ACT ON TRANSPLANTATION OF ORGANS, TISSUES AND CELLS

In Force From 01.01.2004

Prom. SG. 83/19 Sep 2003, amend. SG. 88/4 Nov 2005, amend. SG. 71/1 Sep 2006, amend. SG. 36/15 May 2009, amend. SG. 41/2 Jun 2009, amend. SG. 98/14 Dec 2010, amend. SG. 9/28 Jan 2011, amend. SG. 60/7 Aug 2012, amend. SG. 15/15 Feb 2013, amend. and suppl. SG. 102/11 Dec 2018

Chapter one.
GENERAL

Art. 1. (1) This act settles the conditions and the order of carrying out transplantation of organs, tissues and cells in the human medicine.

(2) (new – SG 60/12) The purpose of this act is to set out rules for provision of quality and safety standards of organs, tissues and cells, intended for transplantation in human medicine and to guarantee a high level of human health protection.

(3) (prev. par. 2 – SG 60/12) Subject to this act shall not be:

1. (amend. - SG 71/06, in force from 01.01.2007) the blood donation, the transfusion of blood and blood components;

2. (amend. - SG 71/06, in force from 01.01.2007; suppl. - SG 36/09) the assisted reproduction and the reproduction organs, tissues and cells related to it;

3. (suppl. - SG 71/06, in force from 01.01.2007) the self-transplantation, as well as the taking and the implantation are carried out in the framework of one invasive procedure;

4. the implantation of artificial tissues and organs;

5. (new – SG 60/12) use of organs for research and development purposes, except for the cases where the organs are intended for transplantation in human medicine.

Art. 2. (1) (suppl. - SG 36/09) The transplantation is a combination of medical and other activities related to taking organs, tissues and cells from a human or animal corpse or from a live person and their implantation in another person with a therapeutic purpose.

(2) Transplantation is also the implantation of hemopoietic truncal cells, as well as of embryo organs, tissues and cells.

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

(4) (new - SG 71/06, in force from 01.01.2007) Transplantation shall also be the self-transplantation, in case the taking and the implantation are carried out in the framework of one invasive procedure.

(5) (prev. text of para 4 - SG 71/06, in force from 01.01.2007; suppl. - SG 36/09; amend. and suppl. – SG 60/12) The transplantation also includes the activities related to the donation, provision, characterization, expertise, processing, labelling, storing, transportation and submission of organs, tissues and cells designated for using in the human medicine.

Art. 3. Transplantation shall be carried out in conditions guaranteeing equal rights of the patients needing transplantation, as well as protection of the human rights and freedom of the actual and potential donors and recipients.

Art. 4. (1) Transplantation shall be carried out according to medical standards and criteria for selection approved by an ordinance of the Minister of Health.

(2) Transplantation shall be carried out only when other methods of therapy are less effective or not applicable.

(3) Transplantation shall be carried out only after the implementation of the necessary medical tests according to the approved medical standards for transplantation, guaranteeing a maximal security for the health of the donor and recipient.

(4) The medical specialists shall be obliged to provide conditions for reduction of the risk of transmitting infections and other diseases from the donor to the recipient.

(5) (new - SG 71/06, in force from 01.01.2007) The medical specialists shall be obliged to provide conditions for quality and safety of the tissues and the cells at carrying out self-transplantation, at which the activities related to expertise, taking, processing, storage or implantation are carried out in the framework of more than one invasive procedure.

(6) (new - SG 71/06, in force from 01.01.2007; amend. – SG 60/12) The requirements for qualification and health condition of the persons, carrying out taking, expertise, treatment, processing, labelling, storage and grafting of organs, tissues and cells, shall be determined by an ordinance of the Minister of Health.

(7) (new - SG 71/06, in force from 01.01.2007) The persons under para 6 shall pass a compulsory training course at least once in two years under terms and by manner, established by the ordinance under para 6.

Art. 5. The human organs, tissues and cells may not be a subject of an onerous transaction.

Art. 6. (amend. - SG 36/09) Prohibited is the advertising of the presence of organs, tissues and cells for the purpose of seeking profit, as well as the offering of a profit for the purpose of receiving organs, tissues and cells.

Art. 7. Organs, tissues and cells, which cannot be used for the purposes of transplantation for medical reason may be submitted for other therapeutic, diagnostic and scientific medical purposes under conditions and by an order determined by the Minister of Health.

Art. 8. Prohibited is the spreading of data allowing the identification of the donor or of the recipient.

Chapter two.
NATIONAL SYSTEM OF TRANSPLANTATION

Section I.
Organisation and activities of the National System of Transplantation

Art. 9. The national system of transplantation includes all 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 carry out the state policy in the sphere of transplantation.

(2) (amend. - SG 36/09; revoked – SG 60/12)

Art. 10a. (new - SG 36/09) (1) The Minister of Health shall determine in an order a public donation bank of stem cells and bone marrow, which shall be part of the structure of the medical establishment for hospital care, carrying out extraction, examination, treatment, processing, storage, labelling and transportation of stem cells and bone marrow for transplantation.

