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Act CLIV of 1997 on Health Care

Chapter XI Organ and tissue transplantation

Article 202

(1) For the purposes of this Chapter

a. 'organs and tissue transplantation': removal of organs and tissues from the human body and their transplantation into the body of another living person for the purpose of restoring certain functions of the human body;
b. 'donor': person who donates organs or tissues for transplantation into another person or from whose body organs or tissues are removed after death for transplantation into the body of another person;
c. 'recipient': person into whose body an organ or tissue removed from another person is transplanted for medical treatment;
d. 'brain death': complete and irreversible cessation of brain function, including the brain stem;
e. 'death': when the complete cessation of respiration, circulation and brain function leads to the irreversible disintegration of the body.

(2) The provisions of this Chapter relating to tissue shall apply to cells, with the exception of sperm and ova.

Article 203

(1) Organs and tissues removed from a dead person shall be used primarily for transplantation.
(2) Organ transplantation shall be carried out with the highest possible level of protection for living donors, while guaranteeing the quality and safety of the organ to be transplanted.
(3) Organs and tissues removed from a living or deceased person that can be used for transplantation shall be stored in an organ and tissue bank for permanent storage.
(4)
(5) Detailed rules on organ,tissue and cell transplantation and storage shall be laid down by the Minister in a decree.

Removal of organs and tissues from the body of a living person

Article 204

(1) Every organ or tissue removed from a living person shall - with the exceptions provided in subsection (2) - be subjected to a histopathological examination.
(2) A histopathological examination is not required,

a) if the purpose of the removal is the transplantation into the body of another person,
b) if the purpose of the removal is to carry out a special diagnostic test, and
c) in the case of certain organs or tissues specified in an order by the Minister.

Article 205

(1) Only the following organs and tissues may be removed from the body of a living person for the purpose of transplantation into the body of another person:

a) one of a paired organ the removal of which does not cause serious and permanent disability,
b) a part of an organ (organ segment) which, if removed, will continue to function without significant loss of function;
c) regenerating tissue.

(2) The rules applicable to organ transplantation shall also apply in the case of paragraph 1(b).

Article 206

(1) An organ or tissue may be donated only by a person who is capable of doing so, except for paragraph (5).

(2) An organ may also be donated by a person who has the capacity to act only if the donor for the recipient is

a) a direct relative,
b) a brother or sister of a relative in the same line of kinship,
c) a brother or sister,
d) a relative in the direct line of a brother or sister.

(3) Exceptionally, an organ may also be donated in the absence of the conditions set out in paragraph 2. In this case, the joint application of the donor and the recipient shall be examined by the hospital ethics committee. The hospital ethics committee shall consent to the removal of the organ if it is satisfied that there is a close emotional link between the donor and the recipient and that the donation was made without consideration and free from coercion, threats or deception.

(4) A detained person may be an organ donor only in the case referred to in paragraph (2).

(5) The removal of bone marrow or haematopoietic stem cells or other regenerative tissues from the body of a minor with exceptional incapacity, a person partially incapacitated or a person with partial incapacity with regard to health care rights may also be performed, if the following conditions are met:

a) there is no suitable donor with sufficient capacity,
b) the recipient is a sibling of the donor,
c) the donation is likely to be life-saving for the recipient,
d) the consent of the legal representative has been approved by the hospital ethics committee,
e) the person concerned has been interviewed by the hospital ethics committee before taking a decision under (d), unless his or her health or age precludes it, and it is satisfied that he or she will submit to the intervention free from coercion, threats or deception.

Article 207

(1) The donation of organs or tissues may be made only for no consideration.

(2) The donor shall be entitled to reimbursement of his/her medical expenses incurred in connection with the donation and not reimbursed from other sources, as well as reimbursement of his/her loss of income in connection with the donation and of the expenses actually incurred and certified in connection with the travel, not covered by his/her social security status, upon making a declaration of donation. The additional transport costs incurred in the event of the transfer of the donor to the health establishment where the organ is retrieved shall also be reimbursed. These costs shall be paid by the body responsible for managing the fund and reimbursed by the budget.

(3) The payment to the donor of a justifiable fee for legitimate medical or related technical services provided in connection with the transplantation shall not be considered as consideration for the donation within the meaning of paragraph 1.

Article 208

Before performing the transplantation of an organ or tissue, the physician performing the removal or transplantation of the organ or tissue must document that the conditions for the removal of the organ or tissue are met in the donor, that it is not medically contraindicated, that the transplantation is justified in the recipient, that the conditions for the transplantation are met and that the organ is suitable for transplantation.

Article 209

(1) Prior to the removal of an organ or tissue, the donor shall be informed orally and in writing, in addition to the general rules (Article 13), in detail of all relevant circumstances relating to the intervention, in particular the expected long-term and short-term consequences of the removal of the organ or tissue, the absence of the organ, and the fact that the organ donor must undergo a mandatory autopsy in the event of death. The donor shall be informed by a doctor who is not directly involved in the transplantation.

(2) In the case of organ donation, the donor's consent shall be recorded in a public deed. In addition to the general requirements of consent, the instrument shall also contain a declaration by the donor that the donation has been made free of coercion, threats or deception, without consideration and without any form of compensation, and that he or she consents to a post-mortem examination.
(3) In the case of a donation of tissue, the donor's consent shall be recorded in a private document with full probative value.
(4) The consent of the donor may be withdrawn at any time, without formal obligation, until the removal of the organ or tissue. Even in the case of valid consent, the physician may decide not to proceed with the removal of the organ or tissue if a situation has arisen in the meantime which endangers the life or health of the donor.
(5) The recipient shall be informed in accordance with the general rules (Article 13) of all relevant circumstances relating to the intervention, in particular

a) of the consequences that the donation of the organ may have for the donor's state of health, and
b) that in the event of death the recipient must undergo an autopsy,
c) of the origin of the organ or tissue to be transplanted into his/her body.

(6) The recipient's consent to transplantation must be in writing.

Article 210

If, as a result of the removal of the organ or tissue, the donor has suffered damage to his health or physical integrity, not including damage resulting from the absence of the removed organ or tissue, or has become disabled or has died, and this is not attributable to the health care worker who performed the intervention, the State shall compensate him/her or the dependants for any damage which is not covered by social security.

Article 210/A

(1) Any organ, tissue or biological material from a living person that remains after a diagnostic laboratory examination, with the exception of DNA samples, which, after the purpose of removal has been achieved or failed, can no longer be used for the purpose of removal or for any other purpose in the interest of the person concerned, shall be returned to the person concerned or replaced in accordance with Article 16 or, in the absence of a prior written statement in writing or, in the case of incapacity to write, an oral statement of objection in front of two witnesses, the health care establishment may use it, in a manner that renders it permanently unidentifiable, for the purposes of meeting the quality assurance requirements for diagnostic laboratories and for research and teaching purposes.
(2) The person concerned shall be informed in advance of the possibility of making a statement of objection pursuant to paragraph (1). The statement of objection or, in the case of an oral statement, a record of it shall be kept as part of the medical records of the person concerned.

Removal of an organ or tissue from a dead person

Article 211

(1) Organs or tissues may be removed from a deceased person for transplantation if the deceased person did not object to this during his or her lifetime. An objection may be made in writing (in an authentic instrument or a private document with full probative value) or orally to the attending physician if the person who has the capacity to act is unable to make a written declaration or can make one only with considerable difficulty. A minor with reduced capacity to act and a person with partially reduced capacity to act may make an objection without the assistance of his or her legal representative. A person who lacks capacity may be replaced by his or her legal representative.
(2) The attending physician must ascertain within the time allowed for the removal of the organ or tissue whether the deceased has a statement of objection.
(3) If the written statement is not produced within the time allowed for removal or is not submitted to the attending physician, it shall be presumed to be missing.

(4) If the deceased was a minor and no statement of objection can be found, the removal of organs or tissues may only be started if the legal representative has given his/her written consent.

Article 212
(1) The removal of an organ or tissue may be commenced if the members of a three-member medical committee (hereinafter referred to as "the committee"), independently of each other, have unanimously established the presence of brain death in the manner specified in the Minister's decree.
(2) The members of the committee shall be medical specialists appointed by the director of the medical institution for this purpose, who have sufficient experience and have undergone further training for this purpose.
(3) A physician who is involved in the removal or transplantation of an organ or tissue or in the treatment of the recipient shall not be a member of the committee.
(4) The committee shall record in a report the results of the clinical and instrumental examinations and the probable cause of death.
(5) After brain death has been established, mechanical ventilation and artificial maintenance of other functions of the body shall be justified only if it is carried out in order to preserve the functionality of the organs or tissues to be used for transplantation.

