Organ, Tissue and Cell Transplantation Act

Update, SG No. 83 of 19.09.2003, in force since 1.01.2004, amended, SG No. 88 of 4.11.2005, amended and supplemented, SG No. 88 of 4.11.2005. 71 of 1.09.2006, in force from 1.01.2007, Art.36 of 15.05.2009, suppl., Art. 41 of 2.06.2009, in force from 2.06.2009, amend. 98 of 14.12.2010, in force from 1.01.2011, art. 9 of 28.01.2011, amend. and supplemented, issue 60 of 7.08.2012, amend., issue 15 of 15.02.2013, in force from 1.01.2014, amend. and supplemented, Art. 102 of 11.12.2018, in force from 1.01.2019, amend., Art. 17 of 26.02.2019, amend. and supplemented, Art.54 of 16.06.2020, in force from 16.06.2020.

Chapter one: GENERAL PROVISIONS

Art. 1. (1) This Act shall regulate the conditions and procedure for the medical transplantation of organs, tissues, and cells.

(2) (new, SG No. 60/2012) The purpose of this Act is to establish rules to ensure quality andsafety standards for organs, tissues and cells intended for medical transplantation and to ensure a high level of protection of human health.

(3) (former paragraph 2 - SG 60/2012) Not subject to this Act;

1. (amend. - SG 71/06) blood donation, transfusion of blood and blood components;

2. (amend. - SG 71/06, suppl., SG 36/09) assisted reproduction and related reproductive organs, tissues and cells;

3. (suppl. - SG 71/06) autotransplantation, when the procurement and the transplantation are performed within the same invasive procedure;

4. implantation of artificial tissues and organs;

5. (new - SG 60/12) the use of organs for research purposes, except when the organs are intended for medical transplantation.

Art. 2. (1) (suppl. - SG 36/09) Transplantation is a set of medical and other activities related to the procurement of organs, tissues, and cells from a dead body or animal or a living person and their transplantation to another person for therapeutic purposes.

(2) Transplantation includes the procurement and transplantation of hematopoietic stem cells and embryonic organs, tissues, and cells.

(3) Transplantation is also the taking of organs, tissues, and cells of animal origin and their transplantation into the human organism.

(4) (new, SG 71/06) Transplantation shall also include autotransplantation, where the procurement and the transplantation are carried out as part of more than one invasive procedure.

(5) (former para. 4 - SG, issue no. 71 of 2006, suppl., issue 36 of 2009, amend. and suppl., issue 60 of 2012) Transplantation shall also include activities related to donation, procurement, characterisation, expertise, processing, treatment, labelling, storage, transport and supply of organs, tissues and cells intended for medical use.

Art. 3. Transplantation shall be carried out under conditions that guarantee equal rights for patients in need of transplantation and the protection of the human rights and freedoms of actual and potentialdonors and recipients.

Art. 4. (1) Transplantation shall be carried out following medical standards and selection criteria approved by a regulation of the Minister of Health.

(2) Transplantation shall be performed only when other methods of treatment are less effective or not applicable.

(3) Transplantation shall be performed only after the necessary medical examinations have been carried out following established medical standards for transplantation, ensuring maximum safety for the health of the donor and the recipient.

(4) Medical professionals are obliged to provide conditions to reduce the risk of transmissionof transmissible infections and other diseases from the donor to the recipient.

(5) (new, SG 71/06) Medical professionals shall ensure conditions for the quality and safetyof tissues and cells when performing autotransplantation where the activities of examination, procurement, processing, storage, or transplantation are carried out in the framework of more than one intervention procedure.

(6) (new, SG 71/06, amended, SG 60/12) The requirements for qualification and health statusof persons who perform procurement, examination, processing, treatment, labelling, storage, and transplantation of organs, tissues, and cells shall be determined by a regulation of the Minister of Health.

(7) (new, SG 71/06) The persons referred to in paragraph 6 shall undergo a compulsory training course at least once every two years under the conditions and in the order determined by theregulation referred to in paragraph 6.

Art. 5. Human organs, tissues, and cells may not be the subject of a transaction consideration.

Art. 6. (amend. - SG 36/09) Advertising the availability of organs, tissues, and cells to seek materialbenefit, as well as offering material benefit to obtain organs, tissues, and cells shall be prohibited.

Art. 7. Organs, tissues, and cells that cannot be used for transplantation for medical reasons may be made available for other therapeutic, diagnostic, and scientific-medical purposes under the conditionsand following the procedure laid down by a regulation of the Minister of Health.

Art. 8. (suppl. - SG 54/2020, in force from 16.06.2020) Data dissemination that enables theidentification of the donor or the recipient, including in the case of cross-donation, shall be prohibited.

Chapter two: NATIONAL TRANSPLANT SYSTEM

Section I

Organisation and activities of the National Transplantation System

Art. 9. The national transplantation system shall comprise state bodies and medical establishments carrying out activities related to the organisation, management, and control of the transplantation process.

Art. 10. (1) The Minister of Health shall develop the state policy in the field of transplantation.(2) (amend. - SG 36/09, amend., SG 60/12).

Art. 10a. (New, SG 36/09) (1) The Minister of Health shall designate by order a public stem cell andbone marrow donor bank, which shall be a structure of a hospital care facility, carrying out the procurement, examination, processing, processing, storage, labelling, and transportation of stem cellsand bone marrow for transplantation.

(2) The medical establishment referred to in par. 1;

1. it has 100 percent state participation in the capital;
2. it is authorised for the activities referred to in par. 1, issued following Article 47of the Medical Institutions Act;
3. (amend. - SG 102/2018, in force from 1.01.2019).

(3) The donor bank designated under par. 1 and 2 shall be a National Public Donor Bank and shall aim at providing stem cells and bone marrow nationwide for transplantation of persons sufferingfrom diseases for which other methods of treatment are less effective or not applicable.

Art. 11. (1) (amend. - 1. 71 of 2006, amend., SG 102 of 2018, in force from 1.04.2019).(2) (amend. - SG 102/2018, in force from 1.04.2019).

(3) (amend. - SG 102/2018, in force from 1.04.2019).

(4) (new - SG No. 71 of 2006, amend., SG 102 of 2018, in force from 1.04.2019) The Executive Agency "Medical Supervision" shall be the competent authority for management, coordination, and control of transplantation in the Republic of Bulgaria.

(5) (former para. 4 - SG, issue no. 71 of 2006, amended, SG 102 of 2018, in force from 1.04.2019) The Executive Agency "Medical Supervision":

1. coordinate and supervise the activities in the field of transplantation carried out in medical establishments;

2. propose to the Minister of Health medical standards for organ, tissue, and cell transplantation, as well as medical criteria for selection of donors and recipients;

3. (suppl. - SG 60/2012, amend., SG 17/2019) establish and maintain the public and officialregister, collecting, processing, storing, and making available information in relation to transplantation in compliance with the requirements for the protection of personal data;

4. (new - SG 71/06, amend., SG 36/09) ensure round-the-clock access for physicians directlyinvolved in the medical care of the potential donor to the official register of persons who have expressed their disagreement for the procurement of organs, tissues, and cells after their death, underthe conditions and following the procedure established by a regulation of the Minister of Health;

5. (former item 4 - SG 71/06, amend., SG 36/09) coordinate the import and export of organs,tissues, and cells;

5a. (new - SG 36/09, amend., SG 102/2018, in force from 1.04.2019) issue the permits and certificates referred to in this Law;

6. (former item 5 - SG 71/06) distribute the organs provided for transplantation and control the distribution of tissues and cells;

7. (former item 6, amend. - SG 71/06, SG 60/12) register, store and analyse information on the donor's data, the health status of the living donor and the recipient during the transplantation andthe post-transplantation period, as well as serious adverse reactions and serious incidents related to the transplantation;

8. (former item 7 - SG 71/06) investigate and analyse the medical, legal, ethical, religious, economic, and social implications of transplantation;

9. (former item 8 - SG 71/06) inform the public about transplantation processes in order to ensure transparency and equal access for all persons in need;

10. 71 of 2006, as amended, issue 36 of 2009, supplemented, issue 60 of 2012) shall coordinate the cooperation between European organ exchange organisations, competent authorities of the Member States of the European Union, of the other States Parties to the Agreement on the European Economic Area, of the Swiss Confederation and third countries, public authorities, scientific organisations and non-governmental organisations concerning transplantation;

11. (former item 10 - SG 71/06) participate in the development of national strategies and programmes, international projects, analyses, and forecasts on transplantation processes;

12. (new - SG 71/06, suppl., SG 36/09) supervise the quality and safety of organs, tissues, andcells intended for transplantation;

13. (new - SG 71/06, amend., SG 36/09) ensure traceability from donor to recipient of all organs, tissues, cells, materials, and products in contact with them, which are received, processed, treated, stored or made available on the territory of the Republic of Bulgaria;

14. (new - SG 71/06) shall control the activities of collection, insertion, examination,processing, and labelling, and storage of human ova, spermatozoa, and zygotes intended for assistedreproduction and shall ensure the traceability of such ova, spermatozoa, and zygotes, and the materialsand products coming into contact with them from the donor to the recipient;

15. (new - SG 71/06, in force from 1.01.2007) prepare every three years a report to the European Commission on the activities carried out in the Republic of Bulgaria to promote and encourage the voluntary and unpaid donation of tissues and cells;

16. 71 of 2006, in force as from 1.01.2007, supplemented, issue 36 of 2009) submit every threeyears a report to the European Commission on the quality and safety assurance activities carried outin the expertise, collection, processing, treatment, labelling, storage, supply, transplantation, control,and inspections carried out;

16a. (new - SG 60/12) submit every three years a report to the European Commission on allorgan transplantation activities and the experience gained in the transplantations carried out;

17. (new - SG 36/09) organise quality and safety training in the performance of transplantation activities for the persons referred to in Article 15d and for persons who carry out procurement, examination, handling, processing, labelling, storage, supply, and transport of organs, tissues, and cells;

18. (new - SG 60/12) shall provide the European Commission or a Member State of the European Union, another State party to the Agreement on the European Economic Area and the Swiss.

Confederation, upon request, with information on the requirements for issuing authorisations and certificates to medical establishments for organ transplantation activities, as well as with informationon medical establishments performing transplantation activities;

19. (new - SG 60/12) issue authorisations for import and export of organs, tissues, and cells from and to third countries;

20. (new - SG 60/12) control the exchange of organs with the Member States of the EuropeanUnion, with the other States Parties to the Agreement on the European Economic Area and with the Swiss Confederation, as well as the import and export from and to third countries.

(6) (new, SG 36/09, amend., SG 102/2018, in force from 1.04.2019) When carrying out the activities referred to in paragraph 5, item 5a, the Executive Agency "Medical Supervision" shall collect fees in an amount determined by a tariff approved by the Council of Ministers upon a proposalof the Minister of Health.

Art. 11a. (new - SG 36/09, amend., SG 15/2013, in force from 1.01.2014, amend., SG 102/2018, in force from 1.04.2019).

Art. 12. (1) A Transplantation Ethics Committee shall be established under the Council of Ministers.

