out and an import activity a list of all standard operating procedures for the quality and safety of imported tissues or cells and the obligation to transmit such procedures immediately at the request of the Tissues and Cells Institute carrying out the imports;

12) the obligation on the third-country supplier to inform immediately in writing the supplier of a Tissues and Cells Institute carrying on an import activity of the location and time of collection of tissues or cells, together with the identification data of the foreign entity, within the framework referred to in Article 34, paragraph 4) point 2);

3. A Tissues and Cells Institute carrying on an import activity shall provide a copy of the agreement referred to in paragraph 1, certified by a person authorized to represent the Tissues and Cells Institute, concluded with a supplier from third countries, supplier of the National Centre for Tissue and Cell Institutes, within 14 days of its conclusion.

4. The conclusion of the Agreement referred to in paragraph 1 shall not be required if the tissues and cells imported under a single importation are transplanted or used only in the intended receiver.

Article 32. The Tissues and Cells Institute must:

1) mark, pack and document tissues and cells;

2) ensure the highest quality of tissues and cells during distribution;

3) ensure that all activities related to the preservation of tissues and cells are carried out under controlled conditions appropriate for each activity.

Article 32a. 1. The Tissues and Cells Institute shall conclude a contract for the storage of cells and tissues with the person who supplied these cells or tissues for storage.

2. The agreement referred to in paragraph 1 shall contain the following:

1) the expiry date of the period referred to in Article 26, paragraph 1);

2) the Tissues and Cells Institute or Institutes authorized in the case of Article 26, paragraph 1), to which the stored cells or tissues will be transferred in the event of cessation of the activities of the Tissues and Cells Institute, including in the event of removal of authorization by the Minister of Health.

3. The Tissues and Cells Institute shall inform persons who have deposited cells or tissues for storage in that Tissues and Cells Institute, of the removal of authorization by the Minister of Health.

Article 33. (repealed)

Article 34. 1**.** The Tissues and Cells Institute:

1) is required to keep, collect and maintain records of activities carried out on tissues and cells;

2) importing tissues or cells from a third country, including individual imports, shall collect and maintain records of the activities undertaken, including the types and quantities of tissues or cells imported and the origin and destination of the imported tissues or cells.

– for a period of 30 years from the date of release of tissues or cells for transplantation or human use, in order to allow the identification of donors and receivers of tissues or cells.

2. The Tissues and Cells Institute shall transmit an annual report on the activities undertaken at the National Centre for Tissues and Cells Institutes, which shall include the types and quantities collected, processed, stored and preserved of tissues or cells and their origin and purpose.

3. The documentation referred to in paragraph 1 may be collected, kept in and available in electronic form.

4. The documentation referred to in paragraph 1 shall include the following data:

1) donor identification data:

a) first and last name;

b) gender;

c) date of birth;

d) the social security number, if any;

c) the number of medical records associated with the donation;

f) the results of diagnostic tests to identify contraindications to being a donor of tissues or cells, including the presence of pathogens within the meaning of Article 2, paragraph 2) of 5 December 2008 act on the prevention and control of infections and infectious diseases in humans (Official Journal 2020, heading 1845),

g) the results of tests for tissue compatibility antigens, if any;

h) the number of tests for tissue compatibility antigens carried out, if any;

i) the availability of the donor (donor and eligible or unfit for removal) if present;

2) identification data on the removal, including:

(a) the identification of the foreign institute for the collection of tissues and cells, including:

– name(company);

— organizational and legal form;

– the address of the registered office;

– telephone number;

– e-mail address;

b) a unique donation number;

c) the date and time of start and end of the removal;

d) the place of sampling;

c) data on the type of removal, including:

- the amount of tissue or cells taken;

– type of tissues or cells taken;

– type of supply (for autologous or allogenic access);

– the origin of the tissues or cells collected (sampling from a living donor or corpse);

3) tissue or cell identification data, including:

a) identification data for the Tissues and Cells Institute;

b) the type of tissues and cells or tissues and cells processed (basic nomenclature of the European General List, if this list has been drawn up),

c) the division number, if any;

d) the expiry date of tissues or cells, if any;

e) if the tissues or cells are quarantined, or if they have been placed for distribution or circulation,

f) the description and origin of tissues or cells, the stages of processing applied, medical devices and materials coming into direct contact with tissues and cells, affecting their quality or safety,

g) the identification data of the Tissues and Cells Institute which places, on tissues and cells or processed tissues and cells, a final label for their distribution;

4) a single European code, if any;

5) identification data on the use of tissues or cells in human, including:

a) the date of distribution or release or the date of disposal;

b) the identification data of the doctor using the tissues or cells, including:

- the professional title, degree or degree together with the title of scientific officer;

– first name (or names) and surname;

— the number of the license to practice;

– specializations held.