Article 213
Organs and tissues removed from the deceased for transplantation but not used shall be subjected to histopathological examination.

Article 214
Unless otherwise provided by law, organs and tissues may also be removed from the victim of a crime for the purpose of organ and tissue transplantation, within the limits set out in Article 211, if the court, the prosecution or the investigating authority has given its prior written consent. In this case, the lesions caused during the operation must be documented in detail.

Organ and tissue transplantation

Article 215
(1) A patient in whom organ or tissue transplantation is medically justified and meets the conditions laid down in a special act shall be included in the national waiting list for each type of organ or tissue. Admission is initiated by the healthcare provider who has established the indication for organ or tissue transplantation.
(2) The patient shall be informed of all relevant circumstances relating to his/her inclusion on the waiting list.
(3) The selection of recipients from the waiting list shall be carried out exclusively in accordance with professional rules.
(4) Professional control of the placement on the waiting list, selection from the list and investigation of patients' complaints shall be carried out by the public health administration.
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Decree 18/1998 (XII. 27.) of the Ministry of the Environment on the implementation of the provisions of Act CLIV of 1997 on Health Care concerning organ and tissue transplantation and storage and certain pathological examinations

Act CLIV of 1997 on Health Care (hereinafter referred to as the Health Care Act)

203 (5), 204 (2) (c) and 204 (2) (c) of the 247(2)(q), I hereby order the following:

Article 1

This Regulation shall apply to

a) the donation, removal, testing, processing, preservation, storage and distribution of human tissues and cells intended for human use [Article 3/A (a) the Act], except for tissues and cells used as autologous transplants in the same surgical procedure;
b) the health care service related to organ or tissue transplantation, the providers of the service and the recipients of the service, including the making and recording of the statement of objection pursuant to Article 211 (1) of the Act;
c) the pathological examination [Article. 204 of the Health Care Act];
d) for human tissues and cells products manufactured.

Article 1/A

For the purposes of this Regulation

1. donation: the provision of organs for transplantation and of tissues and cells for human use;
2. disposal: the final disposal of an organ that is not transplanted;
3. distribution: the transport and transfer of tissues and cells intended for human use;
4. human use: the use of tissues and cells on or in the body of the recipient, or use outside the body;
5. 'organisation responsible for human application' means a healthcare provider or an organisational unit of a healthcare provider providing in-patient specialist care that uses human tissues and cells for transplantation;
6. processing: all operations related to the preparation, handling, preservation and packaging of tissues and cells intended for human use;
7. authorised organisation: an organ exchange organisation which is party to the agreement on the basis of an agreement concluded between the competent authorities pursuant to § 1/B and the National Blood Service (hereinafter referred to as the "NBS") for the performance of specific quality and safety tasks in connection with organ exchange to and from a Member State and third countries party to the Agreement on the European Economic Area;
8. collection: the process by which tissues and cells are made available, i.e. by which tissues and cells are removed and then transported to the first tissue bank for storage;
9. procurement organisation: a healthcare provider that collects human tissues and cells without processing or storing them;
10. gametes: all tissues and cells intended for use in assisted reproduction;
11. quarantine: the physical or other isolation of removed tissues or cells pending a decision on their acceptance or rejection;
12. critical: any relevant activity, condition or means that may affect the quality and safety of cells and tissues in contact with them during their collection, processing, preservation, storage, transport and distribution;
13. quality management system: the organisational structure, defined responsibilities, processes, procedures and resources for implementing quality management, including activities that contribute directly or indirectly to quality;
14. certification: the verification that a process, professional procedure, equipment or environment consistently meets the specifications and quality requirements set out in standards; certification is used to assess the effectiveness of a system;
15. operational specifications: the steps in a specific process - including the materials and methods to be used and the expected end result;

16. national donor/recipient identification number: the identification code assigned to a donor or a recipient in accordance with the identification system established at Member State level pursuant to Article 16/D(2);
17. traceability: the location and identification of a tissue, cell or organ at each step of the process from collection or donation, through processing, testing and storage, to organ or tissue transplantation, or destruction or disposal, including identification of the donor, recipient, tissue bank, and the health care provider performing the procurement and transplantation; and includes the provision of all relevant non-personally identifiable information relating to products and materials that come into contact with tissues, cells or organs;
18. donation between partners: donation of gametes between a man and a woman who meet the requirements of Decree 30/1998 (VI.24.) NM on the detailed rules for the performance of special procedures for human reproduction, the disposal and frozen storage of gametes and embryos;
19. preservation: the use of chemicals, modified environmental conditions or other means to prevent or delay changes in the biological or physical condition of cells, tissues and organs during processing;
20. Member State of destination: a Member State party to the Agreement on the European Economic Area to which the organ is being sent for transplantation;
21. serious adverse event: an unintended, unexpected, adverse event related to any stage of the process of testing, processing, storage and distribution of tissues and cells, and from donation to transplantation of an organ, which may lead to the transmission of a communicable disease, death of the patient, or endanger life, permanent disability, loss of working capacity or incapacity, or which requires or results in, or prolongs, institutionalisation, and, in the case of special procedures for human reproduction, any misidentification or inversion of gametes or embryos;
22. serious adverse reaction: an adverse reaction, including the transmission of an infectious disease, on the part of the donor or recipient's organisation to the human use of tissues and cells and to any stage of the process from donation to transplantation of an organ - which results in death, or endangers life, permanent disability, incapacity or disability, or which requires or may result in, or prolong, institutionalisation;
23. professional procedure: a written instruction describing the steps of a process, including the materials and methods to be used, and the expected result;
24. Member State of origin: a Member State party to the Agreement on the European Economic Area in which the organ was removed for transplantation;
25. procurement: the process by which donated organs become available;
26. cell bank: a healthcare provider that carries out the screening of cell donors, the processing, preservation, storage, distribution and transfer of cells to the healthcare provider performing the transplantation;

26a. tissue bank: a health care provider that provides tissue donors screening, processing, preservation, storage, distribution and transfer of tissues to the health care provider performing the transplant;

27. storage: the holding of tissues and cells under properly controlled conditions until distribution;
28. donation identification character set: first character of the unique European code

which consists of the tissue bank code and the unique donation number;

29. sublot number: a number that distinguishes and uniquely identifies tissues and cells from the same tissue bank with the same unique donation number and the same product code, as set out in Annex 15;

30. unique donation number: a unique number assigned to the specific case in accordance with the system for assigning such numbers in the Member State concerned, as set out in Annex 15;

31. pooling: the physical contact or mixing in a single container of tissues and cells from more than one collection from the same donor or from two or more donors;

32. Single European Code: for tissues and cells distributed in the European Union

an identifier unique to each cell, including the donation identification string and the product identification string, as set out in Annex 15;

33. EUTC: product coding system developed by the European Union for tissues and cells, which registers all types of tissues and cells in the European Union and the corresponding product codes;

34. released: a cell and tissue product distributed or transferred for human use, whether or not it is returned to the original tissue bank;

35. expiry date: the date until which tissues and cells can be used;

36. tissue bank EU code: the unique identifier of the tissue bank, which consists of an ISO country code and the number of the tissue bank as defined in the EU collection of tissue banks;

37. EU Collection of Tissue and Cell Products: a collection of tissue and cell types marketed in the European Union and product codes corresponding to the permitted coding systems (EUTC, ISBT128 and Eurocode);

38. EU collection of tissue banks: a collection of all tissue banks accredited, designated, authorised or licensed by the competent authority of the Member States and containing the information as specified in Annex 15;

39. product identification character set: second part of the European Unified Code,

which consists of the product code, the number of sublots and the expiry date;

40. product code: identifier that specifies the specific type of tissue and cell, consisting of the product coding system identifier indicating the coding system used by the tissue bank ('E' for EUTC, 'A' for ISBT128, 'B' for Eurocode) and the tissue and cell product number of the product type in the relevant coding system or in the EU collection of tissue and cell products.

Article 1/B

The competent authority in the context of organ transplantation for the implementation of the provisions of this Regulation and the

legislation on organ transplantation as a health service are the responsibility of the National Chief Medical Officer, the PDSO and the Minister responsible for health (hereinafter referred to as the Minister).