(2) The Commission referred to in par. 1 shall consist of 9 members and shall necessarily include physicians, psychologists, theologians and lawyers. The composition of the Commission shallbe determined by a decision of the Council of Ministers on the proposal of the Minister of Health fora period of 5 years.

(3) Persons performing activities under Article 2 may not be members of the EthicsCommittee on Transplantation.

(4) The Ethics Committee on Transplantation shall give opinions on deontological and ethical issues in the field of transplantation and shall authorise the procurement of organs and tissuesfrom persons in the cases provided for in this Act.

(5) The meetings of the Ethics Committee on Transplantation shall be closed.

(6) The Council of Ministers shall, on a proposal of the Minister of Health, determine by regulations the conditions and procedure for the work of the Ethics Committee on Transplantation.

(7) (New, SG No. 71 of 2006, amended, SG 102 of 2018, in force from 1.04.2019) The financing of the activities of the Ethics Committee on Transplantation shall be provided by the Executive Agency "Medical Supervision".

Art. 13. (1) (amend. and supplement. – SG 36/09, amend. 54/2020, in force from 16.06.2020). Procurement and/or expertise, processing, treatment, labelling, storage, supply and transplantation oforgans, tissues and cells shall be performed by hospital care facilities authorised under Art. 48, par. (3) of the Medical Establishments Act in which the relevant activities are explicitly specified.

(2) (amend. and supplement. - SG 36/09, amend. 98 of 2010, in force as of 14.12.2010, Art.54 of 2020, in force as of 16.06.2020) Collection, examination, handling, processing, labelling, storage, supply and transplantation of tissues and cells may also be carried out by outpatient care establishments registered under Art. 40, par. 13 of the Medical Establishments Act, the registration certificate of which indicates the relevant activities.

(3) (amend. - 88 of 2005, suppl., issue 36 of 2009, amend., issue 102 of 2018, in force from 1.04.2019) The activities referred to in paragraph 1 may also be carried out in the medical establishments under the Council of Ministers, the Ministry of Defence, the Ministry of the Interior and the Ministry of Transport after obtaining a certificate from the Executive Agency "Medical Supervision" that the medical establishment may carry out organ, tissue and cell transplantation in accordance with the approved medical standards.

(4) (new - SG 71/06, suppl., SG 36/09) The medical establishments referred to in par. 1, 2 and 3 and tissue banks shall register all activities performed by them in the field of examination, collection, grafting, processing, storage, supply, transport and receipt, and labelling of organs, tissues and cells under the conditions and in the manner determined by a regulation of the Minister of Health.

(5) (New, SG No. (5) Medical establishments shall annually prepare a report on the activitiescarried out under paragraph 4 in a form specified in the Ordinance under paragraph 4 and submit it to the Executive Agency "Medical Supervision".

(6) (new - SG 71/06) The data from the report referred to in paragraph 5 shall be entered in the register referred to in Article 39, paragraph 1. 1, and. 1.

(7) (former paragraph 4, supplemented, SG 71/06) The transport of organ donors and organsfor transplantation shall be carried out by the emergency medical care centres.

(8) (former para. 5 - SG 71/06) The transport of tissues and cells for transplantation shall becarried out by the medical establishments referred to in para. 1, 2 and 3, as well as by tissue banks.

Art. 14. (amend. - SG 71/06, SG 36/09) (1) Tissue banks may carry out activities of collection, examination, processing, labelling, storage, supply and transport of tissues and cells intended for transplantation and processing.

(2) Tissue banks may carry out activities of procurement, examination, processing, labelling, storage and transportation of organs only when they are intended for processing.

Art. 15. (1) (Amend. - (1) Tissue-cell allograft products may be used both for transplantation and forthe manufacture of medicinal products and medical devices.

(2) (amend. - SG 36/09, SG 54/2020, in force from 16.06.2020) For the manufacture of medicinal products and medical devices, medical establishments may provide the tissue-cell allograftproducts obtained from processing to manufacturers of medicinal products and medical devices.

(3) (amend. - SG No. 71 of 2006, supplemented by SG 60 of 2012, amended by SG 54 of 2020, in force from 16.06.2020) The conditions and procedure for the examination, labelling, processing, processing, storage, quality and safety assurance and supply of organs, tissues and cells,as well as tissue-cell allograft products obtained from processing, shall be determined by a regulationof the Minister of Health.

Art. 15a. (1) (amended, SG No 60/2012) Medical establishments shall conclude written contracts with each other when they jointly carry out activities referred to in Article 2 of organs, tissues and cells.

(2) Medical establishments shall conclude written contracts with third parties for the supplyof goods and services which may affect the quality and safety of organs, tissues or cells.

(3) Medical establishments shall establish and maintain a register of contracts concludedunder par. 1 and 2.

(4) (amend. - SG 102/2018, in force from 1.04.2019) Medical establishments shall send copies of the contracts referred to in par. 1 and 2 to the Executive Agency "Medical Supervision" within 7 days after their conclusion.

Art. 15b. (New, SG 71/06) (1) (amend. - SG 36/09, suppl., SG 60/12, amend., SG 102/18, (1) Medical establishments shall be obliged to report to the Executive Agency for Medical Supervision within 7 days of the detection of any severe adverse reactions or serious incidents where they result from theprocurement, transplantation, supply, examination, characterisation, handling, processing, storage, supply and/or transport of organs, tissues and cells intended for transplantation, observed during andafter transplantation in the donor and the recipient, and are related to their quality and safety.

(2) (Supplemented, SG No 36/2009, SG No 60/2012) Medical establishments shall establish and implement a system for the immediate blocking, withdrawal or destruction of all organs,tissues and cells which may lead to a serious adverse reaction or have been the subject of a serious incident.

(3) (suppl. - SG 60/12) The conditions and procedure for the notification, recording, reporting and transmission of information on severe adverse reactions and serious incidents and for the blocking, withdrawal and destruction of organs, tissues and cells shall be laid down by a regulationof the Minister of Health.

Art. 15c. (1) (amend. - SG 36/09) Medical establishments shall label the organs, tissues and cells collected in accordance with the requirements of the medical standard for organ, tissue and cell transplantation.

(2) (amend. - SG 36/09) Medical establishments shall be obliged to establish conditions forthe traceability of organs, tissues and cells from the donor to the recipient and vice versa, as well as of the products and materials that come into contact with them and are related to their quality and safety, under conditions and in accordance with a procedure determined by a regulation of the Minister of Health.

(3) (new, SG 36/09) Medical establishments shall be obliged to establish and implement a quality system for all transplantation activities.

Art. 15d. (New, SG 71/06) (Supplemented, SG 36/09) (1) Each establishment carrying out transplantation activities shall designate a person on its staff who shall organise, supervise and be responsible for the examination, procurement, processing, handling, labelling, storage, supply and transplantation of organs, tissues and cells and the reporting of serious adverse reactions and seriousincidents.

(2) The person referred to in par. (1) shall comply with the following conditions:

1. have completed higher education with a degree of Master of Science in:

(a) a specialty of the professional field of medicine - in cases related to organ transplantation;

(b) (amend. - SG 36/09) a specialty of the professional field "Medicine", "Dentistry" or "BiologicalSciences" - in cases related to the transplantation of tissues and cells;

2. have at least two years' experience in the field of the activities for which he/she is responsible.

(3) (new - SG 36/09) The person referred to in par. (1) shall undergo a compulsory training course at least once every two years under the conditions and in the order determined by the Regulation referred to in Article 4, paragraph 6.

(4) (Former par. 3 - SG 36/09, amend., SG 102/2018, in force from 1.04.2019) Medical establishments shall notify the Executive Agency "Medical Supervision" within 7 days of the name,education and duration of the training of the person referred to in par. 1.

(5) (former paragraph 4 - SG 36/09, amend., SG 102/2018, in force from 1.04.2019) Medical establishments shall notify the Executive Agency "Medical Supervision" of the change or replacement of the person referred to in paragraph 1. 1, as well as of the time of its occurrence and the duration of the replacement.

(6) (former para. 5 - SG 36/09) The duties and responsibilities of the person referred to in para. (1) shall be determined by the regulation referred to in Art. 15b, par. 3.

Art. 15e. (new - SG 71/06, suppl., SG 36/09) Medical establishments shall keep the information related to the activities carried out by them under this Law for not less than 30 years and shall ensurethe conditions for its protection against unauthorised access, unauthorised alteration and destruction.

Section II

Funding

Art. 16. (amend. - SG 71/06) (1) (amend. - SG 36/09, SG 60/12) The Ministry of Health shall reimburse the costs incurred by the medical institutions for the following activities:

1. (supplemented, SG No. 60/2012) organs and all related costs, including the costs of the donorand the recipient, as well as the costs of diagnosis and treatment of the donor and the recipient in the post-transplantation period;

2. tissues and cells for the treatment of diseases defined by an ordinance of the Minister of Health.

(2) (new - SG 36/09) The Ministry of Health shall finance and:

1. the establishment of information systems for the integration, registration and control of the transplantation process;

2. medical research projects in the field of transplantation;

3. national health programmes in the field of transplantation.

(3) (new - SG 98/10, in force from 1.01.2011) The medicinal products intended for the treatment of post-transplantation conditions shall be paid for by the National Health Insurance Fund under the Health Insurance Act.

(4) (former para. 2 - SG 36/09, former para. 3, Art. 98 of 2010, in force from 1.01.2011, amended,issue 60 of 2012, in force from 7.08.2012, issue 102 of 2018, in force from 1.04.2019) The NationalHealth Insurance Fund and insurers licensed under Section II, point "A", item 2 or items 1 and 2 of Annex No 1 to the Insurance Code may finance transplantation activities on the basis of a contract with the medical institution, which shall take effect after approval by the Executive Agency "MedicalSupervision" and entry in its register.

(5) (Former par. 3, amend. - 36 of 2009, former para. 4, Art. 98 of 2010, in force from 1.01.2011)The conditions, procedure and amount of reimbursement of the costs under par. 1, as well as the relative share of the work performed, shall be determined by a regulation of the Minister of Health.

Art. 16a. (new - SG 60/12, amend., SG 102/18, in force from 1.04.2019) The Executive Agency "Medical Supervision" shall finance activities to promote donation and to pay tribute and respect to deceased donors and their relatives.

Art. 17. (Art. 71 of 2006, issue 102 of 2018, in force from 1.04.2019, issue 54 of 2020, in force from16.06.2020) Natural and legal persons may donate funds for transplantation activities.

Chapter Three

PROCUREMENT OF ORGANS, TISSUES AND CELLS

Section I

Procurement of organs, tissues and cells from deceased donors

Art. 18. (1) The procurement of organs, tissues and cells for the purpose of transplantation may be carried out from a human corpse after death has been established in accordance with the medical criteria and procedure laid down by regulation of the Minister of Health.

(2) (amend. - SG 102/2018, in force from 1.04.2019) In case of irreversible cessation of all brain functions and cardiac activity, death shall be established by a standing committee composed of three physicians. The commission shall be appointed by the director of the medical institution whereorgans, tissues and cells are taken, after obtaining the consent of the executive director of the Executive Agency for Medical Supervision.