(2) The medical establishment under Para 1 shall meet the following criteria:

1. be with 100 percent share of the state in the capital;

2. have a permission for the activities under Para 1, issued under the order of Art. 47 of the Medical Establishments Act;

3. (repealed – SG 102/18, in force from 01.01.2019)

(3) The donation bank, determined under the order of Para 1 and 2, shall be a National Public Donation Bank with the purpose of providing stem cells and bone marrow nationwide for transplantation to persons, suffering from diseases, to which other methods of treatment have less efficiency or are inapplicable.

Art. 11. (1) (amend. - SG 71/06, in force from 01.01.2007, repealed – SG 102/18, in force from 01.01.2019)

(2) (Repealed – SG 102/18, in force from 01.04.2019)

(3) (Repealed – SG 102/18, in force from 01.04.2019)

(4) (new - SG - 71/06, in force from 01.01.2007, amend. – SG 102/18, in force from 01.04.2019) The Executive Agency "Medical Supervision" shall be the competent body in charge of management, coordination and control of the transplantation in the Republic of Bulgaria.

(5) (prev. text of para 4 - SG 71/06, in force from 01.01.2007, amend. – SG 102/18, in force from 01.04.2019) The Executive Agency "Medical Supervision" shall:

1. coordinate and control the activities in the sphere of transplantation carried out in the medical establishments;

2. propose to the Minister of Health medical standards for transplantation of organs, tissues and cells, as well as medical criteria for a choice of donors and recipients;

3. (suppl. – SG 60/12) create and maintain a public and official register, gathering, storing and submitting information related to the transplantation subject to compliance with the provisions of the Protection of Personal Data Act;

4. (new - SG 71/06, in force from 01.01.2007; amend. - SG 36/09) provide 24-hour access of the doctors, directly taking part in the medical services for the potential donor to the official register of the persons, who have expressed dissent for taking organs, tissues and cells after their death under conditions and by manner, determined by an ordinance of the Minister of Health;

5. (prev. text of item 4 - SG 71/06, in force from 01.01.2007; amend. - SG 36/09) coordinate the import and export of organs, tissues and cells;

5a. (new - SG 36/09, amend. – SG 102/18, in force from 01.04.2019) issue the permits and certificates, specified in this Act;

6. (prev. text of item 5 - SG 71/06, in force from 01.01.2007) distribute the organs provided for transplantation and control the distribution of the tissues and cells;

7. (prev. text of item 6, amend. - SG 71/06, in force from 01.01.2007; amend. – SG 60/12) register, store and analyse the information regarding the data for the donor, the health status of the live donor and the recipient during the transplantation and post-transplantation period, as also the serious adverse reactions related to the transplantation;

8. (prev. text of item 7 - SG 71/06, in force from 01.01.2007) study and analyse the medical, legal, ethical, religious, economic and social consequences from the transplantation;

9. (prev. text of item 8 - SG 71/06, in force from 01.01.2007) inform the public about the transplantation processes for the purpose of guaranteeing transparency and equal access of all persons in need;

10. (prev. text of item 9 - SG 71/06, in force from 01.01.2007; amend. - SG 36/09; suppl. – SG 60/12) coordinate the cooperation between European organizations for organs exchange, competent bodies of the European Union Member States, of the other states – parties to the Agreement on the European Economic Area, of the Confederation of Switzerland and of third countries, state bodies, scientific organisations and non-government organisations in the sphere of transplantation;

11. (prev. text of item 10 - SG 71/06, in force from 01.01.2007) participate in the working out of national strategies and programmes, international projects, analyses and prognoses regarding the processes of transplantation;

12. (new - SG 71/06, in force from 01.01.2007; suppl. - SG 36/09) control the activities of providing quality and safety of the organs, tissues and cells, intended for implantation;

13. (new - SG 71/06, in force from 01.01.2007; suppl. - SG 36/09) provide opportunity for donor-to-recipient tracing of all organs, tissues and cells and the materials and products coming in contact with them, which are received, treated, processed, stored or granted on the territory of the Republic of Bulgaria;

14. (new - SG 71/06, in force from 01.01.2007) control the activities related to removal, insertion, expertise, treatment and labelling and preserving human ovum, sperm and zygotes, intended for assisted reproduction, and provide opportunity for donor-to-recipient tracing thereof and of the materials and products coming in contact with them;

15. (new - SG 71/06, in force from the date of coming into effect of the Treaty concerning the Accession of the Republic of Bulgaria to the European Union) compile a report to the European commission in every three years concerning the activities related to popularization and encouragement of the voluntary and gratuitous donation of tissues and cells, carried out in the Republic of Bulgaria;

16. (new - SG 71/06, in force from in force from the date of coming into effect of the Treaty concerning the Accession of the Republic of Bulgaria to the European Union; suppl. - SG 36/09) present to the European commission in every three years a report on the activities carried out in relation to ensuring quality and safety of the expertise, the removal, treatment, processing, labelling, storing, providing, implantation, control and the inspections carried out;