Article 1/C

Donation, collection and testing of human tissues and cells, processed, stored and distributed, unless otherwise provided for in the legislation on the protection of personal data, it must be ensured that the donor and the recipient and their families do not know each other's identity.

Removal of an organ or tissue from a living person

Article 2

(1) In the case of organ or tissue transplantation as defined in Section 206 (3) of the Act, the hospital ethics committee (hereinafter referred to as the "ethics committee") of the health care provider where the organ or tissue transplantation is performed shall act.

(2) In the case of tissue transplantation as defined in Article 206(5) of the Act, the ethics committee of the health care provider where the tissue removal is performed shall act.

(3) A doctor may not be a member of the Ethics Committee when it is considering a case as provided for in paragraphs 1 to 2, if

(a) he or she is involved in the removal or transplantation of the organ or tissue,

(b) he or she is treating the recipient,

(c) he or she is the doctor directly involved in the removal or implantation of the organ or tissue, and/or may exercise, directly or indirectly, decisive influence.

(4) In the cases referred to in paragraphs 1 to 2, the Ethics Committee shall proceed at the joint request of the donor and the recipient, with the exception of paragraph 5. The request shall be made using the form set out in Annex 1. In the case of a minor, the application shall be submitted to the Ethics Committee by the legal representative of the minor.

(5) A joint application is also considered a joint application if the donor and the recipient make a separate request for organ or tissue transplantation on a separate form.

(6) If the recipient is not able to submit the application due to his/her health condition, the provisions of Article 16 (1) to (2) of the Act shall apply mutatis mutandis, except that the donor and the person making the declaration on behalf of the recipient may not be the same person unless the recipient is a minor.

(7) The Ethics Committee shall meet within a reasonable time, justified by the recipient's state of health, but preferably within 15 working days of receipt of the request.

Article 3

(1) The Ethics Committee shall interview the donor and the recipient in person. If the donor or the recipient is a minor in possession of his or her faculties of judgement, his or her statement shall be taken into account as far as is professionally possible.

(2) If it is not possible to interview the recipient due to his or her state of health, the provisions of Article 2 (6) shall apply mutatis mutandis.

(3) The donor and the recipient shall be interviewed separately in accordance with paragraph (1). The donor and the recipient may be heard together if the Ethics Committee considers that their joint hearing is essential to a thorough knowledge of the facts and circumstances.

(4) At the hearing, the Ethics Committee shall in particular satisfy itself

(a) whether the donor has been informed in accordance with Section 209 (1) of the Act, in particular with regard to the fact that the declaration may be withdrawn without any formal obligation,

(b) whether the donor is willing to give his or her consent in a public deed in the case of organ donation or in a private deed with full evidentiary value in the case of tissue donation,

(c) whether the recipient has been informed in accordance with Article 209(5) of the Act and whether the recipient is willing to give written consent to the transplantation,

(d) whether the conditions for organ or tissue donation pursuant to Article 206 (3) and (5) and Article 207 (1) of the Act are met.

(5) The Ethics Committee shall, as necessary, hear the physician who removes or transplants the organ or tissue on the basis of Article 208 of the Ethics Act.

Article 4

(1) The Ethics Committee shall take its decision at the meeting. The chairman of the Ethics Committee shall communicate the decision to those present. If the Ethics Committee does not grant the request, the persons concerned shall be informed of the remedies available to them.

(2) The Ethics Committee shall record its decision in the minutes of the proceedings within three working days of its adoption. It shall send the decision and the reasons for it to the parties concerned.

(3) *

Article 4/A

(1) Two persons who are not in compliance with Article 206(2) or (3) of the Ethics Act

for donor and recipient couples who meet the criteria and for whom an approved transplantation has been carried out - after the decision of the Ethics Committee pursuant to § 4 and the application of Art. following an examination in accordance with § 208 of the Ethics Committee, but the two transplants can be carried out on the basis of a specialist recommendation by exchanging the donor and recipient pairs, the two transplants may be carried out on joint application to the Ethics Committee of the health care provider who issued the specialist recommendation and who will carry out the transplants, which must be made in a public document and approved by the Ethics Committee.

(2) A joint application under paragraph (1) shall include

(a) the contents of Annex 1 for the two donors and the two recipients,

(b) a joint declaration from the two donors

ba) that the offers are made without consideration and free from coercion, threats or deception; and

bb) acknowledgement that, if the conditions set out in paragraph (4) of Article 209 of the Eütv. are met, another simultaneous organ removal and transplantation may take place in the absence of medical contraindications,

(c) a declaration by the two donors and the two recipients that they have received and acknowledged the information on the provisions of § 209 (4) and

(5) of the Act.

(3) A health care provider within the meaning of paragraph 1 may carry out organ removal and, where possible, organ transplantation under the professional conditions, on the same schedule and at the same time.

Article 5

Invasive tests may only be carried out as part of the donor's examination after a decision by the hospital ethics committee.

Article 5/A

For the collection of umbilical cord blood for haematopoietic stem cell transplantation, the rules for the collection of cells or tissue from a living donor shall apply.

Removal of an organ or tissue from a dead person

Article 6

The removal of organs or tissues from a dead person for transplantation into the body of another person may commence if

a) the health care worker designated by the head of the donor institution (hereinafter referred to as the designated health care worker) is satisfied, in accordance with the provisions of § 8, that the deceased person did not make an objection during his or her lifetime, and
b) the death was established by a medical post-mortem examination in accordance with the professional rules, or the brain death was established by a medical committee of three members (hereinafter referred to as "the Committee") as set out in Annex 2, and
c) the doctor who removed the organ or tissue has determined that the organ or tissue to be removed is professionally suitable for transplantation, based on the tests performed and the available medical history of the deceased.

Article 7

(1) Until brain death is established, the care of the patient, including resuscitation, shall be carried out with the utmost care, in accordance with professional rules and using all available means.

(2) The members of the committee shall complete and sign the report in Annex 3 when determining brain death. The report shall be retained in the medical records of the deceased.

Article 8

(1) The designated health worker shall verify whether the patient made a statement of objection during his/her lifetime by examining the medical records and documents of the deceased. He shall make a note of this in the medical records.

(2) If a statement of objection has been submitted to the attending physician during the time available for removal of the organ or tissue, the attending physician shall immediately give it to the designated health care worker.
(3) If the objection statement is not found during the procedure under paragraphs (1) and (2), the designated health care worker shall initiate a query from the National Organ and Tissue Donation Objection Registry (hereinafter referred to as NADR) operated by the OHS to verify the objection. If the NSZTR does not contain a declaration by the deceased objector, subject to the provision of Article 211(4) of the Eütv.

(4) The available time according to paragraph (2) is the time period within which the organ or tissue removal can be performed without increased risk for the recipient, depending on the biological and vegetative state of the prospective donor. The rules on the transplantation of organs and tissues shall be laid down in the relevant professional guidelines.

(5) When contacting the next of kin of the deceased, the next of kin must be informed that no objection was found or was not included in the NUSTR and which organ or tissue was removed from the deceased.

Article 8/A

The donor's body must be restored to resemble as closely as possible its original appearance, taking into account the aspects of the donor's dignity.

Making a statement of objection

Article 9

(1) If the statement of objection is made in an authentic instrument or a private instrument with full probative value as defined in Article 211(1) of the Eütv

a) in person,

b) by registered post, or

c) with the assistance of his/her general practitioner

by a health care provider, together with a declaration in accordance with Annex 4(a) to this Regulation (hereinafter referred to as the 'declaration of consent'). By completing the consent form, the patient consents to the registration in the NSTC and to the processing of his/her personal data.

(2) The inclusion of a statement of objection in the NSTR is not a condition for the validity of the objection.

(3) In the case referred to in paragraph (1)(c), the general practitioner shall forward the statement of objection and the statement of consent to the NSTR by registered post within 3 working days. A note of this will be made in the patient's medical record.

(4) The patient may withdraw the statement of objection without any formal obligation. However, the withdrawal of a declaration entered in the NSTC becomes effective when the declaration is deleted from the NSTC.

(5) Deletion from the NSSTR by the patient

(a) in person at the NSZTR,

(b) by registered mail addressed to the NSSR, or

(c) by his/her general practitioner

(6) In the case referred to in paragraph (5)(a), the patient proves his/her identity by presenting his/her identity card and completes the form provided for in Annex 4(b), which is handed over to the patient by the staff of the NSTC.