(3) Physicians establishing the death referred to in paragraph (2) may not participate in teams performing organ procurement and transplantation.

Art. 19. (1) (amend. - SG 71/06) No organs, tissues and cells may be taken for transplantation if theperson during his/her lifetime has expressed his/her written disagreement for this.

(2) No organs, tissues and cells may be taken from the corpse of a person under 18 years of age or of a person under guardianship, except with the written consent of his parents, guardian or custodian.

(3) No organs, tissues or cells may be taken for transplantation from the corpse of a person of unknown identity.

(4) (amend. - SG 36/09) If the corpse is subject to forensic examination, the procurement of organs, tissues and cells from it shall be carried out after written authorisation of a forensic expert who is not involved in transplantation activities.

Art. 20. (1) (amend. - SG 71/06, SG 9/11) Every non-disabled Bulgarian citizen, as well as a foreignerresiding permanently, long-term or permanently in the Republic of Bulgaria, shall have the right to express explicitly, in writing, his/her disagreement to the procurement of organs, tissues and cells after his/her death.

(2) (amend. - SG 71/06) The expressed disagreement under par. 1 may relate to particular or all organs, tissues and cells, as well as to their procurement for other therapeutic, diagnostic, scientific, medical, educational and teaching purposes.

(3) (amend. - SG 71/06, SG 102/18, in force from 1.04.2019) The disagreement for the procurement of organs, tissues and cells shall be expressed in writing to the general practitioner by

signing a declaration approved by the Minister of Health upon proposal of the Executive Agency"Medical Supervision".

(4) (amend. - SG 71/06, SG 36/09) The general practitioner shall immediately enter the disagreement in the person's health insurance booklet and inform the director of the relevant regionalhealth inspection in writing within 7 days.

(5) (New, SG No. (5) Persons who have interrupted health insurance rights, are not insured orhave not chosen a general practitioner may express their disagreement for the procurement of organs,tissues and cells after their death by signing a declaration approved by the Minister of Health upon proposal of the Executive Agency "Medical Supervision". The declaration shall be submitted in duplicate to the municipality of residence, one copy to be given to the person expressing his/her opposition and the other to the Executive Agency for Medical Supervision within 7 days of its submission.

(6) (former para. 5, amend. - SG No. 71 of 2006, amended and supplemented, issue 36 of 2009,amend., issue 102 of 2018, in force from 1.04.2019) Within 7 days after receiving the information under paragraph 4 about the persons who have expressed disagreement, the directors of the regionalhealth inspectorates shall inform the Executive Agency "Medical Supervision" in writing.

(7) (former para. 6, amend. and supplement. - SG No. 71 of 2006, amend., SG 102 of 2018, inforce from 1.04.2019) The written disagreement expressed under par. 1 and 5 shall be entered in theofficial register of the Executive Agency "Medical Supervision" within three days from the receipt ofthe notification under paragraph 6.

Art. 21. (amend. - SG 71/06) (1) The procurement of organs, tissues and cells from a deceased personmay be carried out if the following conditions are met:

1. the person's health insurance booklet does not contain a statement of disagreement for the procurement of organs, tissues and cells after his or her death, in cases where such a statement has been issued;

2. (amend. - SG 102/2018, in force from 1.04.2019) the name of the person is not entered in the official register of the Executive Agency "Medical Supervision" under Art. 39, par. 1, and. 2;

3. mandatory notification of the forthcoming procurement of organs, tissues or cells has been given and no written refusal has been submitted within a reasonably short period of time:

(a) spouse or parent;

(b) a child;

(c) a brother or sister;

(d) (new - SG 54/1920, in force from 16.06.2020) other relatives by consanguinity up to the fourthdegree, including in the case of kinship by adoption, but not earlier than three years from the adoption.

(2) (new - SG 54/2020 in force from 16.06.2020) The written refusal under par. 1, item 3 shallbe expressed by:

1. the persons referred to in par. 1. the person(s) referred to in point 1(3)(a) shall;

2. the persons referred to in par. 1(3)(b), if the deceased person has no relatives referred to inpar. 1(3)(a);

3. the persons referred to in par. 1(3)(c), if the deceased has no relatives referred to in par. 1(3)(a) and (b);

4. the persons referred to in par. 1(3)(d), if the deceased has no relatives referred to in par. 1(3)(a), (b) and (c).

(3) (former para. 2 - SG 54/2020 in force from 16.06.2020) The procedure for establishing and certifying the circumstances referred to in paragraph 1 shall be determined by a regulation of the Minister of Health.

Art. 22. (amend. - SG 71/06) After the procurement, all necessary measures shall be taken to restorethe appearance of the body of the deceased person.

Art. 23. (amend. - SG 102/06, in force from 1.01.2019) Any medical institution where the procurement of organs, tissues and cells from a human corpse has been performed shall, within 7 days, register the performed procedure with the Executive Agency "Medical Supervision".

Section II

Recovery of organs, tissues and cells from a living donor

Art. 24. (1) The procurement of organs, tissues and cells from a donor shall be carried out only on condition that it does not constitute a danger to his life and that the donor has emitted a certified written consent has, after the risks which he assumes have been explained to him in advance in an accessible language.

(2) (New, SG 71/06) The notarisation of the consent referred to in par. 1 shall be carried outby a notary in whose area of operation the medical institution which will perform the procurement oforgans, tissues and/or cells is located.

(3) (former paragraph 2 - SG 71/06) The donor shall be informed of his/her rights, medical procedures and safety measures under this Act by a doctor who is not included in the team performingthe procurement or transplantation.

(4) (former paragraph 3 - SG 71/06) The donor may withdraw the consent given at any time before the procurement of organs, tissues and cells has been carried out.

(5) (former paragraph 4 - SG 71/06) Organs for transplantation shall not be removed from a person under the age of 18. The procurement of tissues and cells from persons under 18 years of ageshall be permitted only in the cases specified in this Act.

(6) (former para. 5 - SG 71/06) The procurement of organs, tissues and cells for transplantationfrom a person under legal guardianship shall not be allowed.

(7) (former para. 6, amended and supplemented - SG 71/06) The physical and mental health of the donor shall be established by a committee appointed by the director of the medical institution performing the procurement of organs, tissues and cells, consisting of at least three physicians who are not members of the procurement or transplantation team, with a report signed by all members ofthe committee.

(8) (new, SG 71/06) The offering of a material benefit to a donor of organs, tissues and cells, as well as the acceptance of a material benefit from the donor shall be prohibited.

(9) (New, SG No 60/2012) Living organ donors may receive compensation only if it is strictlylimited to the reimbursement of donation-related costs and loss of income.

Art. 25. (suppl. - SG 54/10, in force from 16.06.2020) Only one of the paired organs or part of a self-regenerating organ, as well as a uterus from a living donor, may be taken for transplantation under the following conditions:

1. after it has been established in advance that the organ or part thereof to be taken and the remaining organ or part thereof have fully preserved function;

2. after the necessary tests have been carried out in advance to exclude the possibility of transmission of infection and to establish the biological compatibility between the donor and the potential recipient.

Art. 26. (1) (Suppl. - SG, issue no. 71 of 2006, issue 36 of 2009, issue 54 of 2020, in force from 16.06.2020) Only an adult person who is the spouse or relative of the recipient in the direct line or inthe consanguineous line up to the fourth degree, including in the case of kinship by adoption, but notearlier than three years from the adoption, in cases where the recipient is the adoptive parent, as evidenced by an official document.

(2) (amend. - SG 71/06, suppl., SG 36/09) Exceptionally, with the permission of the EthicalCommittee on Transplantation, a person shall be allowed to be an organ and tissue donor who:

1. has actually cohabited with the recipient without a civil marriage for more than two yearsand there is indisputable evidence thereof;

2. is the biological parent of the recipient and has not acknowledged the recipient in the manner prescribed by law;

3. (new - SG 54/2020 in force from 16.06.2020) is included in the official register for organ procurement under the conditions of cross-donation;

4. (new - SG 54/54 of 2020, in force from 16.06.2020) has given birth to a live child and is premenopausal according to the selection criteria laid down in the Ordinance referred to in Article 4, paragraph 1. 1 - only in the case of uterus harvesting.

(3) (amend. - SG 36/09).

Art. 26a. (new - SG 54/1920, in force as from 16.06.2020) (1) In the case of cross-donation, the procurement of organs shall be carried out if the following conditions are met simultaneously:

1. the first donor has given notarised written consent to be a donor, including in the case of cross-donation, and has designated the first recipient as the person to whom he or she has consentedto be a donor, including in the case of cross-donation;

2. the second donor has given notarised written consent to be a donor, including in the case ofcross-donation, and has named the second recipient as the person to whom he or she consents to be adonor, including in the case of cross-donation;

3. the first and second donors and the first and second recipients are included in the official register of the Executive Agency for Medical Supervision;

4. there are biologically compatible first and second recipients of the first and second donors who have given written informed consent to the transplantation under the conditions of cross- donation;

5. prior to the procurement, the first and second recipients have been identified by the ExecutiveAgency for Medical Supervision in accordance with the criteria laid down in the regulations referredto in Article 4(1)(a) and (b). 1 and Article 33;

6. not less than two months have passed since the first and second donors and the first and second recipients were entered in the official register of the Executive Agency for Medical Supervision.

(2) In the case of cross-donation, organ procurement shall be carried out simultaneously on the first and the second donor.

Art. 27. (1) (suppl. - SG 71/06) The procurement of self-healing tissues from persons under 18 yearsof age shall be carried out only when the transplantation is intended for a parent, spouse, sibling, sonor daughter and the following conditions are met:

1. there is no suitable donor over the age of 18;

2. the transplant is a life-saving treatment;

3. (amend. - SG 102/2018, in force from 1.01.2019) the recipient is included in the officialregister of the Executive Agency "Medical Supervision";

4. authorisation has been granted by the Ethics Committee for Transplantation.

(2) (Amended, SG 71/06) In the cases referred to in par. 1, a notarised consent of the donor's parents, guardian or custodian shall be required.

(3) (amend. - SG 36/09).

Art. 27a. (new, SG 36/09) (1) Haematopoietic stem cells and bone marrow may be taken from any non-disabled person, irrespective of his/her relationship to the recipient, after obtaining his/her writteninformed consent.

(2) Hematopoietic stem cells may be taken from a minor, regardless of relationship to the recipient, after obtaining written informed consent from both parents or guardians.

(3) Bone marrow may be taken from a minor only if the minor is related to the recipient, after obtaining written informed consent from both parents or guardians.

(4) The consent of the minor's parents or guardians must represent the minor's presumedwishes and may be withdrawn at any time.

(5) Hematopoietic stem cells and bone marrow may be removed from a minor after obtainingwritten informed consent from the minor and both parents or guardian.

(6) The consent of the minor, parents or guardian may be withdrawn at any time.

(7) Persons shall be provided with information in a manner that they can understandconcerning the procurement of haematopoietic stem cells and bone marrow.

(8) In the cases referred to in par. (3) and (5), bone marrow procurement activities shall be carried out after obtaining the authorisation of the Ethics Committee for Transplantation referred to in Article 12, par. 1.