Article 35. 1. The Minister of Health shall carry out checks at:

1) Tissues and Cells Institute regarding the fulfilment of:

a) the conditions required to obtain the license referred to in Article 26, paragraph 2);

b) the requirements laid down by law;

2) the entities referred to in Article 26, paragraph 4) point 7) concerning:

a) compliance with the requirements laid down for Tissues and Cells Institutes in accordance with the provisions adopted pursuant to Article 27, paragraph 7) regarding the activities of the contract concluded with Tissues and Cells Institute;

b) the fulfilment by the persons employed in those bodies of the specified requirements of the provisions adopted pursuant to Article 27, paragraph 6);

c) compliance with the requirements for Tissues and Cells Institutes referred to in the provisions adopted pursuant to Article 29, paragraph 3);

3) the institutes referred to in Articles 16a, paragraph 1) and 16c paragraph 1) regarding the requirements laid down by law;

4) the institutes referred to in Article 31a, regarding the requirements of this Law.

1a. The Minister for Health shall carry out the inspection referred to in paragraph 1 in Tissues and Cells Institutes carrying out import activities and shall monitor the activities of suppliers from third countries at the justified request of the competent authority of a Member State of the European Union responsible for organizing inspections and monitoring Tissues and Cells Institutes in the Member State concerned.

1b. The application referred to in paragraph 1a) shall contain:

1) the full name and address of the registered office of the authority;

2) the legal basis determining the powers of the authority to organize and monitor the Tissues and Cells Institutes in the State in which it is established;

3) the purpose of the inspection.

1c. If the application does not meet the conditions set out in paragraph 1b, the Minister of Health shall invite the authority to complete the proposal, specifying the deadline for its completion. If the application is not completed within the prescribed period, the checks shall not be carried out.

1d. The competent authority of the Member State requesting the inspection may take part in the inspection. The method of participation of the authority of the Member State shall be determined in

writing by the Minister for Health. The refusal to participate in relation to the need to protect public interests or public health must be notified to the Member State requesting the inspection.

1e. The measures taken as a result of the checks shall be implemented after consultation with the Member State which requested the inspection.

1f. At the request of another Member State of the European Union or the European Commission, the European Minister for Health shall provide information on the results of checks on tissue and cell institutions operating as suppliers from third countries.

2. The Minister of Health may instruct the National Centre for Tissue and Cell Institutes to carry out the tasks referred to in paragraph 1.

3. Inspection shall be carried out whenever there is a serious adverse reaction or serious adverse events, but not less than once every two years.

4. The control activities shall be carried out by personnel authorized by the Minister for Health or, in the case referred to in paragraph 2, the staff of the National Centre for Tissue and Cell Institutes, on the basis of a staff authorization, containing:

1) an indication of the legal basis;

2) the identification of the control body;

3) the date and place of issue;

4) the name and surname of the authorized worker;

5) the designation of the controlled entity;

6) an indication of the start date and the expected date for completion of the control;

7) the purpose of the controls;

8) the signature of the person granting the license, indicating the position or function held;

9) information on the rights and obligations of the entity inspected.

5. The authorized personnel referred to in paragraph 4, hereinafter referred to as "the inspectors", shall have the right to:

1) free access to the structures and premises of the controlled entity;

2) access to all documents relating to the activities of the controlled entity;

3) request oral and written explanations from the employees of the controlled entity.

6. The inspector shall present the results of the inspection carried out in an inspection report.

7. The inspection report shall indicate the deficiencies found in the operation of the controlled entity and shall contain post-inspection recommendations for the removal of irregularities found and the time limit for their removal or indicate the absence of irregularities.

8. Within 14 days of the date of delivery of the inspection report to the audited body, that body shall have the right to lodge objections with the Minister of Health.

9. The Minister of Health accepts or rejects objections within 14 days of the date of their submission, while the office of Minister of Health is final.

10. In the event of non-implementation by the audited entity of recommendations within the prescribed period, the Minister of Health may, in accordance with Article 26, paragraph 2), revoke the license.

11. The Minister of Health shall determine, by means of an order, the procedures for carrying out inspections carried out by persons authorized under the provisions of the Law, for:

1) Tissues and Cells Institutes;

2) the institutes referred to in Articles 16a, paragraph 1), 26, paragraph 4), point 7), 36, paragraph 1) and 37 paragraph 1) in the case of activities subject to licenses issued based on the provisions of this Law;

3) qualified centers, in order to satisfy the requirements laid down in the provisions laid down in accordance with Article 16c, paragraph 10);

– considering the way in which the various control activities are carried out, their scope and documentation during the checks, considering the need to ensure that controls are carried out smoothly.

Article35a. 1. In the event of the declaration of an epidemic emergency or in case of risk of spread of an infection or contagious disease which may pose a risk to public health, in particular the occurrence of a particularly dangerous and highly contagious disease within the meaning of Article 2, paragraph 4 of the Law of 5 December 2008 on the prevention and control of infections and infectious diseases in humans, or other exceptional circumstances that threaten the health and life of many people, the Minister of Health may move the deadline for inspection referred to in Article 35, paragraph 3) once, and no more than 6 months from the expiry date of 2 years from the date of the last inspection. If the circumstances underlying the postponement of the inspection date do not persist the Minister of Health may postpone the inspection period again for a period not exceeding three months.