(7) In the case referred to in paragraph 5(c), the patient's general practitioner shall complete the form provided for in Annex 4(b) and send it to the OTNY by registered post within 3 working days. A note of this shall be made in the patient's medical file.

Article 10

(1) A statement of objection received by registered mail together with the statement of consent shall be recorded in the NSSR within three working days of receipt. The entry in the NSTC is valid from the date of registration.

(2) The NSSR shall record the statement of consent and the date of receipt and shall ensure the preservation of the private document or authentic instrument with full probative value as defined in Section 211 of the Act on the Protection of Industrial Property.
(3) In the event of withdrawal of the statement of objection, the statement of objection shall be deleted from the NSSTR without delay.

(4) Within ten working days of the date of receipt, the NSTC shall notify the patient of the registration or deletion of the statement of objection, or - in the case of paragraph 9(1)(c) and (7) the family doctor.

(5) The data of the NSSTR shall be handled in accordance with the provisions of Act XLVII of 1997 on the processing and protection of health and related personal data. Data on individual patients are accessible only to the designated health worker.

(6) From the NSSTR, data on a patient can be retrieved by telephone or fax. The name, registration number and unique identifier of the health care provider, which allows the retrieval of the NSSR, are used to identify the designated health care professional.

(7) For each query, the NSTR will produce a document on whether the patient's statement of objection is in the register. The responsible staff member designated by the NSI (hereinafter referred to as the "responsible staff member") shall inform the designated health worker by telephone of the result of the search. The responsible staff member shall send the patient's statement of objection, or a document certifying the absence thereof, to the designated medical staff member, which shall be attached to the patient's medical records before the planned removal of organs or tissues.

(8) The NSTC shall keep a record of the date of the request, the information provided and the data specified in paragraph (5).

(9) The data provided by the NSTC shall be available 24 hours a day.

(10) When requesting the declaration of objection of a Hungarian citizen who died abroad, the employee in charge shall ensure that the deceased did not make a declaration of objection. In this case, the communication of the data is limited to the requirements of Directive 2010/53/EU of the European Parliament and of the Council of 31 December 2010 setting standards of quality and safety of human organs intended for transplantation This may be achieved through communication between the members of the network of competent authorities referred to in Article 19 of Chapter 3 and the OCC.

Article 11

(1) The head of the healthcare provider (hereinafter referred to as the "Head of the institution") shall determine the person and number of the designated healthcare staff. The head of the institution shall send the data sheet in accordance with Annex 4 (c) * by registered post to the NSTC. The designation is valid until revoked.

(2) The health care provider shall report any change in the content of the form in accordance with Annex 4 (c) to the NSTR without delay.

Health documentation

Article 12

(1) The donor's medical records shall be accompanied by

a) documents pursuant to paragraphs (2)-(3) of Article 209 of the Act,

b) the documentation pursuant to § 208 of the Act,

c) in the case of Ethics Committee proceedings, a copy of the minutes of the Committee meeting,

d) a written statement to this effect by the donor in the case of withdrawal of the donor's declaration, or a note to this effect by the doctor in the case of oral withdrawal,

e) the donor documentation according to Annex 9, point 1.2.

(2) The medical documentation of the recipient must be accompanied by

a) the written declaration of consent of the recipient, which must include the acknowledgement or consent of the recipient with regard to the provisions of Section 209 (5) of the Civil Code,

b) the information referred to in paragraph (1)(b) to (c).

Institutional conditions

Article 13

(1) The health care providers specified in Annex 5, point 1 are authorised to transplant organs and to remove organs from a living person for the purpose of transplantation.
(2) The removal of an organ from a deceased person for transplantation is authorised in respect of that organ by the healthcare providers defined in Annex 5, point 2. The removal of organs shall be carried out by the healthcare provider that has a general surgical operating theatre.

(3) Health care providers listed in Annex 5 shall be considered transplantation centres and shall comply with the staffing and equipment requirements laid down in the Ministerial Decree on the minimum professional conditions for the provision of health care services. The operating licence of a transplantation centre must indicate the conditions set out in Annex 5.

(4) In addition to the provisions of paragraph (2), a body coming from a transplantation centre of another State on the basis of an agreement or arrangement concluded by the State Blood Service who meet the conditions set out in § 110 (2), (4), (10) or (10a) of the Act on the Prevention of Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment are also entitled to be removed from the dead person for the purpose of transplantation. Organ procurement shall take place at a health care provider as referred to in paragraph 2.

(5) The legislation on the transplant waiting list shall also apply to organ transplantation.

Article 14

(1) Tissue transplantation shall be performed by the health care providers specified in Annex 6 (a).

(2) The removal of tissue from a living person for transplantation shall be carried out by the health care providers specified in Annex 6(b).

(3) The removal of tissue from a deceased person for transplantation and the storage of such tissue until processing may be carried out in the pathology department of the healthcare provider and in a tissue bank.

(4) Tissues removed from a cadaver for transplantation may be processed and stored after processing only in a tissue bank.

(5) In the case referred to in paragraphs (1) to (4), the health care provider shall comply with the personnel and material conditions laid down in specific legislation.

Article 15

(1) Serological tests shall be carried out on the organ donor in accordance with special legislation.

(2) The grounds for excluding an organ donor from organ removal shall be determined by the current state of scientific medical knowledge.

(3) The eligibility of a tissue or cell donor, except for donors of special procedures for human reproduction, shall be subject to compliance with the conditions set out in Annex 7.

(4) A tissue or cell donor, except for donors of special procedures for human reproduction, shall be subject to the tests set out in Annex 8.

Article 15/A

In the application of Section 243(7) of the act, the approval of organ exchanges with other countries requires that organs are traceable from donor to recipient or recipient to donor and meet the quality and safety requirements of this Regulation. The approval of organ exchange with third countries should be based on a declaration by the third country.

Article 15/B

Tissues and cells may only be imported from a third country where requirements equivalent to those laid down in this Regulation are ensured. The necessary supporting documents for this purpose shall be obtained by the National Medical Officer, acting in his capacity under Article 243(7) of the Eütv.

Article 15/C

For the purpose of transplantation, blood stem cells may be sent directly from the tissue bank to the health care provider performing the transplantation if the health care provider is licensed to perform the transplantation.

Article 15/D

The National Medical Officer shall publish on its website a register of the

tissue and cell banks. The register includes the name of the healthcare provider, the name of the provider's registered office and the location of the healthcare service provider's premises, as well as the licensed health professions and activities, among the data required by law for the registration of healthcare providers.

Article 15/E

(1) The tissue and cell bank shall keep records of the types and quantities of tissues and cells collected, tested, preserved, processed, stored and distributed or otherwise used, and the origin and destination of tissues and cells intended for human applications.

(2) On the basis of the records referred to in paragraph (1), the tissue and cell bank shall, by 31 January of each year, send a report on its activities in the previous year to the National Medical Officer, containing the elements set out in Annex 12. The national chief medical officer shall publish the report on his website.

Tissue and cell storage provisions

Article 16

(1) Tissues may only be stored in tissue banks, cells only in cell banks. A packaging containing tissues and cells must be labelled during storage and processing. During storage of the tissues and cells, until processing, the label shall include the following information:

a) the date of removal,
b) the name and address of the health care provider that performed the removal and storage,
c) the name of the tissue or cell type,
d) the donor identification number,
e) warning of possible risks to health,
f) in the case of donations for private use, a reference to this fact.

(2) During post-processing storage, the following data must be included on the tag:

a) the name of the tissue or cell type,
b) the name and address of the cooperative bank processing the data,
c) the expiry date,
d) the recommended storage method,
e) the sterilisation method used,
f) the amount or dimensions of the tissue, a possible reference to a chemical residue, and
g) the donor identification number.

(3) The donor's name must not appear on the label. To identify the donor, use the

donor identification number. The health care provider carrying out the removal of tissue or cells shall keep a register of tissue or cell donors in accordance with the legislation on health data management and Annex 9.

(4) During transport of tissue or cells, Annex 9, point 1.4 the labelling requirements for the container must be followed.

Requirements for the procurement of human tissues and cells

Article 16/A

(1) The procurement of human tissues and cells shall be carried out in accordance with the provisions of paragraphs (2) to (9).. The provisions of paragraphs 2 to 9 shall not apply in cases of specific procedures for human reproduction where gametes are used without being stored (direct use).