Art. 28. (amend. and supplemented, SG 36/09) The procurement of amniotic tissue, umbilical cord tissue and placental cells shall be carried out for the purposes of allogeneic and autologous transplantation after informed consent has been obtained from the pregnant or parturient woman.

Art. 29. (amend. - SG 71/06) (1) (amend. - SG 102/2018, in force from 1.04.2019, SG 54/2020, in force from 16.06.2020) Any medical institution which will perform organ procurement from a livingdonor shall notify the Executive Agency "Medical Supervision" thereof at least 7 days in advance.

(2) (amend. - SG 102/2018, in force from 1.04.2019) Within 7 days of the procurement of organs, tissues or cells from a living donor, the medical establishment shall register the procedure with the Executive Agency "Medical Supervision".

Section III

Procurement of embryonic organs, tissues and somatic, placental and amniotic cells

Art. 30. (1) Embryonic organs, tissues and somatic, placental and amniotic cells may be taken from an aborted foetus for the purpose of transplantation after informed consent has been obtained from thewoman who aborted the foetus.

(2) The Minister of Health shall determine by regulation the conditions and procedures for the procurement of embryonic organs, tissues and somatic, placental and amniotic cells.

Section IV

Procurement of organs, tissues and cells from animals

Art. 31. Animal organs, tissues and cells may be used for transplantation under conditions and in accordance with the procedure laid down by a regulation of the Minister of Health.

Chapter Four

TRANSPLANTATION OF ORGANS, TISSUES AND CELLS

Art. 32. Transplantation of organs, tissues and cells shall be carried out only provided that:

1. the recipient or his/her legal representatives have given informed consent to the forthcoming transplantation procedure;

2. (amend. - SG 102/2018, in force from 1.04.2019) the organ recipient is included in the official register of the Executive Agency "Medical Supervision".

Art. 33. (amend. - SG 102/2018, in force from 1.04.2019) The inclusion of persons in need of organ transplantation in the official register of the Executive Agency "Medical Supervision", as well as theselection of the specific organ, tissue or cell recipient, shall be carried out under the conditions and in accordance with the procedure established by a regulation of the Minister of Health.

Art. 33a. (new - SG 54/1920, in force from 16.06.2020) In the case of cross-donation, the organ transplantation shall be performed simultaneously on the first and the second recipient.

Art. 34. The medical establishments referred to in Article 13, par. 1, 2 and 3 shall carry out all medicalactivities related to the selection and preparation of the potential recipient, as well as to the continuousmonitoring, control of the health condition and the supportive treatment of the recipient.

Art. 35. (amend. - SG 102/2018, in force from 1.04.2019) Each medical establishment where organ,tissue or cell transplantation has been performed shall be obliged to register the transplantation procedure with the Executive Agency "Medical Supervision" within 7 days.

Chapter Five

IMPORT AND EXPORT OF ORGANS, TISSUES AND CELLS CONTROL

(amended, SG 36/09)

Art. 36. (SG 36/09, suppl., SG 41/09, in force from 2.06.2009, amend., SG 60/12, SG 102/18, in force from 1.04.2019, SG 54/2020, in force from 16.06.2020) (1) Import of organs for transplantationfrom third countries shall be allowed under the following conditions:

1. there are contracts signed by the Republic of Bulgaria in which the conditions and procedure for import of organs are explicitly specified;

2. the organ is provided by an institution which is recognised in accordance with the procedure established in the respective country and applies all the requirements for quality, safety, traceability, reporting of serious incidents and adverse reactions, as well as for the supply of information on the characterisation of organs and organ donors established in this Act;

3. an appropriate recipient of the organ concerned is included in the official register of the Executive Agency for Medical Supervision.

(2) Import of organs may be carried out by:

1. a medical institution referred to in Article 13, par. 1, which has a permit for the transplantation of the respective type of organ issued in accordance with Art. 48(3) of the Medical Establishments Act;

2. a medical establishment referred to in Article 13, par. 3, which has a certificate issued by the Executive Agency "Medical Supervision" for the transplantation of the relevant type of organ andthis activity is included in the relevant regulations under Art. 35, par. 3(2) of the Medical Establishments Act.

(3) To obtain a permit for organ import, the head of the medical establishment referred to in paragraph (2) shall apply to the Executive Director of the Executive Agency "MedicalSupervision" for each individual donor, to which he/she shall attach:

1. documents required under the contracts referred to in par. 1, and. 1;

2. documents certifying the compliance of the institution providing the organ with the requirements of par. 1 and 2;

3. information on the organ and the donor - documents on clinical, laboratory, virological, serological, immunological, microbiological and imaging tests;

4. documents of compliance with the requirements of Article 26 in the case of import of organsor parts of organs from a living donor.

(4) The Executive Agency "Medical Supervision" shall examine the application and the documents attached thereto, carry out an official check for compliance with par. 1, item 3, for the existence of contracts referred to in par. 1, item 1, as well as for compliance of the submitted documents under par. 3(1) with the requirements of those contracts.

(5) The Executive Agency "Medical Supervision" shall issue a model import permit or make a reasoned refusal within a time limit consistent with the ischemic time of the authority, but not longerthan 24 hours from the submission of the application.

Art. 36a. (New, SG No. 60/2012, amended, SG No. 102/2018, in force as of 1.04.2019, SG No. 54/2020, in force as of 16.06.2020) (1) The exchange of organs shall take place between Member States of the European Union and the European Economic Area and the Swiss Confederation and shall include:

1. receiving organs for transplantation from Member States of the European Union and of the European Economic Area and from the Swiss Confederation;

2. the supply of organs for transplantation to Member States of the European Union and the European Economic Area and to the Swiss Confederation.

(2) The exchange of organs under par. (1) shall be carried out in compliance with the proceduresfor the transmission of information ensuring quality, safety, traceability, reporting of serious incidentsand severe adverse reactions, as well as with the procedures for the supply of information on the characterisation of organs and organ donors laid down in this Law.

(3) Exchange of organs with a country of shipment shall be carried out under the conditions of paragraph (2) and when the following conditions are met:

1. the organ is accompanied by documents for clinical-laboratory, virological, serological, immunological, microbiological and imaging examinations;

2. an appropriate recipient of the organ concerned is included in the official register of the Executive Agency for Medical Supervision.

(4) Exchange of organs with a recipient country shall be carried out under the conditions of paragraph (2) and when the following conditions are met:

1. the organ is accompanied by documentation of clinical laboratory, virological, serological, immunological, microbiological and imaging tests;

2. no suitable recipient of the organ concerned is included in the official register of the ExecutiveAgency for Medical Supervision.

(5) Exchange of organs with European organ exchange organisations shall be carried out after an agreement between the Executive Agency "Medical Supervision" and the relevant organisation has been concluded, if the organisation ensures compliance with the procedures for the transmission of relevant information on quality, safety, traceability, reporting of serious incidents and serious adverse

reactions, as well as with the procedures for the supply of the information on the characterisation of organs and organ donors set out in this Act.

Art. 36b. (new - SG 54/2020, in force from 16.06.2020) Exchange of bodies referred to in Art. 36a,par. 3 may be carried out by:

1. a medical establishment referred to in Article 13(1)(a) 1, which has a permit for transplantation of the respective type of organ issued in accordance with the procedure laid down in Art. 48(3) of the Medical Establishments Act;

2. a medical establishment referred to in Article 13, par. 3, which has a certificate issued by the Executive Agency "Medical Supervision" for the transplantation of the relevant type of organ and this activity is included in the relevant regulations under Art. 35, par. 3(2) of the Medical Establishments Act.

Art. 36c. (New, SG 54/1920, in force from 16.06.2020) (1) The exchange of organs referred to in Article 36a, paragraph 4 may be carried out by:

1. a medical establishment referred to in Article 13, par. 1, which has an authorisation for the procurement of the respective type of organ issued pursuant to Art. 48, par. 48 (3) of the Medical Establishments Act;

2. a medical establishment referred to in Art. 13, par. 3, which has a certificate issued by the Executive Agency "Medical Supervision" for the taking of the relevant type of organ and this activityis included in the relevant regulations under Art. 35, par. 3(2) of the Medical Establishments Act.

(2) The medical establishment shall provide the Executive Agency for Medical Supervision with documents for clinical-laboratory, virological, serological, immunological, microbiological and imaging examinations.

Art. 36d. (new - SG 54/1920, in force from 16.06.2020) (1) The Executive Agency "Medical Supervision" shall be the competent authority for liaison of the Republic of Bulgaria with the competent transplantation authorities in the countries of sending and receiving, the organ exchange organisations or the medical establishments to which the information on organ exchange and the resulting activities shall be transmitted.

(2) The Executive Agency "Medical Supervision" shall ensure round-the-clock availability for the performance of its functions under par. (1) relating to the organisation of organ exchange in emergency situations.

(3) Information concerning organ exchange and donor characterisation shall be transmitted in advance between the Executive Agency for Medical Supervision, on the one hand, and the competenttransplantation authority of the country of dispatch and of destination, the organ exchange organisation or medical establishment, on the other hand.

(4) The information referred to in par. (3) shall be transmitted immediately after its receipt and verification in writing by electronic means or by fax.

(5) In emergency situations, information concerning the characterisation of organs and donors, as well as the reporting of serious incidents and serious adverse reactions, may be transmitted orallyand shall be prepared and made available in writing immediately thereafter.

(6) Where part of the organ and/or donor characterisation information is not known at the time the information under par. (3), it shall be transmitted as soon as it becomes available by the ExecutiveAgency "Medical Supervision" or by the relevant medical institution.

(7) For the purpose of organ exchange, the Executive Agency "Medical Supervision" shall draw up a form "Information for organ exchange" in triplicate, and where the exchange is carried out witha country of the European Free Trade Association - in 4 copies, which it shall provide to the medicalestablishment referred to in Article 36b or Article 36c. The form shall contain the followinginformation:

1. the name and contact details of the assurance centre;

2. the name and contact details of the transplantation centre;

3. specification of the organ;

4. date of supply;

5. national donor identification number;

6. national identification number of the recipient or, if the organ has not been transplanted,information on its end use;

7. date and time of transfer;

8. contact details of the person responsible for the transfer;

9. date of transplantation, if applicable;

10. information that it contains personal data and should be protected from unauthorised disclosureor access.

(8) When carrying out customs procedures with the countries of the European Free TradeAssociation, the medical establishment shall submit copy No. 4 of the "Information for Organ Exchange" form.

(9) Information relating to organ exchange shall be transmitted in a language understood by bothparties or in English.

(10) The Executive Agency "Medical Supervision" shall enter the information referred to in par. (7) in the register referred to in Article 39, par. (1) (2) in Bulgarian, irrespective of the language inwhich it is received.

(11) In case of exchange of authorities with countries of dispatch, the Executive Agency "Medical Surveillance" shall confirm to the country of dispatch the receipt of the information.

(12) In the case of an exchange of authorities with a receiving State, the Medical Surveillance Executive Agency must secure from the receiving State confirmation of receipt of the information sent.