2. In case of:

1) the need to safeguard the proper functioning of the institutions referred to in Articles 16a paragraph 1), 16c) paragraph 1), 25, 31 paragraph 1), 36 paragraph 1) and 37 paragraph 1);

2) urgent matters other than those referred to in point 1;

- the Minister of Health can carry out an inspection through an information and communication system (ICT).

Chapter 7

Treatment of cells, tissues and organs

Article 36. 1. The treatment of cells, tissues and organs consists of:

1) removal of cells, tissues and organs from living donors - may be performed exclusively in health facilities;

2) removal of organs for transplantation from human corpses - may be performed only in health facilities;

3) removal of cells and tissues from human corpses - it may be performed in health facilities, forensic facilities, departments of pathological anatomy of higher education institutions carrying out scientific and educational activities in the field of medical sciences, in the research institutes referred to in Article 3 of the Act of 30 April 2010 on research institutes, and in funeral homes with an autopsy hall;

4) organ preservation – can only be conducted in qualified health facilities enabled to carry out transplantation;

5) transplantation or human use - can be conducted exclusively in health facilities.

1a. The activities referred to in paragraph, points 1), 4) and 5) may be carried out by establishments authorized by the Minister for Health.

2. (repealed)

3. The authorization referred to in paragraph 1a) shall be used accordingly for the granting of the provisions of Articles 26 and 27, paragraphs from 1 to 5, including the fact that the tasks and activities of the National Centre for Tissue and Cell Institutes are carried out by the Transplantation Organization and Coordination Center "Poltransplant".

4. The license application of the entity referred to in paragraph 1 points 1), 4) and 5) shall specify the scope laid down or for transplant procedures.

5. The activities referred to in paragraph 1 shall be carried out by persons with appropriate professional qualifications.

6. Before issuing a license for the activities referred to in paragraphs 1 points1), 4) and 5), the Minister for Health shall consult the National Council of Ministers.

7. The Minister for Health shall establish, by means of an order:

1) the professional qualifications of persons taking cells, tissues, organs and persons carrying out or applying transplantation in human beings;

2) the professional qualifications of the coordinators of cell, tissue and organ removals and transplantation;

3) the conditions to be fulfilled by the entities referred to in paragraph 1 under which the processes for the collection, storage, and transplantation of cells, tissues or organs or for human use of cells or tissues are carried out;

4) the arrangements for cooperation between the entities referred to in paragraph 1 on the supply and storage of cells, tissues and organs for transplantation or use in man;

5) the requirements to be met by medical records relating to the collection, storage of cells, tissues and organs for transplantation or use in humans;

– stressed the need to ensure the health safety of receivers and donors of cells, tissues or organs.

Article 36a. 1. At the request of the Tissues and Cells Institute, the head of the entity referred to in Article 36, paragraph 1) point 3) may organize a recovery team.

2. The head of the recovery team must be a doctor.

3. The tasks of the recovery team shall include, in particular:

1) the organization of the collection and supply of cells and tissues from human corpses;

2) the transfer of cells and tissues taken to tissue and cell institutes;

3) cooperation with doctors who take organs for transplantation.

4. Members of the team other than the doctor referred to in paragraph 2 shall have a medical, biological or biotechnological degree and training referred to in Article 40a, paragraph 1).

5. The tasks of the recovery team shall be financed by the Tissues and Cells Institute based on agreements with the bodies referred to in Article 36, paragraph 1) point 3).

6. The substantial control of the activities of the recovery team is exercised by the National Center for Tissue and Cell Institutes.

Article 37. 1. The procedure for the analysis of cells, tissues and organs may be undertaken only in a medical – diagnostic laboratory as defined in the Law of 27 July 2001 on laboratory diagnosis (Official Journal of laws of 2019, point 849 and 2020, points 567 and 1493), in possession of a license from the Minister of Health for the performance of such activities.

2. The provisions of Article 1 shall apply, respectively, to the permits referred to in Articles 26 and 27, paragraphs from 1 to 5.

3. In order to verify whether the laboratory referred to in paragraph 1 fulfils the requirements for obtaining the permit referred to in paragraph 1, the provisions referred to in Article 35, paragraphs from 3) to 10) shall apply respectively.

Article 37a. 1. The exports of bone marrow, hematopoietic cells of peripheral blood and umbilical cord cells from the territory of the Republic of Poland and their imports into the territory of the Republic of Poland shall be carried out by a health facility carrying out the removal or transplantation or human use of marrow, hematopoietic cells of peripheral blood or umbilical cord blood, with the consent of the Director of the Transplantation Organization and Coordination Center "Poltransplant".

2. Exports of cells or tissues taken from human corpses from the territory of the Republic of Poland and imports of such cells or tissues into the territory of Poland shall be carried out by an institute of tissues and cells with the consent of the National Centre for Tissue and Cell Institutes.

3. The transport of regenerating cells or tissues other than cells and tissues referred to in paragraph 2, from the territory of the Republic of Poland and imports of such cells and tissues into the territory of the Republic of Poland shall be carried out by a tissue and cells institute and with the consent of the Director of the National Centre for Tissue and Cell Institutes.