(2) The collection of human tissues and cells may be carried out by a person qualified and practising as a specialist doctor in accordance with the minimum conditions of the legislation on minimum professional requirements for health services.

(3) The written agreement between the tissue bank or procurement organisation and the healthcare provider carrying out the donor selection shall set out the procedures to ensure the correct application of the selection criteria set out in Annex 7.

(4) The agreement between the **credit union** tissue bank and the collection service provider must specify the nature of the tissues, cells or test samples to be collected and the procedures to be followed during collection.

(5) The healthcare provider shall establish a professional code of conduct to

(a) identify the identity of the donor,

(b) the consent of the donor or the donor's family,

(c) the evaluation of the donor's selection criteria in accordance with Annex 7, and
(d) the evaluation of the donor's tests in accordance with Annex 8

the verification of compliance with the rules applicable to the donor's donation

(6) The professional rules for the donation and procurement of tissues and cells and the professional requirements for reception in the tissue bank are set out in Annex 9, points 1.1 and 1.5.

(7) The health care provider shall draw up a professional protocol, taking into account the provisions of Annex 9, setting out the procedures for the collection, packaging, labelling and transport of tissues, cells and tissue and cell samples. The procedures shall be drawn up in such a way that they include the steps in the procedures up to the arrival of the tissues, cells or samples thereof at the tissue establishment and the health care provider performing the transplantation or screening.

(8) The collection shall be carried out by a healthcare provider holding an operating licence which also covers this activity, subject to the provisions of Annex 9, in such a way as to minimise the possibility of bacterial or other contamination of tissues and cells.

(9) Tissue and cell collection shall be carried out using devices, collection materials and equipment in accordance with Annex 9, which also comply with the requirements of the legislation on in vitro medical devices and the relevant professional rules.

Quality and safety requirements for organ procurement

Article 16/B

(1) The data of the organ removed and the donor shall be recorded before the transplantation in accordance with the Annex 9/A

(2) When determining donor data, information on donor characteristics should be collected to assess the suitability of the donor to donate organs, in order to carry out an appropriate risk assessment, minimise the risks to the recipient and optimise organ allocation.

(3) When defining the organ data, the necessary information on the characteristics of the organ to assess the suitability of the organ should be collected in order to carry out an appropriate risk assessment, minimise the risks to the recipient and optimise the allocation of the organ.

(4) The determination of organ and donor data may be carried out by a qualified and experienced health worker in a laboratory that meets the conditions laid down in the Ministerial Decree on the minimum professional conditions for the provision of health services. The recording of data requiring examination by a doctor, including donor selection and evaluation, must be carried out by a doctor.

(5) The educational activities related to organ donation are coordinated by the OVSZ.

(6) Annex 9/a sets out the minimum data to be collected for all organ donations, taking into account paragraph 8.

(7) Annex 9/a contains the additional data to be collected in addition to those referred to in paragraph 6, as decided by the medical team. In making its decision, the medical team shall take into account the availability of data and the specific circumstances of the case.

(8) By way of derogation from paragraph 6, where the risk-benefit analysis indicates that in a particular case, including life-threatening situations, the expected benefits to the recipient outweigh the risks due to incomplete data, an organ may be considered for transplantation even if not all of the minimum data set out in Annex 9/a are available.

(9) The data collected under paragraphs 1 to 8 shall be communicated to the DPO.

(10) In order to meet quality and safety requirements, the medical team will seek to obtain all necessary information from living donors and, to this end, provide them with the information they need to understand the consequences of donation. In the case of organ donation from a deceased donor, where possible and necessary, the DPO and the designated medical staff of the donor health care provider shall endeavour to obtain such information from the relatives or other persons of the deceased donor and shall also endeavour to draw the attention of all parties requested to provide information to the importance of the prompt provision of such information.

(11) During procurement, it must be ensured that

a) it is carried out in accordance with professional standards, both in terms of the type of donor and the type of organs to be removed,

b) it does not compromise the quality of the organs and minimises the risk of microbiological contamination,

c) it complies with legal hygiene conditions to minimise the risk of contamination of organs.

(12) After removal, the organs must be packaged in a way that minimises the risk of contamination and stored at a temperature that preserves the necessary characteristics and biological function of the organs. Packaging shall be carried out in such a way as to ensure that contamination of organs and transport personnel is prevented.

(13) Packaged organs must be transported in a container that preserves the safety and quality of the organs inside.

(14) All accompanying tissue and blood samples for testing should be accurately labelled to ensure their identification with the donor and should be accompanied by a note indicating the time and place of collection.

(15) The process of organ donation, including the rules for labelling the containers used for the transport of organs, is detailed in Annex 9/a.

(16) The competent authorities shall ensure that the provisions of this Regulation are followed?

ensuring that a quality and safety system is properly applied at all stages of the chain from donation to transplantation or disposal. To this end, they may develop a recommendation for healthcare providers involved in all stages of the chain from donation to transplantation or disposal, which may include a recommendation to collect relevant information on the post-transplantation status to assess the quality and safety of the organs transplanted. On the basis of this recommendation, healthcare providers involved in the process may develop operational standards.

Article 16/C

(1) The health care provider performing or participating in the transport of organs shall develop an operational standard to ensure the integrity of the organ during transport and an appropriate transport time.

(2) The organs supplied must be accompanied by a report on the organ and donor characterisation.

(3) Where the transport takes place within the same building, the requirements of Annex 9/a, point 2, sub-points 2.1.1, 2.1.2, 2.1.4, 2.1.7, 2.1.8 need not be met.

(4) On arrival of the removed organs at the receiving establishment, documented evidence shall be provided that the organ, including transport conditions, packaging, labelling, related documentation and samples, complies with the requirements of this Regulation and the legal provisions on minimum professional requirements and salvage.

(5) The host institution must have in place professional procedures for the control of the hosted bodies. The professional procedures must also cover the verification of technical requirements and other conditions that are essential under the relevant professional rules.

(6) Before the organ is removed, the transplant centre checks that

(a) organ and donor data were identified and recorded,

(b) the conditions of preservation and transport of the human organs transported are ensured.

(7) For organs removed for transplantation, but not transplanted and sent for histopathological examination, the health care provider carrying out the removal must have a professional procedure to ensure traceability of the organs. The EMO shall keep records of the results of histopathological examinations of organs removed for transplantation and not transplanted.

Article 16/D

(1) In order to protect donors and recipients, the distribution and the monitoring of all organs transplanted shall be ensured in accordance with this Regulation.

(2) The OVSZ ensures the unique identifiability of all donations and related organs and recipients by providing a unique identifier, in accordance with the legal requirements for the protection of the donor's and recipient's health and identity. The system shall ensure that no unauthorised access to or use of this data is possible.

(3) The OVSZ shall operate the National Organ Donation and Transplantation Follow-up Registry and the Registry for the Tracking of Living Donors who apply for organ donation, in which data shall be recorded by healthcare providers according to the OSS procedures.

(4) In the case of an organ, the data required for traceability will be retained by the DPO for 30 years after donation. The data may be kept in electronic form.

Article 16/E

Materials and equipment used for organ removal must meet the requirements of the Ministerial Decree on Medical Devices and the relevant professional regulations.

Article 16/F

The OVSZ

(a) participates in the network of competent authorities and coordinates the contribution to the activities of the network at national level,

(b) keeps a register of the activities of transplant centres, including the total number of living and deceased donors and the types and quantities of organs removed and transplanted or otherwise disposed of,

(c) prepares an annual report on the activities referred to in point (b) and publishes it on its website,

(d) ensures that, in the event of an organ exchange between Hungary and a Member State of the European Union, the organ and donor data in accordance with Annex 9/a are transmitted to the Member State concerned,

(e) monitors the performance of the service providers and analyses the national situation of transplants.

Article 16/G

The National Chief Medical Officer shall keep a register of transplantation centres in accordance with the legislation on the registration of health care providers.

General rules of procedure for the exchange of human organs for transplantation between Member States party to the Agreement on the European Economic Area

Article 16/H

(1) The OSA shall act in accordance with paragraphs (2) and (3) when transmitting data pursuant to Section 16/I.

(2) The data shall be sent in writing, by electronic means or by fax, in the language agreed with the Member State of destination, failing that in English, as soon as the data are available, indicating the date of transmission and the contact details of the person responsible for the transmission. After the transmission, it shall be ensured that the Member State of destination confirms receipt of the data.