16a. (new – SG 60/12) submit every three years a report to the European Commission regarding all activities for organs transplantation and the acquired experience from the carried out transplantations;

17. (new - SG 36/09) organise training for quality and safety of the transplantation activities of the persons under Art. 15d and of persons, carrying out extraction, examination, treatment, processing, labelling, storage, provision and transportation of organs, tissues and cells;

18. (new – SG 60/12) submit to the European Commission or to an European Union Member State, to another state – a party to the Agreement on the European Economic Area, and to the Confederation of Switzerland upon request information regarding the requirements for granting of permits and certificates to medical establishments for activities for transplantation of organs, and also information about health care facilities, where transplantation activities are carried out;

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

20. (new – SG 60/12) control organs exchange with the European Union Member States, with

other states – parties to the Agreement on the European Economic Area and with the Confederation of Switzerland, and also the import and export from and to third countries.

(6) (new - SG 36/09, amend. – SG 102/18, in force from 01.04.2019) For carrying out the activities referred to in Para 5, Item 5a the Executive Agency "Medical Supervision" shall collect fees in amounts, specified in a tariff, approved by the Council of Ministers upon proposal of the Minister of Health.

Art. 11a. (new - SG 36/09, repealed – SG 102/18, in force from 01.04.2019)

Art. 12. (1) Established at the Council of Ministers shall be an Ethical Commission for the transplantation.

(2) The commission under para 1 shall consist of 9 members and shall obligatorily include physicians, psychologists, theologises and lawyers. The members of te commission shall be determined by a decision of the Council of Ministers at a proposal of the Minister of health, for a period of 5 years.

(3) Persons carrying out activities under art. 2 may not be members of the Ethical Commission for the transplantation.

(4) The Ethical Commission for transplantation shall give opinion on deontological and ethical issues in the sphere of transplantation and shall permit taking of organs and tissues of persons in the cases stipulated by the act.

(5) The sittings of the Ethical Commission for transplantation shall be held behind closed doors.

(6) The Council of Ministers, at a proposal of the Minister of health, shall determine by a regulation the conditions and the order of the work of the Ethical Commission for transplantation.

(7) (new - SG 71/06, in force from 01.01.2007, amend. – SG 102/18, in force from 01.04.2019) The funding of the activity of the Ethical Commission for transplantation shall be provided by the Executive Agency "Medical Supervision".

Art. 13. (1) (amend. and suppl. - SG 36/09) Extraction and/or examination, treatment, processing, labelling, storage, provision and implantation of organs, tissues and cells shall be carried out by medical establishments for hospital care having obtained permit by the order art. 48, para 1 of the Medical Establishments Act, explicitly indicating the respective activities.

(2) (amend. and suppl. - SG 36/09; amend. – SG 98/10, in force from 14.12.2010) Extraction, examination, treatment, processing, labelling, storage, provision and implanting of tissues and cells may also be made by medical establishments for non-hospital care, registered by the order of art. 40, para 3 of the Medical Establishments Act, the registration certificate of which explicitly states the respective activities.

(3) (amend. SG 88/05; suppl. - SG 36/09, amend. – SG 102/18, in force from 01.04.2019) The activities under para 1 may be carried out by the medical establishments at the Council of Ministers, the Ministry of Defence, the Ministry of Interior and the Ministry of Transport, after receiving a certificate from the Executive Agency "Medical Supervision" that the medical establishment may carry out transplantation of organs, tissues and cells in compliance with the approved medical standards.

(4) (new - SG 71/06, in force from 01.01.2007; suppl. - SG 36/09) The medical establishments under para 1, 2 and 3 and the tissue banks shall register all activities, related to expertise, removal, implantation, treatment, processing, storing, provision, transportation and receiving and labelling of organs, tissues and cells, carried out by them, according to the conditions and the procedures, established by an ordinance of the Minister of Health.

(5) (new - SG 71/06, in force from 01.01.2007, amend. – SG 102/18, in force from 01.04.2019) The medical establishments shall annually prepare a report on the activities carried out under para 4 according to a model, determined in the ordinance under para 4, and shall submit it at the Executive agency "Medical Supervision".

(6) (new - SG 71/06, in force from 01.01.2007) The data from the report under para 5 shall be entered in the register under Art. 39, para 1, item 1.

(7) (prev. text of para 4, suppl. - SG 71/06, in force from 01.01.2007) The transportation of organ donors and of organs for implantation shall be carried out by the centres for emergency medical care.

(8) (prev. text of para 5 - SG 71/06, in force from 01.01.2007) The transportation of tissues and cells for implantation shall be carried out by the medical establishments under para 1, 2 and 3, as well as by tissue banks.

Art. 14. (amend. - SG 71/06, in force from 01.01.2007; amend. - SG 36/09) (1) The tissue banks may carry out activities of extraction, examination, treatment, processing, labelling, storing, provision and transportation of tissues and cells, intended for transplantation and processing.