Art. 36e. (New, SG 54/54 of 2020, in force from 16.06.2020) (1) The Executive Agency "Medical Supervision" shall request from the recipient States information on the date of the transplantation oforgans subject to exchange, as well as on the name of the medical establishment where it was performed and contact details of the latter.

(2) If the organ that is the subject of an exchange is not transplanted, the Executive Agency for Medical Supervision shall request from the competent organisation of the recipient country information on its final use.

Art. 36f. (New, SG 54/2020, in force from 16.06.2020) (1) In the event of a severe adverse reactionand a serious incident involving the organs subject to exchange and the donor, the Executive Agencyfor Medical Supervision shall immediately report it to the relevant competent transplant authority inthe country of dispatch or in the country of destination under the conditions and in accordance with the procedure laid down in the Regulation referred to in Article 15b(1). 3.

1. Information relating to the exchange of organs shall be kept at the Executive Agency "Medical Supervision" and may be made available to the State upon request of dispatch or of receipt.

(2) The Medical Surveillance Executive Agency shall communicate to the European Commissioncontact details which shall include at least: name, telephone number, e-mail address, fax number andpostal address.

(3) The Medical Surveillance Executive Agency shall inform the European Commission in duetime of any changes in the data referred to in paragraph (1). 3.

Art. 36g. (new - SG 54/1920, in force from 16.06.2020) (1) Export of organs for transplantation to third countries shall be allowed under the following conditions:

1. there are contracts concluded by the Republic of Bulgaria in which the conditions and procedure for the export of organs are explicitly specified;

2. the organ shall be provided to an institution which is recognised in accordance with the procedure established in the respective State;

3. there is no suitable recipient for the organ in the Member States of the European Union and the European Economic Area and in the Swiss Confederation;

4. there is an appropriate recipient in the country concerned.

(2) Organs may be exported from:

1. a medical establishment referred to in Article 13, par. 1, which has an authorisation for the procurement of the respective type of organ issued pursuant to Art. 48, par. Article 48(3) of the Medical Establishments Act;

2. a medical establishment referred to in Art. 13, par. 3, which has a certificate issued by the Executive Agency "Medical Supervision" for the taking of the relevant type of organ and this activityis included in the relevant regulations under Art. 35, par. 3(2) of the Medical Establishments Act.

(3) In order to obtain an organ export permit, the head of the medical establishment referred to in paragraph (2) shall submit an application to the Executive Director of the Executive Agency "Medical Supervision" for each individual donor, to which he/she shall attach:

1. documents required under the contracts referred to in par. 1, and. 1;

2. documents certifying the compliance of the institution to which the organ is donated with the requirements of par. 1, and. 2;

3. evidence of compliance with par. 1, and. 4;

4. information on the organ and the donor, including documentation of clinical, laboratory, virological, serological, immunological, microbiological and imaging exams, as well as evidence thatremoval, examination, labelling, storage and transport have been carried out in accordance with the regulatory requirements in the Republic of Bulgaria.

(4) The Executive Agency "Medical Supervision" shall examine the application and the documents attached thereto and shall carry out a check for compliance with par. 1, item 3, for the existence of contracts referred to in par. 1, item 1, as well as for compliance of the submitted documents under par. 3(1) with the requirements of those contracts.

(5) The Executive Agency "Medical Supervision" shall carry out verification of compliance withpar. (1)(3) by making a request to the competent transplantation bodies of the Member States of the European Union and the European Economic Area and of the Swiss Confederation and to the European Organ Exchange Organisations concerning the presence/absence of potential recipients onthe transplant waiting lists.

(6) The Executive Agency "Medical Supervision" shall issue an export authorisation or make a reasoned refusal within a time limit appropriate to the ischaemic time of the organ, but not longer than 24 hours from the submission of the application.

(7) In the case of exchange, import and export of organs to expedite the relevant procedure, it shall be allowed for the documentation to be submitted by the medical establishments to the Executive Agency "Medical Supervision" also by electronic means.

Art. 37. (SG 36/09, supplemented by SG 41/09, in force from 2.06.2009, amended by SG 60/12, SG102/18, in force from 1.04.2019, (1) The export of tissues, cells and ova, spermatozoa and zygotes, hereinafter referred to as "reproductive cells", shall be permitted under the following conditions:

1. the needs of the Republic of Bulgaria are met;

2. the tissues, cells and reproductive cells shall be made available to an institution recognised in accordance with the procedure laid down in the State concerned for carrying out this type of activity;

3. the tissues, cells and reproductive cells are collected, stored and transported in accordance withthe requirements of this Act and the Health Act, as well as with the established medical standards andrules of the respective country;

4. the tissues and cells are included in the official register of the Executive Agency "Medical Supervision".

(2) Export of tissues and cells shall be carried out by:

1. a medical establishment referred to in Article 13, par. 1, which has a permit issued under Art. 48, par. 3 of the Medical Establishments Act, or a medical establishment referred to in Article 13, paragraph 2, which has a certificate issued in accordance with Article 40, paragraph 1 of the MedicalEstablishments Act. 13 of the Medical Establishments Act, which includes activities for the procurement of the relevant type of tissues and cells;

2. a medical establishment referred to in Article 13, par. 3, which has a certificate issued by the Executive Agency "Medical Supervision" for the collection of the relevant type of tissues and cells and this activity is included in the relevant regulations under Art. 35, par. 3(2) of the Medical Establishments Act;

3. a tissue bank which has a permit issued under Art. 48, par. 3 of the Medical Establishments Act, which includes activities for the collection or storage of the relevant type of tissues or cells.

(3) Export of reproductive cells shall be carried out by:

1. a hospital care facility and a tissue bank which have a permit issued pursuant to Art. 48, par. 48 (3) of the Medical Establishments Act, which includes activities in assisted reproduction, supply,use or storage of the respective type of reproductive cells;

2. an outpatient care facility registered under Art. 40, par. 13 of the Medical Establishments Act,whose certificate of registration includes activities in assisted reproduction, supply, use or storage ofthe respective type of reproductive cells;

3. a medical establishment referred to in Article 13, par. 3, which has a certificate issued by the Executive Agency "Medical Supervision" for assisted reproduction, supply, use or storage of the relevant type of reproductive cells and this activity is included in the relevant regulations under Art.3(2) of the Medical Establishments Act.

(4) To obtain a permit for the export of tissues, cells and reproductive cells, the head of the medical establishment referred to in paragraphs (2) and (3) shall apply in a form to the Executive Director of the Executive Agency "Medical Supervision" for each specific export, to which he shall attach:

1. documents certifying compliance of the institution to which the tissues and cells are to be supplied with the requirements of par. 1, and. 2;

2. documents on how the tissues, cells and reproductive cells are removed, stored and transported;

3. information on tissues, cells and reproductive cells, which shall include documentation of virological, serological and microbiological tests, as well as information on how tissues and cells arehandled, processed and labelled, and, for reproductive cells, information on collection, storage and transport.

(5) The Executive Agency "Medical Supervision" shall examine the application and the documents attached thereto and shall carry out an official check for compliance with par. 1, items 1 and 4.

(6) The Executive Agency "Medical Supervision" shall issue an export permit or make a reasonedrefusal within 7 days from the submission of the application.

(7) The medical establishment shall submit a copy of the authorisation referred to in paragraph (6) when customs procedures are carried out.

Art. 38. (SG 36/09, suppl. SG 41/09, in force from 2.06.2009, amend. SG 60/12, SG 102/18, in forcefrom 1.04.2019, 54 of 2020, in force from 16.06.2020) (1) Import of tissues, cells, tissue-cell allograftproducts and reproductive cells from third countries shall be subject to the authorisation of the Executive Director of the Executive Agency "Medical Supervision". The following shall be entered in the permit:

1. the full name of the establishment, telephone, fax, e-mail address, the European Union directorycode for tissue establishments and website;

2. the registered office and management address of the establishment;

3. the name and number of the act under which the establishment carries out its treatment activities;

4. the full name of the person representing the establishment;

5. the country providing the tissues/cells/tissue allograft products/reproductive cells;

6. the institution, including the subcontractor(s) providing the tissues/cells/reproductive cells, telephone, fax and e-mail;

7. type and quantity of the tissue/cell/tissue allograft product/reproductive cell;

8. unique identification number of the donor and unique identification number of the recipient; for tissues/cells/tissue allograft products, method of handling, processing, labelling, storage and transport; for reproductive cells, method of collection, storage and transport;

9. a description of the documents attached to the tissue/cell/tissue-cell allograft product or reproductive cell containing data on virological, serological and microbiological tests;

10. whether the authorisation is single, with the recipient's details, and/or multiple, for the tissue/cell/tissue allograft product/reproductive cell types indicated and, in the circumstances defined,with the possibility of noting which is applicable;

11. the name of the Executive Director of the Medical Surveillance Executive Agency, signature,date and time, seal, and date and time of delivery of the tissue/cell/tissue allograft product/reproductive cell;

12. the name, telephone, fax and e-mail of the person responsible for handing over the tissues/cells/tissue allografts/reproductive cells;

13. the conditions, if any, attached to the import;

14. the Member States of the European Union to which the imported tissues, cells, tissue-cell allograft products, reproductive cells, where known, will be distributed.

(2) The requirements to be met by the quality of the tissues, cells and tissue-cell allograft productsreferred to in par. (1) shall be determined by regulation of the Minister of Health.

(3) The import of tissues, cells and tissue-cell allograft products from third countries shall be permitted under the following conditions:

1. the quality of the tissues, cells and tissue-cell allograft products meets the requirements of the Ordinance referred to in paragraph 2;

2. the tissues, cells and tissue-cell allograft products are provided by an institution recognised in accordance with the procedure laid down in the country concerned for carrying out this type of activity;

3. there is a proven positive effect from the use of tissues, cells and tissue-cell allograft productsobtained and processed by methods and technologies not practised in the Member States of the European Union and of the European Economic Area and in the Swiss Confederation.

(4) The import of reproductive cells shall be allowed under the conditions of par. 3, and. 2.

Art. 38a. (new - SG 54/1920, in force from 16.06.2020) (1) Import of tissues, cells or tissue-cellallograft products shall be carried out by:

1. a medical establishment referred to in Article 13, par. 1, which has a permit issued in accordance with Art. 3 of the Medical Establishments Act or a medical establishment referred to in Article 13(2) which has a certificate issued in accordance with Article 40(3) of the MedicalEstablishments Act. 13 of the Medical Establishments Act, which includes activities for the transplantation or storage of the relevant type of tissues or cells;

2. a medical establishment referred to in Article 13, par. 3, which has a certificate issued by the Executive Agency "Medical Supervision" for the transplantation or storage of the relevant type of tissues or cells and this activity is included in the relevant Regulations under Art. 35, par. 3(2) of theMedical Establishments Act;

3. a tissue bank which has a permit issued under Art. 48, par. 3 of the Medical Establishments Act, which includes activities for storage of the relevant type of tissues or cells.