3a. The importation for the single use of tissues or cells in the territory of the Republic of Poland by a supplier of third countries is carried out by a tissue and cell institute with the consent of the Director of the National Center for Tissue and Cell Institutes.

4. The transport of organs from human corpses from the territory of the Republic of Poland and the transport of these organs to the territory of the Republic of Poland shall be carried out by the medical operator who collects or transplantation organs from human corpses, with the consent of the Director of the Transplantation Organization and Coordination Center "Poltransplant".

5. The consents or refusals referred to in paragraphs 1 to 4 shall be issued immediately to the entities listed in those provisions, by means of an administrative decision, on request accompanied by information on the fulfilment of the requirements referred to in paragraph 8. Such decisions shall be immediately enforced.

6. The decision of the Director of the Transplantation Organization and Coordination Center "Poltransplant" and the Director of the National Centre for Tissue and Cell Institutes may be appealed to the Minister of Health.

7. Export authorization for cells, tissues or organs shall be refused if there is a potential receiver on the compatible transplantation list.

8. The bodies which have obtained the consents referred to in paragraphs 1 to 4 shall ensure:

1) monitoring the condition of cells, tissues and organs exported and imported on the journey between donor and receiver;

2) the quality and safety of imported and exported cells, tissues and organs intended for transplantation or intended for human use.

9. The import and export data listed:

1) in paragraphs 1 and 4 - are taken and stored by the Transplant Organization and Coordination Center "Poltransplant";

2) in paragraphs 2 to 3a – are taken and preserved by the National Centre for Tissue and Cell Institutes.

10. The data referred to in paragraph 9 shall be made available to the Minister for Health and the National Council of Transplantation.

11. The Minister for Health shall lay down, by means of an order, the conditions for the transport of human cells, tissues and organs from the territory of the Republic of Poland and for imports of such cells, tissues and organs into the territory and the procedures for monitoring the condition of human cells, tissues and organs during the journey between donor and receiver, in order to ensure the quality and safety referred to in paragraph 8, point 2), and taking into account the health safety of the receiver.

Chapter 7

Labelling, monitoring and criteria for the safety and quality of cells, tissues and organs

Article 37b. 1. The Tissues and Cells Institute shall label cells and tissues in such a way as to identify the donor by means of a single European code at the latest before they are put into circulation or distributed for transplantation or human use.

2. Tissue and cell institutes, the medical institution referred to in Article 36, paragraph 1) points 1) 2) and (5) and the medical diagnostic laboratory referred to in Article 37, paragraph 1) shall label, in such a way that the donor can be identified with a single or code, without the need for a single European code:

1) organs;

2) cells and tissues:

a) imported into the territory of the Republic of Poland in the event of an emergency;

b) distributed directly for immediate transplantation or human use by a tissue and cell institution, which holds valid licenses;

c) intended for experimentation.

3. The identification referred to in paragraph 1 shall ensure that data concerning the collection of cells, tissues or organs, their admission to a tissue and cell institution or health facility referred to in Article 36, paragraph 1) points1) 2) and 5) or to a medical-diagnostic laboratory referred to in Article 37, paragraph 1) and their control, processing, sterilization, preservation and distribution can be identified.

4. The institution of tissues and cells, the health structure referred to in Article 36, paragraph 1), points 1) and 3) and the medical-diagnostical laboratory referred to in Article 37, paragraph 1) shall be required to:

1) assign a sequence of identification of donations after tissue or textile removal or when they are received by a receiving foreign entity, or when tissues or cells are imported from a supplier in a Member State which includes:

a) the European Code for Tissue and Cell Institutes as defined in the European compendium of tissue and cell institutes;

b) the single donation number assigned by the institute of tissues and cells, unless this number is centrally assigned at national level and used under the ISBT 128 coding system;

2) maintain the sequence of identification of donations after it has been assigned to tissues or cells put into circulation, unless this is necessary for the purpose of having any coding error, and requires confirmation by the head of a tissue and cell institute, or in a health facility referred to in Article 36, paragraph 1), points 1) and 3), or by the diagnostic laboratory referred to in Article 37, paragraph 1);

3) use one of the authorized tissues and cell coding systems and their tissue and cell numbers included in the European compendium of tissues or cells processed at the latest before distribution for transplantation or human use;

4) use an appropriate division number and the expiry date of the tissues or cells; in the case of tissues or cells for which there is no expiry date, the expiry date shall be, at the latest, the date specified as "00000000" before their distribution for transplantation or human use;

5) use a single European code on the label of the tissues or cells in question, affixed in an indelible and lasting manner, and the indication of this code in the dossier referred to in Article 34, paragraph 1) no later than the date of distribution of tissues and cells for transplantation or human use;

6) notify the National Center for Tissue and Cell Institutes if:

a) the information contained in the European compendium of Tissues and Cells institutions requires updating or correction;

b) the European compendium of processed Tissues and Cells requires updating or correction;

c) a Tissues and Cells institute shall note a case of non-compliance with the Single European Code for tissues or cells received from other Tissues and Cells institutes established in the territory of the Member States of the European Union;

7) take the necessary measures in the event of incorrect application of the single European code on labelling, to take in formed, corrective and preventive action.