(2) The tissue banks may carry out activities of extraction, examination, processing, labelling, storing and transportation of organs, only if they are intended for processing.

Art. 15. (1) (amend. - SG 36/09) Biological products, obtained after processing of organs and tissues, may be used for production of medical products and medicinal goods.

(2) (amend. - SG 36/09) For production of medical products and medicinal goods medical establishments may provide the biological products obtained from the processing to producers of medical products and medicinal goods.

(3) (amend. - SG 71/06, in force from 01.01.2007; suppl. – SG 60/12) The conditions and the order of expertise, labelling, treatment, processing, storing, ensuring quality and safety and submission of organs, tissues and cells, as well as of the biological products obtained by the processing, shall be determined by an ordinance to be issued by the Minister of Health.

Art. 15a. (new - SG 71/06, in force from 01.01.2007) (1) (amend. – SG 60/12) The medical establishments shall conclude written contracts between them, in case they carry out jointly activities referred to in Art. 2 of organs, tissues and cells.

(2) The medical establishments shall conclude written contracts with third parties for providing goods and services, which can influence the quality and the safety of the organs, tissues or the cells.

(3) The medical establishments shall create and maintain a register of the contracts concluded under para 1 and 2.

(4) (Amend. – SG 102/18, in force from 01.04.2019) The medical establishments shall send copies of the contracts under para 1 and 2 to the Executive Agency "Medical Supervision" in 7-days term from their conclusion.

Art. 15b. (new - SG 71/06, in force from 01.01.2007) (1) (amend. - SG 36/09; suppl. – SG 60/12, amend. – SG 102/18, in force from 01.04.2019) The medical establishments shall inform the Executive Agency "Medical Supervision" in seven-days term from the ascertainment of all adverse reactions or serious incidents, in case they are result of taking, implantation, providing, expertise, characterization, treatment, processing, storing, provision and/or transportation of organs, tissues or the

cells, intended for transplantation, monitored during the transplantation and thereafter with the donor and the recipient, and are related to their quality and safety.

(2) (suppl. - SG 36/09; suppl. – SG 60/12) The medical establishments shall be obliged to create and apply system for immediate blocking, withdrawal or destruction of all organs, tissues and cells, which may lead to serious adverse reaction or have suffered a serious incident.

(3) (suppl. – SG 60/12) The terms and the procedure for notification, registration, reporting and conceding of information on the serious adverse reactions and the serious incidents and on blocking, extraction and destruction of organs, tissues and cells shall be determined by an ordinance of the Minister of Health.

Art. 15c. (new - SG 71/06, in force from 01.01.2007) (1) (amend. - SG 36/09) The medical establishments shall label the organs, tissues and cells, taken by them, in compliance with the requirements of the medical standard for transplantation of organs, tissues and cells.

(2) (amend. - SG 36/09) The medical establishments shall be obliged to create conditions for tracking of the organs, tissues and cells from the donor to the recipient and backwards, as well as of the products and materials, coming into contact with them, which are related to their quality and safety, under conditions and following procedure, established by an ordinance of the Minister of Health.

(3) (new - SG 36/09) The medical establishments shall be obliged to create and apply a system for quality when carrying out all transplantation activities.

Art. 15d. (new - SG 71/06, in force from 01.01.2007) (1) (suppl. - SG 36/09) All medical establishments, carrying out activities, related to transplantation, shall assign a person from its personnel, who organizes, controls and bears responsibility for the expertise, taking, treatment, processing, labelling, storing, provision and implantation of organs, tissues and cells and the announcement of serious adverse reactions and serious incidents.

(2) The person under para 1 shall satisfy the following conditions:

1. to have completed higher education with educational and qualification degree "master" of:

a) specialty of professional direction "Medicine" – in the cases, related to transplantation of organs;

b) (amend. - SG 36/09) speciality of professional direction "Medics", "Dental Medics" or "Biological sciences" – in the cases, related to transplantation of tissues and cells;

2. to have at least two years of professional experience in the field of activities with regards to which he/she is in charge.

(3) (new - SG 36/09) The person under Para 1 shall attend a mandatory training course at least once every two years under conditions and order specified in the ordinance referred to in Art. 4, Para 6.

(4) (prev. text of Para 03 - SG 36/09, amend. – SG 102/18, in force from 01.04.2019) The medical establishments shall notify the Executive agency "Medical Supervision" in seven-days term of the name, education and the duration of the professional experience of the person under para 1.

(5) (prev. text of Para 04 - SG 36/09, amend. – SG 102/18, in force from 01.04.2019) The medical establishments shall notify the Executive Agency "Medical Supervision" of the change or the replacement of the person under para 1, as well as of the moment of its occurrence and the term of the replacement.

(6) (prev. text of Para 05 - SG 36/09) The obligations and the responsibilities of the person under para 1 shall be set forth by the ordinance under Art. 156, para 3.