(2) Import of reproductive cells shall be carried out by:

1. a hospital care facility and a tissue bank which have a permit issued pursuant to Art. 48, par. 48 (3) of the Medical Establishments Act, which includes activities of assisted reproduction, supply,use or storage of the respective type of reproductive cells;

2. an outpatient care facility registered under Art. 40, par. 13 of the Medical Establishments Act,whose certificate of registration includes activities in assisted reproduction, supply, use or storage ofthe respective type of reproductive cells;

3. a hospital care facility under the Council of Ministers, the Ministry of Defence, the Ministry ofthe Interior, the Ministry of Justice and the Ministry of Transport, Information Technologies and Communications, which has a certificate issued by the Executive Agency "Medical Supervision" forassisted reproduction, supply, use or storage of the relevant type of reproductive cells and this activityis included in the relevant regulations under Article 35, Par. 3(2) of the Medical Establishments Act.

(3) In order to obtain a permit for the import of tissues, cells, tissue-cell allograft products or reproductive cells, the head of the medical establishment referred to in par. 1 and 2 shall submit an application to the Executive Director of the Executive Agency "Medical Supervision", which shall include:

1. the full name of the medical establishment, telephone, fax, e-mail, the European Union directory code for tissue establishments, Internet address, registered office and management address,the name and number of the act under which the medical establishment carries out medical activities;

2. the full name of the person representing the establishment;

3. country, institution, including subcontractor(s) providing tissues/cells/tissue allograft products/reproductive cells, telephone, fax and e-mail;

4. the name of the person representing the institution, telephone, fax and e-mail;

5. type and quantity of tissue/cell/tissue-cell allograft products/reproductive cells;

6. unique identification number of the donor and unique identification number of the recipient oftissues and cells; for tissues/cells/tissue allograft products, method of handling, processing, labelling,storage and transport; for reproductive cells, method of collection, storage and transport;

7. description of documents with data for virological, serological and microbiological tests;

8. the name of the person responsible for the transfer of the tissues/cells/tissue-cell allograft products/reproductive cells, telephone, fax and e-mail;

9. conditions attached to the import, if any;

10. the Member States of the European Union to which the imported tissues, cells, tissue-cell allograft products, reproductive cells will be distributed, where known;

11. a statement of the desired method of receipt of the individual administrative act issued.

(4) To the application under par. 3 shall be attached:

1. documents of compliance with Art. 38, par. 3 and 4;

2. a duly certified translation of the third-country supplier's operating permit;

3. a copy of a written agreement with the third-country supplier on compliance with the quality and safety requirements for tissues, cells and tissue-cell allograft products intended for import in accordance with the medical standard for organ, tissue and cell transplantation;

4. information on the tissues, cells, tissue-cell allograft products or reproductive cells, including documentation of virological, serological and microbiological tests, as well as information on each stage of the handling, processing, labelling, storage and transport of the tissues, cells and tissue-cell allograft products and on how they are handled, and for reproductive cells, information on each stageof collection, storage and transport;

5. a description of the criteria used for the identification and evaluation of the donor and of the information provided to the donor or to the persons referred to in Article 21(1). 1, and. 3;

6. information on the control centres used by the third-country suppliers and on the tests carried out by the centres;

7. information on the methods used in the processing of tissues and cells, including the validationof tissue and cell processing procedures;

8. a description of the facilities, critical equipment, critical materials and criteria used for qualityand environmental control for each activity performed by the third-party supplier;

9. information on the conditions for the release of tissues, cells and tissue allograft products by the third-party supplier;

10. details of the third-party supplier's subcontractors - name, identification, place of registrationand of business and description of the activities carried out by the subcontractors;

11. a list of the types of tissues, cells and tissue-cell allograft products and information on the donation, procurement, control, processing or storage activities carried out prior to import by the third-country supplier or its subcontractor, and the countries in which they are carried out;

12. a list of the types of tissues, cells and tissue-cell allograft products and information on the donation, procurement, control, processing or storage activities to be carried out after importation bythe medical establishment;

13. a list of the establishment's standard operating procedures related to import, including the implementation of the Uniform European Code, the receipt and storage of imported tissues and cells,

the management of adverse incidents and reactions and the traceability of tissues and cells from donorto recipient;

14. the job description of the person responsible under Article 15d(1)(b) 1;

15. a copy of the primary label of the tissues, cells and tissue-cell allograft products, the repackaging label, the label of the outer packaging and of the transport containers;

16. documentation of compliance with the requirements of Article 26 for imports of tissues froma living donor;

17. a summary of the results of the last inspection of the third country supplier carried out by therelevant competent authority of the third country, including the date and type of inspection and its main conclusions.

(5) In the case of a single import, the application shall be accompanied by the documents referredto in paragraph 4(11), (12) and (16).

(6) The Executive Agency "Medical Supervision" shall examine the application and the documents attached thereto and shall issue an import permit or make a reasoned refusal within 7 days from the submission of the application.

(7) The medical establishment shall submit a copy of the authorisation referred to in paragraph (6) when customs procedures are carried out.

(8) The requirements of Article 38 and this Article shall not apply to the import of tissues, cells,tissue allograft products and reproductive cells in case of urgent need.

(9) In the cases referred to in paragraph (8), tissues, cells, tissue-cell allograft products and reproductive cells shall be provided by the medical establishment referred to in paragraph (9). 1 and2, which shall register them and notify the Executive Agency "Medical Supervision" to ensure their traceability.

Art. 38b. (new - SG 54/1920 , in force from 16.06.2020) (1) The customs authorities shall immediately notify the Executive Director of the Executive Agency "Medical Supervision" of any case of an infringement found in the import, export and exchange of organs, as well as in the importand export of tissues, cells, tissue allograft products and reproductive cells, in accordance with their powers as in Article 43, paragraph 2, and in accordance with the powers as in Article 229b of the Health Act.

(2) Human organs, tissues, cells and tissue-cell allograft products intended for transplantation and reproductive cells intended for assisted reproduction detained by the customs authorities shall behanded over for quarantine storage and subsequent destruction by a medical institution designated bythe Executive Director of the Executive Agency "Medical Supervision", for which a handover and acceptance protocol shall be drawn up containing information on the type, quantity and unique identification numbers of the donor and recipient.

Chapter Six REGISTER AND

CONTROL

(suppl. - SG 71/06)

Art. 39. (1) (amend. - SG 102/2018, in force from 1.04.2019) The Executive Agency "Medical Supervision" shall establish and maintain:

1. a public register;

2. (suppl. - SG 71/06) an official register, in which the names of the persons who have expressedtheir disagreement for the procurement of organs, tissues and cells shall also be entered.

(2) The circumstances and data to be entered in the registers referred to in par. (1), the procedurefor entry and the use of the information shall be regulated by a regulation of the Minister of Health. The public register referred to in par. 1(1) shall not contain personal data.

(3) The data in the public register shall be accessible for use by all persons under the conditionsand in accordance with the procedure of the Act on Access to Public Information.

(4) (amend. - SG 71/06) The data from the public register shall be kept for 30 years. Citizens shall have the right to verify whether the expressed opposition to the procurement of organs, tissues and cells is correctly reflected in the service register.

(5) (amend. - SG 71/06) Health information from the service register shall be provided in accordance with the procedure laid down in Article 28 of the Health Act.

Art. 39a. (new, SG 71/06) (1) (amend., SG 36/09, SG 102/18, in force from 1.04.2019) The ExecutiveAgency "Medical Supervision" shall carry out inspections of medical establishments carrying out activities under this Act and under Section III "Assisted Reproduction" of Chapter Four of the HealthAct at least once every two years.

(2) (amend. - SG 102/2018, in force from 1.04.2019) Inspections shall be carried out in case ofany serious adverse reaction or serious incident, as well as at the request of a competent authority ofanother state.

(3) (amend. - SG 102/2018, in force from 1.04.2019) The inspections referred to in par. (1) and (2) shall be carried out by qualified employees of the Executive Agency "Medical Supervision" underconditions and in accordance with the procedure determined by the Regulation under Article 7c, paragraph 4 of the Medical Establishments Act.

(4) (amend. - SG 54/2020, in force from 16.06.2020) The persons referred to in par. (3) shall undergo a compulsory training course at least once every two years under the conditions and in the order determined by the regulation under par. 3.

Chapter Seven

ADMINISTRATIVE PROVISIONS. COMPULSORY ADMINISTRATIVE MEASURES

(amend. - SG 36/09)

Art. 40. (1) (amend. - SG 36/09, suppl., SG 60/12) Whoever carries out an activity of removal, examination, supply, characterisation, processing, treatment, storage, transport, supply or transplantation of organs, tissues or cells or disseminates information in violation of these provisions,this Law or of the normative acts implementing it, shall be punished with a fine of BGN 10.000 to BGN 30.000, insofar as the act committed does not constitute a criminal offence.

(2) Where the violation under par. 1 is committed by a legal person, a pecuniary sanction of BGN 20.000 to BGN.50 000 shall be imposed.

Art. 40a. (New, SG 71/06) (1) Whoever violates the prohibitions under Article 6 or Article 24, paragraph 8 shall be punished with a fine of BGN 20.000 to BGN 40.00.

(2) Where the violation under par. 1 is committed by a legal person, a pecuniary sanction of BGN 30 000 to BGN 50 000 shall be imposed.

Art. 40b. (New, SG 71/06) A medical institution which violates the provisions of Article 13, paragraphs 4 and 5, Article 15a, 15b, 15c, 15d, 15e or 29 shall be subject to a pecuniary sanction in the amount of BGN 30.000 to BGN 50.000.

Art. 41. (1) (amend. - 36 of 2009, suppl., issue 60 of 2012, amend., issue 54 of 2020, in force as of 16.06.2020) Whoever carries out the activity of import and export of organs, tissues and cells, importof tissue-cell allograft product and exchange of organs in violation of the provisions of this Law or of the normative acts implementing it, shall be punished with a fine of 100.000 to 500.000 BGN, if not subject to a more severe penalty.

(2) Where the violation under par. 1 is committed by a legal person, a pecuniary sanction of BGN 750.000 to BGN 2 000.000 shall be imposed.

Art. 41a. (new, SG 36/09) (1) Whoever violates the provisions of this Law or the normative acts implementing it, outside the cases referred to in Articles 40-41, shall be punished with a fine of BGN5 000 to BGN 10 000.

(2) Where the violations referred to in par. 1 are committed by a legal person, a pecuniary sanction of BGN 7.000 to BGN 12.000 shall be imposed.

Art. 42. (1) (Supp. - 1. 71 of 2006, amended, issue 36 of 2009, issue 102 of 2018, in force from 1.04.2019) Violations under Articles 40, 40a, 40b and 41a shall be established by acts drawn up by officials appointed by the Executive Director of the Executive Agency "Medical Supervision".

(2) (Suppl. - (2) The provisions of Art. 71 of 2006, amended, issue 36 of 2009, issue 102 of 2018, in force from 1.04.2019) Penalty decrees for the offences under Articles 40, 40a, 40b and 41a shall be issued by the Executive Director of the Executive Agency "Medical Supervision".