(3) Transfers of data pursuant to paragraph 1 shall indicate that they contain personal data, in compliance with data protection legislation.

(4) In urgent cases, the transfer may be made orally, in particular in accordance with Article 16/K in the case of notification of serious adverse events and reactions. Following oral transmission, the procedure set out in paragraphs (2) and (3) shall be followed.

(5) The OSS shall provide a 24-hour on-call service for the reception of emergency case data.

Article 16/I

(1) The OSS shall transmit the organ and donor data available to it in accordance with Annex 9/a to the competent authorities or authorised organisations of the Member State of destination before the exchange of organs takes place.

(2) Where not all the data to be provided in accordance with Annex 9/a were available during the transmission of data pursuant to paragraph 1, the DPO shall ensure that the necessary data are transmitted as soon as they are available.

(3) The data according to Annex 9/a shall be determined and sent to the PSI for the transmission of data according to paragraphs (1) and (2) as provided for in § 16/B.

Traceability data for organs

Article 16/J

(1) To ensure the traceability of the organs, the OVSZ shall, in addition to the data set out in Annex 9/a and in the case of organs originating in Hungary, transmit to the competent authorities or authorised bodies of the Member State of destination the data identifying the organ and the national donor identification number.

(2) The anatomical description of an organ (organ name), the location of the organ in the body, its laterality and whether it is a whole organ, a part of an organ or which lobes or segments of an organ are to be specified as organ identification data under paragraph 1.

(3) In the case of an organ arriving in Hungary, the DPO shall transmit the following data to the competent authorities or authorised bodies of the Member State of origin:

a) the national recipient identification number or, in the absence of transplantation, the destination of the organ,

b) the date of transplantation,

c) the name and contact details of the transplant centre.

Article 16/K

(1) If the OVSZ is informed of a serious adverse event or is informed of an incident which is presumably related to an organ received from another Member State party to the Agreement on the European Economic Area, it shall immediately inform the competent authority or the authorised organisation of the Member State of origin in accordance with Article 17/C and shall send them a preliminary report containing the information available from them, as specified in Annex 13(A).

(2) If the SIO becomes aware of a serious adverse event or complication which is presumed to be related to a donor whose organs have been sent to another Member State party to the Agreement on the European Economic Area, it shall immediately send a preliminary report containing the information referred to in paragraph 1 to the competent authority or delegated body of the Member State of destination.

(3) If, following the submission of a preliminary report pursuant to paragraphs 1 and 2, further information on the serious adverse event and complication comes to the attention of the OCC, it shall immediately forward it to the bodies referred to in paragraphs 1 and 2.

(4) Where the serious adverse event or reaction is suspected to be related to a donor whose organs have been sent to another Member State party to the Agreement in the European Economic Area, the SIO as the competent authority of the Member State of origin shall forward the final report referred to in Annex 13(B) to the competent authority or delegated body of each Member State of destination within three months of the date of the preliminary report referred to in paragraph 2. The information sent by the competent authority or delegated body of the Member State of destination shall be used for the final report.

Article 16/L

In order to ensure liaison between the Member States party to the Agreement on the European Economic Area, the OSSO will send the European Commission its contact details (name of the organisation, telephone number, e-mail address, fax number, postal address). It will inform the European Commission of any changes to this information.

Histopathological examination

Article 17

In the case of removal of organs and tissues from the body of a living person, no pathological examination is required for the following organs and tissues [§ 204 (2) c) of the Act]:

a) tooth,

b) vitreous body,

c) fingernails,

d) the placenta in the case of physiological birth.

Responsible person

Article 17/A

(1) The head of the tissue bank and the person designated by him/her (hereinafter referred to as the "responsible person") shall be responsible for the protection, registration and safekeeping of the tissues within the tissue bank.

(2) The responsible person must meet at least the following qualification requirements:

a) higher education qualification in medicine or biological sciences, and

b) at least two years' professional experience in the field referred to in (a).

(3) The person responsible

a) enforces legal requirements and institutional rules for the collection, storage, processing and distribution of human tissues intended for human applications;

b) regularly informs the head of the tissue bank about the activities of the tissue bank;

c) in the event of improper operation, initiates the necessary measures to the head of the cooperative bank to restore lawful or professional operation;

d) if it considers that the suspension of the activity with the stored tissues would be justified, it shall directly inform the National Medical Officer, at the same time informing the head of the tissue bank, in order to take the necessary measures;

e) informs the authorities responsible for monitoring the operation of the cooperative bank, at their request, of the data relating to the operation which are essential for the monitoring, as well as of the initiative under point c);

f) shall ensure that the requirements under § 3, §§ 6 to 8, § 12, § 15/A and § 16 are complied with at the tissue bank;

g) approves the exclusion criteria as set out in Annex 7 donor evaluation.

(4) The tissue bank shall inform the National Chief Medical Officer of the name of the responsible person referred to in paragraph (1), indicating the specific institutional tasks for which he is responsible.

Reporting serious adverse events and reactions

Article 17/B

(1) The healthcare provider shall immediately notify the National Medical Officer of all relevant information related to the testing, processing, storage and distribution of tissues and of any serious adverse events, including those that may affect the quality and safety of tissues intended for human use. The National Medical Officer shall notify the health care providers specified in § 14 and the Minister thereof.

(2) The healthcare provider under § 14 shall immediately notify the national public health officer of any serious complication observed during or after the transplantation or removal of the tissue and which is attributable to the unsatisfactory quality of the tissues intended for human use.

(3) Following a notification under paragraphs (1) and (2), the national

public health officer shall immediately take the necessary measures, including, where the consequences of the serious adverse event or serious complication may affect another Member State, notifying the European Commission or the competent authorities of the Member States of the European Economic Area likely to be affected by the serious adverse event or serious complication.

(3a) In addition to paragraph 3, the national public health inspector shall initiate an investigation and take the necessary measures if a reasoned request from a competent authority of a Member State of the European Economic Area so requires.

(4) Notification under paragraphs (1) and (2) shall be made using the form set out in Annex 10.

(5) The National Medical Officer shall, by 30 June of the year following the year in question, submit a report to the Commission of the European Union using the forms set out in Annex 11. Health care providers within the meaning of Article 14 shall provide the data required for the annual report in accordance with Annex 11 by 30 April of the year following the year in question to the National Medical Officer.

Article 17/C

(1) Following a serious adverse event or serious damage to an organ the health care provider who becomes aware of the complication immediately notifies the OSS, which, in addition to immediately informing the Minister and the transplant centres, notifies the National Medical Officer of the immediate notification and investigation of the case. The OSA shall take the necessary measures without delay, including, where the consequences of the serious adverse event or serious complication may affect another Member State, notifying the European Commission or the competent authorities of the Member States of the European Economic Area likely to be affected by the serious adverse event or serious complication.

(2) Formal requirements for the timely reporting and handling of serious adverse events and complications involving an organ shall be issued by the OCR and published on its website.

Article 17/D

The national medical officer shall report serious adverse events and serious

complications, indicating their number and nature.

Article 17/E

The compliance with the provisions of this Regulation shall also be examined in the framework of the professional supervision.

Article 17/F

The competent authorities shall provide, at the request of a Member State party to the Agreement or of the European Commission, information on the results of inspections and controls carried out in relation to the requirements of this Regulation.

Article 17/G

The National Office of the Chief Medical Officer shall carry out systemic inspections

in tissue establishments and may inspect the procedures and activities related to the requirements of this Regulation and examine any documents related to the requirements of this Regulation as part of the inspection.

Single European Code

Article 17/H

(1) The unique European code for human use should be applied to all tissues and cells distributed. Where tissues and cells are released for other purposes, the accompanying documentation shall at least include the donation identification character set.

(2) Paragraph 1 shall not apply to

a) donation of gametes between partners,

b) tissues and cells delivered directly to the recipient for immediate transplantation,

c) in urgent cases, with the direct authorisation of the competent authority for tissues and cells imported into the European Union.

(3) The following cases are exempt from the requirements of paragraph 1:

a) tissues and cells other than gametes intended for donation between partners, if they remain with the same healthcare provider,

b) tissues and cells imported into the European Union, if they remain with the same healthcare provider from importation until use, provided that the healthcare provider has an accredited, designated, authorised or licensed tissue bank to carry out the import activities.