Art. 15e. (new - SG 71/06, in force from 01.01.2007; suppl. - SG 36/09) The medical

establishments shall store the information, related to the activities, carried out by them under this act, for at least thirty years, and shall secure the necessary conditions for protecting it from illegal access, unauthorised changes and destruction.

Section II.
Financing

Art. 16. (amend. - SG 71/06, in force from 01.01.2007) (1) (amend. - SG 36/09; amend. – SG 60/12) The Ministry of Health shall reimburse the expenses made by the medical establishments for the following activities:

1. (suppl. – SG 60/12) organs and all related expenses, including for the donor and the recipient, as well as the expenses for diagnostics and treatment of the donor and the recipient in the post-transplantation period;

2. tissues and cells for treatment of diseases, which are specified in an ordinance of the Minister of Health.

(2) (new - SG 36/09) The Minister of Health shall finance also:

1. the creation of information systems for 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 01.01.2011) The medicinal products intended for treatment of post-transplantation conditions shall be funded by the National Health Insurance Fund as set out in the Health Insurance Act.

(4) (prev. text of Para 02 - SG 36/09; prev. text of Para 03 – SG 98/10, in force from 01.01.2011; amend. – SG 60/12, in force from 07.08.2012, amend. – SG 102/18, in force from 01.04.2019) The National Health Insurance Fund and the insurers, licensed under Section II, Item "A", item 2 or items 1 and 2 of Attachment No. 1 to the Insurance Code can finance the activities related to transplantation on the ground of a contract with the medical establishment, which shall come into effect following an approval by the Executive Agency "Medical Supervision" and entry in the register thereof.

(5) (prev. text of Para 03, amend. - SG 36/09; prev. text of Para 04 – SG 98/10, in force from 01.01.2011) The terms, the manner and the extent of reimbursement of the expenses under Para 1, and the relative share of the labour shall be determined in an ordinance of the Minister of Health.

Art. 16a. (new – SG 60/12, amend. – SG 102/18, in force from 01.04.2019) The Executive Agency "Medical Supervision" shall finance activities for promotion of donation and expression of honor and respect to the dead donors and their close ones.

Art. 17. (amend. - SG 71/06, in force from 01.01.2007, amend. – SG 102/18, in force from 01.04.2019) Natural and legal persons may donate funds for activities related to transplantation by way of concluding a contract for financing with the medical establishment, which shall come into effect following an approval by the Executive Agency "Medical Supervision" and entry in the register thereof.

Chapter three.
TAKING ORGANS, TISSUES AND CELLS

Section I.

Taking organs, tissues and cells from human corpses

Art. 18. (1) Taking organs, tissues and cells for the purposes of transplantation may be made from a human corpse upon establishment of the death according to medical criteria and by an order determined by an ordinance of the Minister of Health.

(2) (Amend. – SG 102/18, in force from 01.04.2019) In case of irreversible stopping of all functions of the brain and presence of cardiac function the death shall be established by a standing commission consisting of three physicians. The commission shall be appointed by the director of the medical establishment where the organs, tissues and cells are taken upon obtaining a consent by the Executive Director of the Executive Agency "Medical Supervision".

(3) Physicians, establishing the death according to para 2, may not participate in teams carrying out taking and implantation of organs.

Art. 19. (1) (amend. - SG 71/06, in force from 01.01.2007) Shall not be admitted taking organs, tissues and cells for implantation if the person has expressed dissent in writing thereof during his/her lifetime.

(2) Not admitted shall be taking of organs, tissues and cells from a corpse of a person under 18 years of age or of a person under judicial disability, except by the written consent of his/her parents, guardian or trustee.

(3) Not admitted shall be taking of organs, tissues and cells for implanting from a corpse of a person with unknown identity.

(4) (amend. - SG 36/09) If the corpse is subject to a forensic expertise the taking of organs, tissues and cells from him/her shall be performed upon a permit in writing by a forensic expert, who shall not participate in transplantation activities.

Art. 20. (1) (amend. - SG 71/06, in force from 01.01.2007; amend. - SG 09/11) Every able-bodied Bulgarian citizen, as well as a foreigner, residing continuously, for a long-term or permanently in the Republic of Bulgaria, shall have the right to express, in his lifetime, explicit dissent in writing for taking organs, tissues and cells after his/her death.

(2) (amend. - SG 71/06, in force from 01.01.2007) The expressed dissent under para 1 may regard definite or all organs, tissues and cells, as well as taking them for other therapeutic, diagnostic, scientific medical, educational and lecturing purposes.

(3) (amend. - SG 71/06, in force from 01.01.2007, amend. – SG 102/18, in force from 01.04.2019) The dissent for taking organs, tissues and cells shall be expressed in writing before the general physician via signing a declaration, approved by the Minister of Health upon proposal by the Executive Agency "Medical Supervision".