Article 37c. 1. The Tissues and Cells Institute, a health facility referred to in Article 36, paragraph 1), points 1), 2) and 5), and the medical-diagnostic laboratory referred to in Article 37, paragraph 1), shall be required to:

1) apply security and data protection measures to prevent unauthorized additions, deletions of information or changes to donor medical records and the transfer of information to unauthorized persons;

2) apply the procedures to resolve data discrepancies;

3) ensure protection against unauthorized disclosure of the data referred to in Article 37b, paragraph 2 while ensuring the traceability of cells, tissues or organs taken, controlled, processed, stored and distributed.

2. Traceability referred to in paragraph 1, point 3) shall mean:

1) the ability to locate and identify cells, tissues or organs at any stage after sampling, during testing, processing, storage, distribution to the receiver or disposal;

2) the ability to identify the receiver of the cell, tissue or organ;

3) the ability to identify and identify all relevant data relating to medical devices and materials that encounter cells, tissues or organs.

3. An institution of tissues and cells, a health facility referred to in Article 36, paragraph 1), points 1) 2) and 5) and the medical-diagnostic laboratory referred to in Article 37, paragraph 1), shall also be required to monitor the following:

1) cells, tissues or organs taken, processed, stored or distributed;

2) medical devices and materials in direct contact with cells, tissues or organs.

Article 37d. An institution of tissues and cells, a health facility referred to in Article 36 paragraph 1) points 1), 2) and 5) and a medical-diagnostic laboratory referred to in Article 37, paragraph 1) shall be required to:

1) validate all processes;

2) identify the critical moments of all processes that should be controlled based on the designated acceptance criteria;

3) to qualify equipment, technical devices and the process environment as a documented action to demonstrate that such environments, equipment or devices are installed and are functioning properly

– in order to ensure the quality and safety required for the type of cells, tissue or organ and to obtain the expected results.

Article 37e. The Minister for Health shall establish, by means of an order:

1) how to create a single label enabling the identification of cells or tissues and the ways in which cells or tissues are to be labelled - in the form of the application of a single European code;

2) how to create a single label enabling the identification of the donor of cells or tissues and the manner in which cells or tissues are to be labelled, without the application of the Single European Code, in the cases referred to in Article 37b, paragraph 2) point 2);

3) how to create a single label enabling organ donors to be identified and how organs are marked with this label

4) the control requirements referred to in Article 37c, paragraph 3)

– stressed the need to ensure the health safety of receivers and the ability to correctly analyze and trace the passage of tissues and cells from donor to receiver and vice versa.

Chapter 8

Transplantation Organization and Coordination Center "Poltransplant", the National Center for Tissues and Cells Institutes and the National Committee of Transplantation

Article 38. 1. The Transplantation Organization and Coordination Center "Poltransplant" is established with its registered office in Warsaw.

2. The Transplantation Organization and Coordination Center "Poltransplant" is a budget unit under the responsibility of the Minister of Health.

3. The tasks of the Transplantation Organization and Coordination Center "Poltransplant" are to:

1) coordinate the collection and transplantation of cells, tissues and organs in the country;

2) keep a central register of objections;

3) keep a national waiting list for transplantation;

4) keep a transplant register;

5) keep a register of living donors;

6) keep a record of bone marrow and umbilical cord blood;

7) coordinate the search for unrelated donors of bone marrow and umbilical cord blood with preliminary research in the bone marrow and umbilical cord blood register;

8) carry out educational activities aimed at spreading the treatment by transplantation of cells, tissues and organs;

9) cooperate with other national and external entities in the field of cell exchange, tissues and organs for transplantation;

10) submit to the Minister of Health the proposals referred to in Article 22, paragraph 4);

11) receive applications from the bodies referred to in Article 36, paragraph 1), points1) 4) and (5);

12) organize training courses referred to in Article 40a, paragraph 1) on the collection, storage and transplantation of organs and bone marrow and peripheral blood cells;

13) keep a list of persons who have completed the training referred to in Article 40a, paragraph 1) on the collection, storage and transplantation of organs and bone marrow and hematopoietic cells of peripheral blood;

14) transfer the data referred to in Article 16, paragraphs 3) and 4) to the European and world registers of bone marrow and umbilical cord blood.

4. The Transplantation Organization and Coordination Center "Poltransplant" shall be managed by the rector appointed and dismissed by the Minister of Health, after consulting the National Committee for Transplantation.

5. The Minister of Health shall assign, by means of an ordinance, the statutes of the Transplantation Organization and Coordination Center "Poltransplant", specifying the detailed organizational structure and specific scope of its tasks, taking into account the safety of the receivers and the need to carry out the tasks referred to in paragraph 3.