(4) For the purposes of paragraph 3, a healthcare provider shall be considered to be the same healthcare provider where all steps in the process from procurement to human application are carried out under the responsibility of the same person, under the same quality assurance and traceability system, and where the same site includes at least one authorised tissue establishment and tissue establishment and one body responsible for human application.

(5) The specifications for the structure of the uniform European code referred to in paragraph 1 are set out in Annex 15.

(6) The single European code must be clearly legible and preceded by the abbreviation "SEC". Other labels or traceability systems may be used in conjunction with the use of the European single code.

(7) The unique European code shall be indicated either with the donation identification string and the product identification string separated by a single space or on two consecutive lines.

Article 17/I

The use of a single European code does not exclude the use of additional codes in accordance with national requirements.

Article 17/J

(1) A tissue bank, including an importing tissue bank, shall provide the following conditions for the application of the Single European Code:

a) assign a unique European code to all tissues and cells for which such a code is to be used, at the latest before distribution for human use;

b) assign a donation identification character sequence to tissues and cells after they have been collected, or upon receipt from the health care provider that performed the collection, or upon import from a health care provider in a third country;

c) notify the national chief medical officer in the following cases:

ca) if the information in the EU collection of tissue banks needs to be updated or corrected;

cb) if the EU collection of tissue and cell products needs to be updated;

cc) if the tissue bank determines that the application of the Uniform European Code for tissues and cells received from another tissue bank in the Union does not comply with the requirements of this Chapter.

(2) The donation identification string referred to in paragraph 1(b) shall consist of the following elements:

a) the code of the EU tissue bank according to the EU collection of tissue banks,

b) the unique donation number issued by the tissue bank, unless it is a unique donation number used worldwide.

(3) In the case of fusion of tissues and cells, a new donation identification number must be assigned to the final product. Traceability of each donation is ensured by the tissue bank performing the fusion.

Article 17/K

(1) The national medical officer shall assign a unique identification number to

any authorised tissue bank. If a tissue bank has several different locations but a single system for issuing unique donation numbers, it is considered a federation bank. If the cooperative bank uses two or more systems for issuing unique donation numbers, the respective site must have a separate cooperative bank code corresponding to the number of systems used.

(2) The donation identification string assigned to tissues and cells already on the market cannot be changed unless necessary to correct a coding error. In the case of a coding error, all corrections shall be properly documented.

(3) One of the permitted product coding systems according to § 1/A, point 37 and the corresponding tissue and cell product number in the Union collection of tissue and cell products shall be applied at the latest before distribution for human application. The label of the tissue and cell product shall indicate the appropriate sublot number and expiry date. In the case of tissues and cells for which no expiry date is specified, the expiry date shall be 00000000, which shall be indicated at the latest before distribution for human use.

(4) Before the product is distributed for human consumption, the unique European code must be indelibly and permanently marked on the label and included in the accompanying documentation. The cooperative bank may entrust this task to a third party or parties, provided that the third party ensures compliance with the requirements of this Regulation, in particular the uniqueness of the unique European code. Where the size of the label does not allow the uniform European code to be indicated on the label, the code shall be included in the accompanying documentation, which shall be clearly linked to the tissues and cells bearing the label concerned.

(5) The tissue bank and the organisations responsible for human use shall keep the minimum data to be retained, as set out in Annex 14, for at least 30 years.

Article 17/L

(1) The National Medical Officer shall

a) checks the use of the European single code when auditing the tissue bank;

b) ensure the validation of the data on tissue banks in the Union collection of tissue banks according to Annex 16 and update the collection within 10 working days at the latest, in particular in the following cases:

ba) in case of authorisation of a new tissue bank;

bb) in the event of a change in the information on tissue banks or incorrect inclusion of tissue banks in the EU collection;

bc) in the event of a change in the information relating to the authorisation of the tissue establishment pursuant to paragraph 2;

c) alert the competent authorities of another Member State if it detects incorrect information about a Member State in the EU collection of tissue banks or if it finds that there is a case of significant non-compliance with the provisions of a European code in relation to another Member State;

d) alert the European Commission and the competent authorities of other Member States when the EU collection of tissue and cell product codes needs to be updated.

(2) In the Union collection of tissue banks, the National Medical Officer shall enter the following changes in the data referred to in paragraph (1)(b)(bc):

a) authorisation for a new tissue or cell type,

b) a permit for a new prescribed activity,

c) imposing a condition or exception to an authorisation,

d) the suspension of function related to a particular activity or tissue or cell type,

e) the withdrawal of the authorisation for our tissue banks,

f) situations where a tissue bank voluntarily ceases the activity or activities covered by the licence.

Article 17/M

(1) The rules of this Regulation shall apply to the tissues and cells, and products derived from human tissues and cells intended for human applications, shall apply to imports into the European Union, subject to the derogations contained in this Chapter.

(2) If the human tissues and cells to be imported are intended solely for use in processed products covered by other Union legislation, this Chapter shall apply only to donation, procurement and testing outside the European Union and to ensure traceability from donor to recipient or recipient to donor.

(3) The provisions of this Chapter shall not apply

a) to imports directly authorised pursuant to Article 15/C;

b) in urgent cases, the importation of tissues and cells directly authorised by the national medical officer.

Article 17/N

For the purposes of this Chapter

1. single import: the import of any type of tissues and cells for a single use for a specified, known recipient;
2. third-country healthcare provider: a tissue bank or healthcare provider established in a third country that is responsible for exporting to the European Union the tissues and cells it supplies to a tissue bank;
3. importing tissue bank: a tissue bank established in the European Union that is party to a contractual agreement with a healthcare provider in a third country for the import of tissues and cells for human use from a third country into the European Union;
4. emergency: an unforeseen situation where there is no practical alternative but to urgently import tissues and cells from a third country into the European Union for immediate use in a known recipient whose health would be at serious risk without such importation.

Article 17/O

(1) The import of tissues and cells from third countries may be carried out by an importing tissue bank holding an operating licence issued by the National Medical Officer and an official certificate issued for this purpose.

(2) When applying for an import activity licence, the applicant importing tissue bank shall send to the National Chief Medical Officier and attach to the application the following information the documents listed in Annex No. The National Chief Medical Officier shall verify the information submitted and the fulfilment of the requirements laid down in this Regulation and, on the basis of the information, shall authorise the imports covered by the application and, if necessary, lay down the conditions and restrictions applicable to imports and issue the official certificate provided for in Annex 19 to the authorised importing tissue banks.

(3) The importing cooperative bank must report any material changes to its import activities to the national medical officer. The national official veterinarian shall amend the official certificate referred to in paragraph 2 in the light of the notification.

(4) A change in the type of tissues and cells intended for import, a change in the quality and safety of tissues and cells intended for import, a change in the activities carried out in the third country or a change in the third country healthcare provider are considered as substantial changes.

(5) A one-off import of tissues or cells from a health care provider in a third country whose activity is not covered by the existing official certificate of the importing tissue bank, but the official certificate covers imports

of the same type of tissues or cells from another health care provider in the same third country, is not considered a substantial change.

Article 17/P

(1) In the case of an importing tissue bank, the time between inspections by the national public health officer pursuant to § 17/G shall not exceed two years.

(2) At the reasoned request of another Member State or of the European Commission, the National Office of the Chief Medical Officer to provide information on the results of investigations and controls carried out on importing tissue banks.

(3) The national public health officer shall, at the reasoned request of the Member State where the imported tissues and cells are distributed, examine the need to control the activities of the importing tissue establishment and the third country healthcare provider.

(4) If an on-the-spot verification is carried out following a request pursuant to paragraph 3, the national official veterinarian shall, by agreement with the competent authority of the requesting Member State, involve the competent authority of the requesting Member State pursuant to paragraph 3 in the verification. In the event of refusal to include the applicant Member State in the inspection, the national official auxiliary shall give reasons for its decision to the Member State which made the request pursuant to paragraph 3.

Article 17/Q

The documentation according to Annex 17, point F, and Annex 19 need not be attached in the case of a single import. In the case of a single import, traceability of the imported tissues and cells from donor to recipient or recipient to donor must be ensured and it must be ensured that the imported tissues and cells are only used for the intended recipient.

Article 17/R

(1) The importing tissue bank shall immediately notify the National Medical Officer of any suspected or actual serious adverse event or complication of which it becomes aware from the third country health care provider that may affect the quality and safety of the tissues and cells it imports. The notification shall include the information specified in Annex 10.