(4) (amend. - SG 71/06, in force from 01.01.2007; amend. - SG 36/09; amend. – SG 98/10, in force from 01.01.2011) The general physician shall be obliged to enter immediately the expressed consent or dissent in the health insurance book of the person and, within 7 days, to notify in writing the director of the respective regional health inspection.

(5) (new - SG 71/06, in force from 01.01.2007, amend. – SG 102/18, in force from 01.04.2019) Persons, whose health insurance rights are suspended, who are not health insured, or who have not chosen a general physician, may express dissent for taking organs, tissues and cells after their death by signing a declaration, approved by the Minister of Health upon proposal by the Executive Agency "Medical Supervision". The declaration shall be submitted in two copies at the municipality according to permanent address, provided that one of the copies shall be presented to the person, who has expresses dissent, and the other one shall be sent to the Executive Agency "Medical Supervision" in seven days

term from its submission.

(6) (prev. text of para 5, amend. - SG 71/06, in force from 01.01.2007; amend. and suppl. - SG 36/09; amend. – SG 98/10, in force from 01.01.2011, amend. – SG 102/18, in force from 01.04.2019) Within 7 days from receipt of the information under Para 4 regarding the persons having expressed dissent, the directors of the regional health inspections shall be obliged to inform in writing the Executive Agency "Medical Supervision".

(7) (prev. text of para 6, amend. and suppl. - SG 71/06, in force from 01.01.2007, amend. – SG 102/18, in force from 01.04.2019) The expressed written dissent under para 1 and 5 shall be entered in the official register of the Executive Agency "Medical Supervision" within three days from receiving the notice under para 6.

Art. 21. (amend. - SG 71/06, in force from 01.01.2007) Taking of organs, tissues and cells from the person, who passed away, may be performed if the following requirements are met:

1. in the health insurance book of the person, in the cases where there is such, there is not a registered dissent of the person for taking organs, tissues and cells after his/her death;

2. (amend. – SG 102/18, in force from 01.04.2019) the name of the person has not been entered in the official register of the Executive Agency "Medical Supervision" under Art. 39, para 1, item 2;

3. the forthcoming taking of organs, tissues or cells obligatorily is announced and there is no dissent in writing presented within reasonably short term from his/her:

a) spouse or parent;

b) child;

c) brother or sister.

(2) The manner of ascertainment and certification of the circumstances under para 1 shall be determined by an ordinance of the Minister if Health.

Art. 22. (amend. - SG 71/06, in force from 01.01.2007) After the removal all necessary measures shall be taken for restoration of the appearance of the body of the deceased person.

Art. 23. (Amend. – SG 102/18, in force from 01.04.2019) Every medical establishment where taking of organs, tissues and cells from a human corpse has been performed shall be obliged, within 7 days, to register the procedure in the Executive Agency "Medical Supervision".

Section II.
Taking organs, tissues and cells of a live donor

Art. 24. (1) The taking of organs, tissues and cells of a donor shall be performed only on condition that it does not pose a danger for his/her life and a notary certified written consent has been received from him, after having explained to him, in a comprehensive language, the risks he/she takes.

(2) (new - SG 71/06, in force from 01.01.2007) The notarial authentication of the consent under para 1 shall be made by a notary, in whose region of activity is located the medical establishment, which shall carry out the taking of organs, tissues and/or cells.

(3) (Prev. text of para 2 – SG 71/06, in force from 01.01.2007) The donor must be informed about his/her rights, the medical procedures and the safety measures under this act by a physician who does not participate in the team performing the taking or implantation.

(4) (Prev. text of para 3 – SG 71/06, in force from 01.01.2007) The donor may withdraw the

given consent at any time before the taking of organs, tissues and cells.

(5) (Prev. text of para 4 – SG 71/06, in force from 01.01.2007) Not admitted shall be the taking of organs for transplantation from a person under 18 years of age. The taking of tissues and cells from persons under 18 years of age shall be admitted only in the cases stipulated by this act.

(6) (Prev. text of para 5 – SG 71/06, in force from 01.01.2007) Not admitted shall be the taking of organs, tissues and cells for transplantation from a person under judicial disability.

(7) (Prev. text of para 6, amen. and suppl. – SG 71/06, in force from 01.01.2007) The physical and psychic health of the donor shall be established by a commission appointed by the director of the medical establishment performing the taking of organs, tissues and cells, consisting of at least three physicians who will not participate in a team for taking or implantation by a protocol, signed by all members of the commission.

(8) (new - SG 71/06, in force from 01.01.2007) It shall be prohibited to offer material profit to a donor of organs, tissues and cells as well as to receive material profit from the donor.

(9) (new – SG 60/12) Alive donors of organs may get a compensation only if it is strictly limited to refunding of incurred donation related expenses and income loss.

Art. 25. Taken for transplantation may only be one of the pair organs or a part of a self-restoring organ of a live donor under the following conditions:

1. upon prior establishment that the organ, respectively its part, to be taken, and the remaining organ, respectively its part, have a completely preserved function;

2. after preliminary necessary tests for the purpose of excluding a possibility of transfer of infections and for establishing biological compatibility between the donor and the potential recipient.