Art. 43. (1) (amend. - SG 102/2018, in force from 1.04.2019) The violations under Article 41 shall be established by acts drawn up by the customs authorities or by officials designated by the ExecutiveDirector of the Executive Agency "Medical Supervision".

(2) (amend. - SG 102/2018, in force from 1.04.2019) Penalty decrees for the violations underArticle 41 shall be issued by the Director of the Customs Agency or by officials designated by him, respectively by the Executive Director of the Executive Agency "Medical Supervision".

Art. 44. Establishment of violations, issuance, appeal and execution of penalty decrees shall be carried out in accordance with the procedure laid down in the Law on Administrative Violations andPenalties.

Art. 45. (new - SG 36/09) The revenues from fines and property penalties for established violations under this Law and the by-laws on its implementation shall be credited to the budget of the body which issued the penal decree.

Art. 46. (new, SG 36/09) (1) (amend. - SG 102/2018, in force from 1.04.2019) The Executive Director of the Executive Agency "Medical Supervision" may by order suspend the performance of transplantation activity for a period of up to 6 months if the medical institution does not comply withthe requirements of the medical standard on organ, tissue and cell transplantation.

(2) (amend. - 15 of 2013, in force from 1.01.2014, SG 102 of 2018, in force from 1.01.2019) For the medical establishments referred to in Article 13, par. 3, a copy of the suspension order referredto in par. 1 shall be forwarded to the respective first-ranking authorising officer with budget, to whomthe director of the medical establishment is a second-ranking authorising officer with budget.

(3) (amend. - SG 102/2018, in force from 1.04.2019) If after the expiry of the period under par. 1, the Executive Director of the Executive Agency "Medical Supervision" may:

1. (amend. - SG 102/2018, in force from 1.04.2019) delete the transplantation activity from themedical activity permit of the respective medical establishment - for the medical establishments referred to in Article 13, par. 1;

2. (amend. - SG 102/2018, in force from 1.04.2019) delete the transplantation activity from theactivity certificate of the respective medical establishment - for the medical establishments referred to in Article 13, paragraph 2;

3. (amend. and supplemented - SG 102/2018, in force from 1.04.2019) revoke the transplantation certificate for the medical establishments referred to in Art. 13, par. 3, by notifying the relevant primary budget authorising officer to whom the director of the establishment is a secondary budget authorising officer.

(4) The orders referred to in par. 1 and par. (3) (3) shall be subject to appeal under the Administrative Procedure Code.

(5) An appeal against the orders shall not suspend their execution.

ADDITIONAL PROVISIONS

§ **1**. For the purposes of this Act:

1. "Cell" means the smallest functional unit of which tissues and organs are composed.

2. "Tissue" is a group of body cells, homogeneous in structure and function, which is a constituent part of an organ or has the capacity to regenerate.

3. (Amended, SG No. 60/2012) "Organ" means a part of the human body composed of varioustissues which maintains its structure and vascular system and is capable of performing physiologicalfunctions. Organs are also parts of organs when they are intended to be used for the same purpose asthe whole organ in the human body, while preserving its structure and its vascular system.

4. "Hematopoietic stem cells" are the cells from which all blood cells are derived.

5. "Recipient" means a person to whom organs, tissues and cells have been transplanted for the purpose of treatment.

6. "'Living donor" means a living person from whom organs, tissues or cells are taken for thepurpose of transplanting them into another person for curative purposes.

7. "'Procurement" means the procurement by medical means of organs, tissues and cells fromthe body of a donor for the purpose of transplantation or for other medical, scientific or educational purposes.

8. "Transplantation" means the placement by medical means of organs, tissues and cells into the body of a recipient.

9. "'Embryonic organs, tissues and cells" means organs, tissues and cells taken from a humanembryo.

10. "Reproductive organs" are testes and ovaries that are intended for the procreation and reproduction of individuals.

11. "Ovum" means a female reproductive cell.

12. "Sperm" are the male reproductive cells.

13. "Informed consent" means voluntary consent in writing to the performance of a medical activity. The person giving consent must have received all the necessary information about the activity to be carried out and its expected results, as well as explanations about the alternative ways available to solve the medical problem.

14. (amended, SG 54/2020, in force from 16.06.2020) "Tissue-cell allograft product" means aproduct derived from the processing or treatment of tissues and cells of human origin.

15. "Biocompatibility" means the ability established by medical methods for transplanted organs, tissues and cells from one individual to another to perform their functions without causing anacute rejection reaction of the transplanted organs, tissues or cells.

16. "Amniotic tissue" is a membrane composed of epithelial and connective tissue cells that surrounds the embryo and forms the amniotic chamber.

17. (amend. - SG 36/09) "Autotransplantation (autologous transplantation)" means the takingof tissues and cells from one person and their transplantation elsewhere in the body of the same person.

18. "Implantation of artificial organs and tissues" means the medical placement of artificial organs and tissues into a person's body for the purpose of treatment.

19. "Advertisement" means any communication made through the mass media or otherwise about the supply of organs, tissues and cells for transplantation.

20. "Placental cell" are the cells of the organ through which the foetus takes up oxygen and nutrients and excretes carbon dioxide and other waste products during intrauterine development.

21. "Self-repairing organ" means an organ that can fully recover its mass and function after procurement of part of it.

22. "'Self-repairing tissue" means tissue that can recover its tissue mass after procurement of part of it.

23. "Human corpse" means the body of a person after death.

24. (new, SG 71/06) "Serious adverse reaction" means an unforeseen reaction in a donor or recipient related to the examination, procurement, processing, treatment, storage, transport and transplantation of organs, tissues and cells which has resulted in death or a life-threatening condition,or in the transmission of a communicable disease, permanent incapacity or illness leading toprolonged hospital stay.

25. (new - SG 71/06) "Serious incident" means any adverse event related to the examination, procurement, processing, treatment, storage, transport and transplantation of organs, tissues and cellswhich may result in death or a life-threatening condition, or in the transmission of a communicable disease, permanent incapacity or illness leading to prolonged hospital stay.

26. (new, SG 71/06) "Donor" means any source of organs, tissues or cells of human origin. 26a. (New,

SG No 60/2012) "Donation" means the donation of organs, tissues and cells for transplantation.

27. (New, SG 71/06) "Invasive procedure" means any instrumental disruption of the integrityof the skin or mucous membranes, whereby the human body is penetrated for the purpose of the procurement and transplantation of organs, tissues and/or cells.

28. (new, SG 71/06) "Examination" means an activity related to tests to assess the condition of an organ, tissue or cell, and to establish: immunological status, the presence of disease-causing organisms, chemical or biological substances through which disease, infection or intoxication may be transmitted.

29. (new - SG 71/06) "Handling" means the activity of preparing harvested organs, tissues orcells for transplantation by the application of physical, chemical or biological methods at the time ofharvesting or immediately afterwards, including their packaging, where no change is made to their integrity or physiological state.

30. (new, SG 71/06) "Processing" means the activity of preparing harvested tissues or cells for transplantation or extraction of medicinal substances by the application of physical, chemical or biological methods, including their packaging, whereby their integrity or physiological state is altered.

31. (New, SG 71/06, amended, SG 60/12) "Preservation" means the activity of using chemicaland physical agents, environmental changes or other means to prevent or delay biological or physicaldamage to organs, tissues and cells from procurement until their transplantation.

32. (New, SG 71/06) "Reasonably short period" means the time during which organs, tissues and cells retain their vitality and can be used for transplantation.

33. (new, SG 71/06) “Labelling” means the activity of marking the packaging of organs, tissues and cells in order to identify them.

34. (New, SG 71/06) “Packaging” means the isolation of organs, tissues or cells from the environment by means of suitable materials to prevent their contamination or damage.

35. (new - SG 36/09) “Third countries” are countries which are not members of the EuropeanUnion, the European Economic Area and Switzerland.

36. (New, SG 36/09) “Quality system” means a set of written rules that define the sequence of procedures and processes, the type and quantity of resources and the responsibility of each actor in the organisational structure that carries out transplantation activities. The rules must be applicable to the implementation of quality management at each stage and in all activities directly or indirectly related to it.

37. (new, SG 36/09) “Supply” means the process of allocation, supply and transfer of organs,tissues and cells intended for transplantation from one medical establishment to another.

38. (new, SG 36/09) “Allogeneic transplantation” means the taking of cells and tissues from one person and their transplantation into another person.

39. (new, SG No 60/2012) "Donor characterisation" means the activity of collecting information on a potential organ, tissue and cell donor necessary for assessing the suitability for organ, tissue and cell donation, in order to assess and reduce the risk for the recipient, and to optimisethe organ allocation process.

40. (new, SG No 60/2012) "Organ characterisation" shall mean the activity of collecting information on an organ for transplantation necessary to assess its suitability for transplantation, in order to assess and reduce the risk to the recipient, and to optimise the organ allocation process.

41. (new, SG No 60/2012) "European organ exchange organisation" means a public or privatenon-profit organisation dedicated to national or international organ exchange, in which the majority of its members are Member States of the European Union.

42. (new, SG No 60/2012) "Destruction" means the final destination of an organ when it is notused for transplantation.

43. (New, SG No 60/2012) "Finding" means the process by which donor organs, tissues and cells become available.

44. (New, SG 54/1920, in force from 16.06.2020) "Cross-donation" means a transplantation activity in which the following conditions are simultaneously fulfilled:

(a) a person, who is the first donor, wishes to become a living organ donor of a specific patient,who is the first recipient, provided that the conditions laid down in Article 26(1)(b) and (c) are met.
(1) or (2)(1), (2) or (4), but the first donor is biologically incompatible with the first recipient according to the criteria laid down in the regulations referred to in Article 4(1) or (2). 1 and Article 33;

(b) a second donor wishes to become a living organ or tissue donor of a specific second recipient patient, subject to the conditions laid down in Article 26(1)(b) and (c) of Directive2002/83/EC. 1 or 2(1), (2) or (4), but the second donor is biologically incompatible with the second recipient according to the criteria laid down in the regulations referred to in Article 4(1), (2) or (4). 1and Article 33;

(c) the first donor is biologically compatible with the second recipient and the second donor is biologically compatible with the first recipient.

45. (new, SG 54/2020, in force from 16.06.2020) "Member State of dispatch" means a MemberState of the European Union, the European Economic Area and the Swiss Confederation from whichorgans subject to exchange are procured for the purpose of transplantation.

46. (new, SG 54/2020) "Member State of destination" means a Member State of the EuropeanUnion, the European Economic Area and the Swiss Confederation to which the organs subject to exchange are sent for transplantation.

47. (New, SG 54/2020, in force from 16.06.2020) "Single import" means the import of a specific type of tissues, cells or tissue-cell allograft products for the personal use of a recipient or recipients known to the importing medical establishment and the third-country supplier before the import is carried out. Such importation of a specific type of tissues, cells and tissue-cell allograft products shall not take place more than once for a given recipient. Imports from the same third countrysupplier that are regular or repeated shall not be considered as 'single imports'.

48. (new, SG 54/2020) “Emergency situation” means the occurrence of circumstances which threaten the quality of the transplantation and the safety of the living donor and the recipient and which increase the cold ischaemia time of the organ beyond the recommended time.