(2) In addition to the provisions of paragraph (1), the importing tissue bank shall immediately notify the National Medical Officer if it becomes aware that a health care provider from a third country

a) has had its authorisation to export tissues and cells revoked or suspended, or

b) the competent authority of the Member State of establishment has taken a decision relevant to the quality and safety of the imported tissues and cells.

Article 17/S

(1) If any of the activities of donation, collection, testing, processing, preservation, storage and distribution of tissues and cells to be imported into the European Union are carried out outside the European Union, the importing tissue bank must have a written agreement with the third country healthcare provider.

(2) A written agreement between the importing tissue bank and the third country healthcare provider shall specify the quality and safety requirements to be met to ensure that the tissues and cells to be imported meet quality and safety standards equivalent to those laid down in this Regulation. The written agreement shall include at least the information listed in Annex 20.

Article 17/S

(1) The importing tissue bank shall keep a record of its activities, which shall include - even in the case of a single import - the type, quantity, origin and destination of the imported tissues and cells.

(2) The data referred to in paragraph 1 shall also be included in the annual report as set out in Annex 12.

(3) An importing tissue bank licensed under section 17/O shall also be included in the register under section 15/D.

Transitional and final provisions

Article 18

(1) This Decree shall enter into force on 1 January 1999, with the exception of paragraph (2), and at the same time Decree No 18/1972 (XI. 4.) of the Ministry of Health on the implementation of the provisions of Act II of 1972 on health care concerning the removal and transplantation of organs and tissues, and Decree No 3/1988 (II. 17.) of the Ministry of Health amending it shall be repealed.

(2) The requirements relating to the Uniform European Code set out in Article 17/H and Annex 15 of this Regulation, laid down by EMMI Regulation No 44/2016 (28.12.2016) amending certain Ministerial Regulations on health and health insurance (hereinafter referred to as the "Methodology"), shall not apply to tissues and cells already in storage on the date of entry into force of the Methodology, provided that such tissues and cells are placed on the market in the European Union within five years of the date of entry into force of the Methodology and their full traceability is otherwise ensured under this Regulation.

(3) In the case of tissues and cells that are to be stored for a longer period of time

and are placed on the market only after the expiry of the five-year period referred to in paragraph 2 and for which the single European code cannot be used because they are stored in deep-freeze, tissue banks shall apply the procedures for products bearing the indicating label in accordance with Article 16.

(4) This Regulation shall ensure compliance with the following Union acts follows:

a) Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells;

b) Commission Directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells;

c) Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells;

d) Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 setting standards of quality and safety of human organs intended for transplantation;

e) Commission Directive 2012/25/EU of 9 October 2012 establishing information procedures for the exchange of human organs intended for transplantation between Member States;

f) Directive 2006/17/EC for the testing of human tissues and cells amending Directive 2012/39/EU of the European Parliament and of the Council of 26 November 2012 as regards certain technical requirements for the application of the Directive;

g) Commission Directive 2015/565/EU of 8 April 2015 amending Directive 2006/86/EC as regards certain technical requirements for the coding of human tissues and cells;

h) Commission Directive 2015/566/EU of 8 April 2015 implementing Directive 2004/23/EC as regards the procedures for verifying the equivalence of quality and safety standards for imported tissues and cells.

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Government Decree 323/2006 (XII. 23.) on the National Blood Service

The Government, acting within its original legislative competence as laid down in Article 35(2) of the Constitution, in accordance with the powers conferred on it by Article 40(3) of the Constitution and on the basis of the authorisation granted by Article 247(1)(j) of Act CLIV of 1997 on Health Care, hereby enacts the following Decree:

Status of the National Blood Service

Article 1
The National Blood Service (hereinafter referred to as the "OVSZ") is a central budgetary body under the authority of the Minister responsible for health.

Article 2
The OVSZ is headed by a Director-General.

Organisation of the OVSZ
Article 3
(1) The central organisational unit of the National Blood Service is the National Blood Service Centre (hereinafter referred to as the "OVSzK"). The Director General of the OVSZ shall directly head the OVSzK.
(2) The regional organisational units of the OVSZ are the regional blood supply centres under the direction of the Director General of the OVSZ and the regional blood suppliers under their direction. The regional blood supply centres are listed in the Annex to this Regulation.

Article 4
(1) The Director General shall exercise the powers of employer over the staff of the OVSZ, which may be delegated in full or in part to the head of the regional blood establishment in the organisational and operational rules, subject to the provisions of a special law.
(2) The Regional Coordination Council of the OVSZ, composed of the Heads of the Regional Blood Supply Centres, is the decision-making body of the Director General of the OVSZ.

The tasks of the OVSZ

Article 5
(1) The Government shall designate the OVSZ to perform the tasks of the State Blood Service.
(2) The OVSzK

a. directs and supervises preparative and clinical transfusion activities, performs the tasks of a national institute and supervises compliance with quality standards,
b. strategic planning for blood supply,
c. conducting transfusion research and development,
d. operate a national logistics and information network, a national blood inventory and a dispatching service,
e. issue methodological letters, professional standards and protocols, taking into account the opinions of the relevant professional colleges,
f. carry out continuous data collection, analysis and evaluation in relation to blood supply and transfusion services,
g. cooperating with medical universities in transfusion training and continuing education,
h. *
i. coordinating activities related to the organisation of organ and tissue donation .

(3) The regional blood supply centre shall
a. coordinate the activities of the regional blood establishments under its control,
b. coordinate and facilitate the creation of the human and material conditions necessary for the production and storage of blood products in the professionally justified quantities and qualities,
c. monitor the professional management of blood and blood product stocks,
d. coordinating the production of plasma for further processing (fractionation),
e. continuously analysing the use of blood products in healthcare establishments,
f. contribute to the tasks related to training and further training,
g. carry out the tasks specified in paragraph 4 within its area of responsibility.

(4) The regional blood establishment shall be responsible for
a. in the field of preparative transfusiology:
    i. organising blood donations, recruiting, training and retaining donors and, where necessary, providing donor care,
    ii. donor testing and donor registration,
    iii. blood collection,
    iv. testing of blood collected,
    v. the preparation, distribution and control of blood products (designated regional blood establishment),
    vi. storage and inventory of blood products,
    vii. issuing blood products,
    viii. monitoring the health status of persons receiving blood (hereinafter referred to as 'recipients');
b. clinical transfusiology:
    i. providing transfusion consultation,
    ii. blood grouping of the recipient, antibody screening,
    iii. selection of a compatible blood product,
    iv. investigation of transfusion complications, assistance in treatment,
    v. immunohaematological screening and care of pregnant women,
    vi. participation in autotransfusion, therapeutic apheresis and other transfusion procedures,
    vii. immunohaematological examination of newborns,
    viii. immunological and immunohaematological examination of transplant recipients,
    ix. organisation, testing and registration of bone marrow donors,
    x. contributing to the treatment and care of patients with congenital haemophilia;
c. the continuous performance of quality assurance tests, methodological letters, technological specifications and professional rules in the field of quality assurance.

Article 6

In the performance of its tasks, the OVSZ shall.

a. cooperate with health care institutions, the State Public Health and Veterinary Service, the relevant professional colleges, the processors of blood materials, the Hungarian Red Cross and other civil organisations supporting blood donation,
b. may conclude cooperation agreements with other bodies for the purpose of donor recruitment, product manufacture, diagnostics and other activities within its remit, and for research and development in this field,
c. liaise with national and international professional organisations,
d. to participate in the work of the competent professional bodies of the European Union in the scope of its tasks, as provided for in Government Decision No 1007/2004 (II. 12.) on participation in the decision-making activities of the European Union and related governmental coordination.

Article 7

(1) This Regulation shall enter into force on 1 January 2007.
(2) *

Annex to Government Decree 323/2006 (XII. 23.)

Regional blood supply centres

1 Regional Blood Supply Centre of Central Hungary (seat: 19-21 Karolina u., Budapest),
2. Győr Regional Blood Supply Centre (headquarters: Győr, Magyar u. 8.),
3. *
4. the Regional Blood Supply Centre of Pécs (Pécs, Dischka Gy. u. 7.),
5. the Szeged Regional Blood Supply Centre (Szeged, Pécsi u. 4/B),
6. the Debrecen Regional Blood Supply Centre (Debrecen, Bem tér 1