Art. 26. (1) (suppl. - SG 71/06, in force from 01.01.2007; suppl. - SG 36/09) Donor of organs and tissues may only be a person who is a spouse or relative of the recipient on the direct line or by collateral line up to fourth degree, including by kinship occurred on the grounds of adoption, but not earlier than three years from the adoption, in the cases when the recipient is an adoptive parent, which shall be proved by an official document.

(2) (amend. - SG 71/06, in force from 01.01.2007; suppl. - SG 36/09) As an exception, by a permit of the Ethical Commission for the transplantations it shall be admitted that a donor of organs and tissues may be a person who:

1. actually cohabitates with the recipient without marriage for a period of more than two years, and there is indisputable proof thereof;

2. is a biological parent of the recipient and has not legitimised the child following the procedure, established by the act.

(3) (revoked - SG 36/09)

Art. 27. (1) (suppl. - SG 71/06, in force from 01.01.2007) Taking self-restoring tissues from persons under 18 years of age shall be performed only when the transplantation will be made for a parent, spouse, brother or sister, a son or a daughter and the following conditions are met:

1. there is no appropriate donor over 18 years of age;

2. the transplantation is a life-saving treatment;

3. (amend. – SG 102/18, in force from 01.04.2019) the recipient is included in the official register of the Executive Agency "Medical Supervision";

4. The Ethical Commission for Transplantation has issued a permit.

(2) (amend. and suppl. - SG 71/06, in force from 01.01.2007) In the cases under para 1 the

notarised consent of the parents, guardian or trustee of the donor shall be required.

(3) (revoked - SG 36/09)

Art. 27a. (new - SG 36/09) (1) Homoeopathic stem cells and bone marrow may be extracted from a capable person regardless of his kinship with the recipient with his informed consent in writing.

(2) Homoeopathic stem cells may be extracted from a minor regardless of his kinship with the recipient with the informed consent of both of his parents or guardians in writing.

(3) Bone marrow may be extracted only from a minor in kinship with the recipient with the informed consent of both of his parents or guardians in writing.

(4) The consent of the parents or the guardians of the minor shall represent the probable will of the minor and may be withdrawn any time.

(5) Homoeopathic stem cells and bone marrow may be extracted from a juvenile with his and his parents' or his custodian's informed consent in writing.

(6) The consent of the juvenile, his parents or his custodian may be withdrawn any time.

(7) The persons shall be provided information in a comprehensible way for them regarding the extraction of homoeopathic stem cells and bone marrow.

(8) In the cases of Para 3 and 5 the activities of extraction of stem cells and bone marrow shall be carried out upon permission by the Ethics Commission on Transplantation referred to in Art. 12, Para 1.

Art. 28. (amend. and suppl. - SG 36/09) The taking of amniotic tissue, tissues and cells from navel cord and placenta shall be performed for the purposes of allogeneic and autologic transplantation upon receipt of an informed consent by the pregnant woman or by the maternity patient.

Art. 29. (amend. - SG 71/06, in force from 01.01.2007) (1) (Amend. – SG 102/18, in force from 01.04.2019) Each medical establishment which will carry out taking of organs, tissues or cells from a living donor shall be obliged to notify the Executive Agency "Medical Supervision" thereof at least 7 days in advance.

(2) (Amend. – SG 102/18, in force from 01.04.2019) Within 7-days from explanting the organs, tissues or cells from a living donor the medical establishment shall be obliged to register the procedure in the Executive Agency "Medical Supervision".

Section III.
Taking embryo organs, tissues and somatic, placenta and amniotic cells

Art. 30. (1) Embryo organs, tissues and somatic, placenta and amniotic cells may be taken from an aborted embryo for the purposes of transplantation upon receipt of an informed consent by the woman who has aborted the embryo.

(2) The Minister of Health shall determine by an ordinance the conditions and the order of taking embryo organs, tissues and somatic, placenta and amniotic cells.

Section IV.
Taking organs, tissues and cells from animals

Art. 31. Animal organs, tissues and cells may be used for transplantation under conditions and

by an order determined by an ordinance of the Minister of Health.

Chapter four.
IMPLANTATION OF ORGANS, TISSUES AND CELLS

Art. 32. Implantation of organs, tissues and cells shall be performed only on condition that:

1. the recipient or his legal representatives have given an informed consent for the forthcoming transplantation procedure;

2. (amend. – SG 102/18, in force from 01.04.2019) the recipient of organs is included in the official register of the Executive Agency "Medical Supervision".

Art. 33. (Amend. – SG 102/18, in force from 01.04.2019) The inclusion of persons, needing transplantation of organs, in the official register of the Executive Agency "Medical Supervision", as well as the selection of the concrete recipient of an organ, tissue or cells, shall be carried out under conditions and by an order determined by an ordinance of the Minister of health.