49. (New, SG 54/1920, in force from 16.06.2020) "Emergency" means an unforeseen situationin which there is no other solution than the urgent import of tissues and cells from a third country forimmediate use in a specific recipient or specific recipients whose health would be seriously endangered without such import.

§ **1a**. 71 of 2006, suppl., issue 36 of 2009, issue 60 of 2012, implementing Directive 2004/23/EC of the European Parliament and of the Council on the establishment of traceability requirements, the reporting of severe adverse reactions and events and specific technical requirementsfor the coding, processing, storage, preservation and distribution of human tissues and cells and Commission Directive 2006/17/EC of 8 February 2006 on the implementation of Directive 2004/23/EC of the European Parliament and of the Council on the setting of standards of quality andsafety for the donation, procurement, control, processing, preservation, storage and distribution of human tissues and cells and Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation (OJ L 207/14 of 6 August 2010).) and Commission Directive 2012/25/EU of 9 October 2012 establishing the information procedures for the exchange between Member States of human organs intended for transplantation (OJ L 275/27 of 10 October 2012), as well as Commission Directive (EU) 2015/566 of 8 April 2015 implementing Directive 2004/23/EC as regards procedures for monitoring compliance with equivalent quality and safety standards for imported tissues and cells (OJ L 93/56 of 9 April 2015).

FINAL PROVISIONS

§ **2**. Within one month of the entry into force of the Act, the Council of Ministers shall adopt,and the Minister of Health shall issue, the regulations implementing the Act.

§ **3**. In the Law on National Health (promulgated, State Gazette, No. 88 of 1973; amend. 92of 1973; amended, issue 63 of 1976, issue 28 of 1983, issue 66 of 1985, issue 27 of 1986, issue 89 of 1988, issues 87 and 99 of 1989, issue 15 of 1991; amended, issue 24 of 1991; amended, issue 64 of 1993, No 31 of 1994, No 36 of 1995, Nos 12, 87 and 124 of 1997, Nos 21, 70, 71 and 93 of 1998, Nos 30, 62, 67, 90 and 113 of 1999, Nos 10 and 36 of 2000, No 63 of 2002) shall be amended asfollows:

1. In Article 3a, point 16 is inserted:

"16. transplantation of organs, tissues and cells".

2. Articles 33, 33a, 34 and 35 are repealed.

§ **4**. The following amendments and additions shall be made to the Law on MedicalInstitutions (promulgated, State Gazette, No. 62 of 1999; amended, State Gazette, No. 88 and 113 of1999; amended, State Gazette, No. 114 of 1999; amended, State Gazette, No. 36, 65 and 108 of 2000;amended, State Gazette, No. 51 of 2001 - Decision No. 11 of the Constitutional Court of 2001; amended, State Gazette, No. 28 and 62 of 2002):

1. In Article 2, par. 1, item 6 shall be inserted:"6.

transplantation of organs, tissues and cells."

2. In Article 10, point 7 is inserted:"7.

tissue bank."

3. In Article 19, the following point 4a is inserted:"4a.

transplantation of organs, tissues and cells;".

4. Article 28b is inserted:

"Art. 28b. (1) A tissue bank shall be a medical institution where a physician, with the assistanceof other specialists, takes, examines, stores and processes organs, tissues and cells for medical purposes.

(2) Tissue banks may only take tissues and cells for transplantation or processing and organsonly for processing.

(3) The activities of a tissue bank shall be carried out in accordance with the regulations onthe structure, activities and internal order approved by the head of the medical establishment."

5. Article 36a is inserted:

"Art. 36a. (1) The tissue bank shall be established as a limited liability company or a joint stock company and shall operate after obtaining a permit pursuant to Article 51a.

(2) The subject of activity of the tissue bank shall necessarily include only the performanceof the activities referred to in Article 28b.

(3) The court registration of the company must contain the full designation of the medical institution."

6. In Art. 40 para. 1, paragraph 11 is inserted:

"11. a certificate from the Executive Agency for Transplantation that the medical establishment may perform tissue and cell procurement and transplantation in accordance with the approved medical standards in cases where the medical establishment will perform such activity."

7. In Article 47, point 12 is inserted:

"12. a certificate from the Executive Agency for Transplantation that the medical establishment may perform organ, tissue and cell procurement and transplantation in accordance withthe approved medical standards in cases where the medical establishment will perform such activity."

8. Article 51a is inserted:

"Article 51a. (1) Tissue banks shall operate after obtaining a permit from the Director of the Executive Agency for Transplantation.

(2) A permit under par. 1 shall be issued on the basis of an application to which shall be attached:

1. the court decision on registration, a certificate of current court registration, a certificate of tax registration and a unique identification code;

2. the articles of incorporation of the company and the regulations on the structure, activity and internal order of the medical establishment;

3. the diplomas of the relevant higher education of the persons who will work in the medical establishment;

4. the criminal records of the persons representing the establishment;

5. the hygiene report for the establishment from the hygiene and epidemiological inspection authorities.

(3) In case of incompleteness of the documents submitted under paragraph (2), the Director of the Executive Transplantation Agency shall, within 15 days, notify the applicant thereof in writingand set a deadline for its correction.

(4) Within three months from the submission of the documents referred to in paragraph (2), the Director of the Executive Agency for Transplantation shall issue a permit for the activity of the tissue bank, specifying the types of activities it will carry out, or shall make a reasoned refusal to issue a permit.

(5) The refusal under paragraph (4) shall be subject to appeal under the Administrative Procedure Act.

(6) The Director of the Executive Transplantation Agency may, by order, revoke the permit issued in the following cases:

1. if the tissue bank carries out activities in violation of this Law and the normative acts implementing this Law or carries out activities outside those for which the permit was issued;

2. at the request of the tissue establishment;

3. upon termination of the tissue bank.

(7) The order of the Director of the Executive Transplantation Agency under paragraph 6,item 1 shall be subject to appeal under the Administrative Procedure Act.

(8) An appeal against the order shall not suspend its execution.

9. In Article 63(5), the words "Article 10(4), (5) and (6)" shall be replaced by "Article 10(4),(5), (6) and (7)".

10. In Article 86, par. In Article 86(1), the words 'and diagnostic and advisory centres' shall bereplaced by 'diagnostic and advisory centres and tissue banks'.

§ **5**. The implementation of the Act shall be entrusted to the Minister of Health.

§ **6**. The Act shall enter into force on 1 January 2004.

The law was passed by the 39th National Assembly on 30 July 2003, re-passed on 11 September 2003and is stamped with the official seal of the National Assembly.

———————————————————————————

TRANSITIONAL AND CONCLUDING PROVISIONS to the Act amending and supplementing theAct on Organ,

Tissue and Cell Transplantation

(SG 71/06, in force from 1.01.2007)

§ 26. (1) The Council of Ministers shall amend and supplement the spatial regulations of theExecutive Transplantation Agency in accordance with this Act within one month of its entry into force.

(2) The Minister of Health shall issue the by-laws for its implementation within six monthsfrom the entry into force of this Act.

§ 27. (1) The Ministry of Health shall inform Bulgarian citizens in an accessible manner aboutthe conditions and procedure for organ, tissue and cell procurement and transplantation by 31 March2007.

(2) The information referred to in par. (1) shall be carried out under the conditions and in accordance with the procedure laid down by a regulation of the Minister of Health.

§ 28. (Effective from 1.01.2007) The first report under Article 11, paragraph 5, item 16 shallbe submitted to the European Commission by the Executive Agency for Transplantation by 7 April 2009.

. . . . . .

§ 30. The Act shall enter into force on 1 January 2007, with the exception of the provisions of section 4(3)(e), concerning the creation of sections 15 and 16, and

§ 28, which shall enter into force on the date of entry into force of the Treaty of Accession ofthe Republic of Bulgaria to the European Union.

TRANSITIONAL AND CONCLUDING PROVISIONS to the Act amending and supplementing theHealth Act.

(SG 98/10, in force from 1.01.2011)

. . . . . .

§ 118. 71 of 2006 and issues 36 and 41 of 2009) shall be amended as follows:

. . . . . .

2. Throughout, the words 'the relevant regional health centre' and 'the regional health centres'shall be replaced by 'the relevant regional health inspectorate' and 'the regional health inspectorates' respectively.

. . . . . .

§ 121. The Act shall enter into force on 1 January 2011, with the exception of:

1. paragraphs 1, 16, 20, 29, 30, 32, 33, 34, 35, 42, 44, § 56(1) and (2), § 65, 68, 70, 76, 80, 81, 90, 92, 96, § 102(3), (4), (5), (7) and (8), § 105(1), (3) and (5), § 107(1), (2), (3), (4), (6)(a), sub-para. 7, 10, 11, 13 and 15, letter "a", § 109, 110, 112, 113, § 115, item 5, § 116, items 4 and 6, § 117, items 5 and7 and § 118, item 1, which shall enter into force on the day of the promulgation of the law in the Official Gazette;

. . . . . .

TRANSITIONAL AND CONCLUDING PROVISIONS to the Act amending and supplementing theAct on Organ,

Tissue and Cell Transplantation

(SG No 60/2012)

§ 19. Medical establishments which have obtained authorisations under Articles 36, 37 and 38 before the entry into force of this Act shall carry out their activities on the basis of theauthorisations issued to them.

§ 20. The first report referred to in Article 11, paragraph 5, item 16a shall be submitted to the European Commission by the Transplantation Executive Agency by 27 August 2013.

TRANSITIONAL AND CONCLUDING PROVISIONS to the Act amending and supplementing theHealth Insurance

Act

(SG No 60/2012, in force from 7 August 2012)

. . . . . .

§ 41. 71 of 2006, No 36 and No 41 of 2009, Art. 98 of 2010 and Art. 9 of 2011) in Article 16(4) the words "voluntary health insurance companies" shall be replaced by "insurers licensed underSection II(A)(2) or (1) and (2) of Annex 1 to the Insurance Code".

. . . . . .

§ 44. The Act shall enter into force on the day of its promulgation in the Official Gazette.

TRANSITIONAL AND FINAL PROVISIONS

to the Law on the Budget of the National Health Insurance Fund for 2019.(SG

102/2018, in force from 1.01.2019)

. . . . . .

§ 41. 71 of 2006, No 36 and No 41 of 2009, Art. 98 of 2010, Art. 9 of 2011, issue 60 of 2012and issue 15 of 2013) shall be amended as follows:

. . . . . .

10. (In force from 1.04.2019 - SG 102/2018) In the remaining texts of the Act the words "theExecutive Agency for Transplantation" shall be replaced by "the Executive Agency for Medical Supervision".

§ 43. The Act shall enter into force on 1 January 2019, except for:

1. paragraph 29, point 13, letter "b", points 14 and 15, § 30 and § 42, point 2, which shall enter into force on the day of promulgation of the Law in the State Gazette;

2. paragraphs 28(6)-(12) and (14)-(19), 35(3), except for sections 7a(4) and 7c(4)(5) and (6), (8)-(22) and (36)-(40), 41(2)-(8), (9)(a) and (c) and (10), which come into force on 1 April 2019;

. . . . . .