Article 39. 1. A National Center for Tissues and Cells Institutes shall be established with its registered office in Warsaw.

2. The National Center for Tissues and Cells Institutes shall be a budgetary unit under the authority of the Minister for Health.

3. The National Center for Tissues and Cells Institutes has the tasks of:

1) organize the interaction between tissue and cell institutions;

2) carry out reference and advisory functions;

3) supervise and control tissue and cell institutions in relation to their substantial content;

4) keep a register of tissues and cells institutions;

5) organize the training courses referred to in Article 40, paragraph 1) in the field and sampling, analysis, processing, sterilization, storage and distribution of cells and tissues;

6) keep a list of persons who have completed the training referred to in Article 40a, paragraph 1); in the field of collection, analysis, processing, sterilization, storage and distribution of cells and tissues;

7) exercise substantial control over the activities of the recovery teams;

8) monitor data on tissues and cells institutes taken in the European compendium of tissues and cells institutes and, in the event of irregularities in this regard, inform the entity managing the European compendium of tissues and cells institutes at the European Commission within 10 days.

3a. The National Center for Tissues and Cells Institutes may reimburse, in bone marrow donation centers, the remuneration costs of the persons referred to in Article 16a, paragraph 4) based on a contract.

4. The National Center for Tissues and Cells Institutes shall be managed by the Director appointed and dismissed by the Minister for Health after consulting the National Council of Transplantation.

5. The National Center for Tissues and Cells Institutes may carry out the activities referred to in Article 25 exclusively for scientific and educational purposes, after the opinion of the National Council for Transplantation and obtaining a license referred to in Article 26, paragraph 2);

6. The activities and actions carried out by the National Center for Tissues and Cells Institutes, the operations referred to in Article 25 shall apply to the provisions of Chapter 6, except for Article 26, paragraph 1) and 2). The application for authorization must be submitted to the Minister of Health.

7. The Minister of Health shall assign, by means of an ordinance, the statutes of the National Center for Tissues and Cells Institutes, defining their organizational structure and the specific scope of the tasks, considering the safety of the receivers and the need to carry out the tasks referred to in paragraph 3 smoothly.

Article 40. 1. The National Center for Tissues and Cells Institutes shall keep a register of tissues and cells institutes.

2. The register shall be public.

3. The following data on tissues and cells institutions shall be kept in the register:

1) the name of an institute of tissues and cells;

2) the number of entries in the business register in the National Register of Courts or in a relevant register, provided that the institution of tissues and cells has that number, and the tax identification number (TAX CODE);

3) address;

4) the scope of the activities.

4. The data referred to in paragraph 3 shall also be made available electronically.

5. The register shall also make available the data contained therein within the network of Member States of the European Union in accordance with the procedures established by common agreement with the European Commission.

Article 40a. 1. Training is provided for persons whose activities directly affect the quality of cells, tissues or organs and the safety of donors and receivers by:

1) Transplantation Organization and Coordination Center "Poltransplant", for coordinators of cells, tissues and organ collection and transplantation about the supply, storage and transplantation of organs and marrow, hematopoietic cells of peripheral blood and umbilical cord blood;

2) National Centre for Tissues and Cells Institutes in the field of sampling, analysis, processing, sterilization, storage and distribution of cells and tissues and the removal of bone marrow, hematopoietic cells of peripheral blood and umbilical cord blood.

2. The training referred to in paragraph 1 shall be provided in the form of training:

1) initial - for new recruitment;

2) continues, at least every 2 years - for all employees;

3) updating - in case of changes in procedures or developments in scientific knowledge concerning the collection, storage and transplantation of cells, tissues and organs.

3. The training referred to in paragraph 1 shall be carried out in accordance with a program developed by the bodies referred to in paragraph 1, based on a training framework defined by the provisions issued in the light of paragraph 8.

4. The training referred to in paragraph 1 shall aim to:

1) acquire skills in carrying out the assigned tasks;

2) acquire adequate knowledge and understanding of the processes and principles of the tasks performed;

3) include the organizational structure, quality assurance system and health and safety principles of the unit in which they are employed;

4) obtain relevant information on the ethical and legal aspects of activities related to the collection, analysis, processing, sterilization, storage and distribution of cells, tissues and organs.

5. The training referred to in paragraph 1 shall be documented and, at the end, participation and results shall be certified.

6. The training referred to in paragraph 1 shall be free of charge and financed from the state budget funds available to the Minister of Health, intended to finance the National Centre for Tissues and Cells Institutes and the Transplantation Organization and Coordination Centre "Poltransplant".

7. The training centers referred to in paragraph 1 shall be required to meet the relevant requirements, in particular:

1) ensure a teaching base adapted to the number of people participating in the training;

2) ensure the appropriate teaching staff;

3) ensure an efficient organization of training;

4) consider, in the preparation of the training program, current knowledge of the theory and practice and verified scientific results.

8. The Minister for Health shall, by means of an ordinance, lay down the training framework programs referred to in paragraph 1, the procedures for documenting their progress, a model of the training certificate and the detailed requirements for the units in which these training courses are carried out, taking into account the need to achieve the objectives referred to in paragraph 4.

Article 41. 1. The National Transplant Council ('Council') shall be established as an advisory body of the Minister of Health.

2. The Council shall consist of no more than 31 members appointed for a period of 4 years by the Minister of Health, including experts in various fields of science, and a representative of the Supreme Medical Chamber. The Minister of Health appoints the President of the Council from among its members.

3. Members of the Council shall be entitled to remuneration for their participation in a Council meeting and a meeting of the Ethics Committee.

4. The Minister for Health shall dismiss a member of the Council before the end of his term of office in the event of:

1) resignation;

2) loss of ability to carry out the tasks entrusted to them as a result of a prolonged illness;

3) unjustified absences at four consecutive Council meetings;

4) a final conviction for an intentional offence.

5. In the event of dismissal of a member of the Council or death before the end of his term of office, the Minister for Health shall appoint a new member for a period or ending at the end of that term of office in

accordance with paragraph 2, unless there are less than 3 months remaining at the end of his term of office.

6. The tasks of the Council shall include, in particular:

1) the expression of an opinion on programs for the collection, storage and transplantation of cells, tissues and organs;

2) the expression of an opinion on the activities:

a) of the Transplantation Organization and Coordination Center "Poltransplant",

b) of the National Centre for Tissues and Cells Institutes;

3) the carrying out of information activities in the field of the removal of cells, tissues and organs to save lives and health;

4) the expression of an opinion on draft laws on the collection, storage and transplantation of cells, tissues and organs;

5) cooperation with national and foreign organizations and associations aimed at the development of technology, and with the medical community;

6) the opinion on the applications referred to in Articles 26, paragraph 1) and 36, paragraph 4);

7) the expression of an opinion on requests for transplantation of cells, tissues and organs taken from animals;

8) the expression of an opinion on:

a) compliance with legal requirements by licensed tissues and cells institutions, bodies referred to in Articles 36, paragraph 1) points 1) 4) and (5) and by medical-diagnostic and entity laboratories already in possession of such authorizations;

b) compliance with the procedures laid down for the removal, storage and transplantation of cells, tissues and organs, and compliance with the conditions required by the system set up to ensure quality, on the basis of serious adverse reactions and serious adverse events reported by operators, for the preservation and transplantation of cells, tissues and organs;

c) the quality of health services provided for the removal, storage, transplantation and distribution of cells, tissues and organs;

9) the preparation of annual reports for the Minister of Health on the results of transplantation of cells, tissues and organs, based on the materials made available by the Transplantation

Organization and Coordination Centre "Poltransplant", the National Centre for Tissues and Cells Institutes and other institutions associated with the procedure for the collection and collection of cells, tissues and organs.

7. The Council shall have an ethics committee of 7 people appointed by the Minister for Health, chosen from among its members, whose task is to deliver opinions on the matters referred to in Article 13, paragraph 1).

8. The Minister for Health shall grant, by means of an order, the status of the National Council of Representatives, specifying the scope, organization, procedure of its activities, including the Ethics Committee, the procedures in which members of the Council are remunerated and the procedure for expressing opinions, taking into account the need for the Council's tasks to be carried out efficiently.

Chapter 9

Supervision

Article 42. 1. The Minister of Health supervises the application of the provisions of the law.

2. Within the framework of the supervision referred to in paragraph 1, the Minister for Health shall carry out the following tasks:

1) obtain or request information in the form of reports on the and activities of the Council, the National Center for Tissue and Cells Institutes and the Transplantation Organization and Coordination Center "Poltransplant";

2) check the keeping of the registers and lists referred to in the law;

3) grant or refuse licenses to tissue and cells institutions, to the bodies referred to in Article 36, paragraph 1), points 1) 4) and (5), and to centers and laboratories for bone marrow donation, and revoke such licenses after consulting the Council;

4) carry out or have carried out the inspections provided for by law;

5) provide, at the request of the European Commission or the competent authority of another Member State of the European Union, written information on the results of the checks referred to in Article 35 as regards compliance with the provisions of Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004.

3. The Minister of Health:

1) updates the European Commission once every 3 years:

a) the activities undertaken on the territory of the Republic of Poland concerning the promotion of the donation of cells, tissues and organs;

b) the detailed rules for implementing the provisions of this Directive in the territory of the Republic of Poland;

1a) submit annually to the European Commission, by 30 June, the annual report on the notification of serious adverse events linked to the removal, testing, work, sterilization, storage, distribution, import and export, transplantation or human use of cells and tissues;

2) carry out the inspection referred to in Article 35 based on a written and reasoned request from the competent authority of another Member State of the European Union in the event of a serious adverse reaction or a serious adverse event following a transplant;

3) provide, at the request of the European Commission or the competent authority of another Member State of the European Union, written information on the results of the checks referred to in Article 35, made following the request referred to in point 2.

Chapter 10

Criminal positions

Article 43. A person who makes an announcement to sell, acquire or broker the removal or acquisition of a paid cell, tissue or body is subject to a fine, a restriction of liberty or a prison sentence of up to one year.

Article 44. A person who acquires, disposes a cell, tissue or organ, or participates in the collection, transplantation of cells, tissues or organs, or the use of human cells or tissues, or makes them available not in accordance with the provisions of this Law from a living donor or corpse or hand, shall be subject to the penalty of deprivation of liberty for a period of 6 months to 5 years.

2. Where the author of the act referred to in paragraph 1 has acted in relation to acritical situation in which he himself or the person closest to him was located, the tribunal may apply an exceptional mitigating factor or waive its imposition.

3. If the offender has received a regular source of income from the commission of the offence referred to in paragraph 1, he shall be punishable by a sentence of between 1 and 10 years.

Article 45. Any person who, without the required license, carries out the activities provided for in the provisions of this Law for tissue and cell institutions shall be liable to a fine, a penalty of restriction of liberty or a prison sentence of up to one year.

Article 46. 1. Any person who, without the required license or contrary to the provisions of this Law, collects a cell, tissue or organ, or transplantation a cell, tissue or organ or uses a cell or tissue in human, shall be liable to a fine, a custodial sentence or a prison sentence of up to three years.

2. The head of a medical entity which, contrary to a specific supervision obligation of this entity, allows the removal of a cell, the transplantation of a cell, tissue or organ or the use in man of a cell or tissue without the required license shall not take the measures provided for by the Law on the removal, transplantation or use of a cell, tissue or organ in human, and shall be liable to a fine, a penalty of restriction of liberty or a prison sentence for a period of up to 3 years.

Article 46a. Anyone, without the consent required, exports from the territory of the Republic of Poland or imports a cell, tissue or organ into the territory, is liable to a fine, a penalty of restriction of freedom or a prison sentence of up to three years.

Article 46b. Anyone, contrary to the provisions of the law, it does not report potential receivers of organs or marrow or hematopoietic cells of peripheral blood or umbilical cord blood to the register of transplantation of cells, tissues and organs, or potential donors of bone marrow and hematopoietic cells of peripheral blood to the register of bone marrow and umbilical cord blood, is subject to a fine or penalty of restriction of freedom.

Chapter 11

Changes to existing legislation

Article 47. (omitted)

Article 48. (omitted)

Chapter 12

Transitional, adaptation and final provisions

Article 49. The existing rules shall apply to the provisions of Article 58 of the Act which have been immediately initiated pursuant to Articles 7, 9 and 10 of the Act referred to in Article 58, and not completed by the date of entry into force of this Law.

Article 50. 1. The National Center for Tissues and Cells Institutes assumes all the rights and obligations of the National Center for Tissues and Cells Institutes based on current rules.

2. The ownership of the National Centre for Tissues and Cells Institutes created in accordance with current regulations becomes, by virtue of the law, the property of the National Center for Tissue and Cell Institutes.

3. The transfer of the rights and property of the National Centre for Tissues and Cells Institutes established based on the rules in force on the National Center for Tissues and Cells Institutes shall be exempt from expenses, fees and taxes.

4. Employees of the National Center for Tissues and Cells Institutes, based on the provisions in force, become employees of the National Center for Tissues and Cells Institutes on the day of the entry into force of this Law.

Article 51. 1 The Transplant Organization and Coordination Centre "Poltransplant" assumes all the rights and obligations of the Transplant Organization and Coordination Centre "Poltransplant" operating based on existing rules.

2. The ownership of the Transplant Organization and Coordination Centre "Poltransplant" created according to the current rules becomes, by virtue of the property of the Transplant Organization and Coordination Centre "Poltransplant".

3. The transfer of rights and property of Transplant Organization and Coordination Centre "Poltransplant", established based on the rules in force on the Transplant Organization and Coordination Centre "Poltransplant", is exempt from expenses and taxes.

4. Employees of the Transplant Organization and Coordination Centre "Poltransplant", based on current provisions, become employees of the Transplant Organization and Coordination Centre "Poltransplant" on the day of the entry into force of this Law.

Article 52. (omitted)

Article 53. Health services or other organizational units which keep national lists of persons waiting for transplantation shall forward these lists free of charge within 30 days of the date of entry into force of this Law to the Transplant Organization and Coordination Centre "Poltransplant".

Article 54. The central register of objections kept in accordance with the existing provisions shall become, on the date of entry into force of the central law, the central register of objections.

Article 55. (omitted)

Article 56. (omitted)

Article 57. (omitted)

Article 58 The Law of 26 October 1995 on the collection and transplantation of cells, tissues and organs (Official Journal No 682, 1997, Nos 554 and 661 and 2000 item 1268) expires.

Article 59. The Act shall enter into force on 1 January 2006, except as follows:

1. Articles 22 to 35, paragraph 1), 2) and 11) and Articles 36 and 37;

2. Articles 38, paragraph 3) point 11), Article 39, paragraph 6), 41, paragraph 6), points 6), 8) letter a), Article 42 paragraph 2), points 3) and 5), Articles 45 and 48

– which applies from 31 December 2006