Art. 34. The medical establishments under art. 13, para 1, 2 and 3 shall carry out all medical activities related to the selection and preparation of the potential recipient, as well as to the continuous observation, control of the health status and the post-treatment of the patient.

Art. 35. (Amend. – SG 102/18, in force from 01.04.2019) Every medical establishment having performed implantation of an organ, tissue or cells, shall be obliged, within 7 days, to register the transplantation procedure in the Executive Agency "Medical Supervision".

Chapter five.
IMPORT AND EXPORT OF ORGANS, TISSUES AND CELLS. CONTROL (TITLE AMEND. - SG 36/09)

Art. 36. (amend. - SG 36/09) (1) Import and export from and to third countries of organs, intended for transplantation, shall be admitted only on the grounds of concluded international agreements by the Republic of Bulgaria, explicitly specifying the conditions and order for import and export of organs.

(2) Export to third countries of organs, intended for transplantation, shall be admitted only when there is no appropriate recipient in the Member States of the European Union, the European Economic Area and Switzerland, and when they are designated for an institution, acknowledged by the order established in the respective country.

(3) (amend. – SG 60/12) Import from third countries of organs, intended for transplantation, shall be admitted only when they are provided by an institution, acknowledged according to the procedure extablished in the respective country, applying all the requirements for quality, safety, traceability, reporting of major accidents and serious adverse reactions, and also for provision of information regarding characterization of organs of donors and organs, established by this present act.

(4) (suppl. – SG 41/09, in force from 02.06.2009, amend. – SG 102/18, in force from 01.04.2019) Import and export under Para 1 shall be carried out under a permit of the Executive Director of the Executive Agency "Medical Supervision" under conditions and order, specified in an ordinance of the Minister of Health and the Minister of Finance.

Art. 36a. (new – SG 60/12) (1) Organs exchange with the European Union Member States, with other states – parties to the Agreement on the European Economic Area, and with the Confederation of Switzerland shall be carried out subject to compliance with the requirements for quality, safety, traceability, reporting of information regarding characterization of organs and donors of organs, set out by this present act.

(2) (Amend. – SG 102/18, in force from 01.04.2019) Organs exchange with European organizations for organs exchange shall be carried out upon conclusion of an agreement between the Executive Agency "Medical Supervision" and the respective organization, if the organization guarantees compliance with the requirements for quality, safety, traceability, reporting of major accidents and serious adverse reactions, and also for provision of information regarding characterization of organs and donors of organs, set out by this present act.

(3) The terms and conditions and the procedure of exchange of organs under par. 1 and 2 shall be regulated by the ordinance under Art. 36, par. 4.

Art. 37. (1) (amend. - SG 36/09; suppl. – SG 41/09, in force from 02.06.2009; amend. – SG 60/12, amend. – SG 102/18, in force from 01.04.2019) Export of tissues and cells, intended for transplantation in third countries, shall be carried out after satisfying the needs of the Republic of Bulgaria, by a permit of the Executive Director of the Executive Agency "Medical Supervision" under conditions and by an order determined in the ordinance under Art. 36, Para 4.

(2) (amend. - SG 36/09) A permit under para 1 shall be issued to medical establishments under art. 13, para 1 - 3 and to tissue banks under the following conditions:

1. the tissues or cells are submitted to an institution recognised by the order established in the respective country for this type of activity;

2. the tissues and the cells have been taken, stored and transported according to this act and the established medical standards and rules of the respective country;

3. (amend. – SG 102/18, in force from 01.04.2019) the tissues and the cells have been included in the official register of the Executive Agency "Medical Supervision".

Art. 38. (1) (amend. - SG 36/09 suppl. – SG 41/09, in force from 02.06.2009; amend. – SG 60/12, amend. – SG 102/18, in force from 01.04.2019) Import of tissues and cells from third countries shall be carried out upon a permit of the Executive Director of the Executive Agency "Medical Supervision", under conditions and by an order determined in the ordinance under art. 36, para 4.

(2) (amend. - SG 36/09) The requirements to be met by the quality of tissues and cells under para 1 shall be determined by an ordinance of the Minister of Health.

(3) (amend. - SG 36/09) Permit under para 1 shall be issued to medical establishments under art. 13, para 1 - 3 and to tissue banks.

(4) (amend. - SG 36/09) Import under Para 1 shall be permitted only in cases where the tissues and cells have been provided by an institution acknowledged by an order established by the respective country for carrying out this activity, and one of the following requirements has been met:

1. (amend. - SG 36/09) presence of a proven positive effect of the using of tissues and cells, obtained and processed by methods and technologies not practised in the Member States of the European Union, the European Economic Area and Switzerland;

2. (amend. - SG 36/09) such tissues and cells are not available in the medical requirements in the cases when they are obtained and processed by methods and technologies known in the Member States of the European Union, the European Economic Area and Switzerland.

(5) (new - SG 36/09) Import under Para 1 shall be carried out upon proposal by a medical establishment under Art. 13, Para 1 - 3 or by a tissue bank.

Chapter six.
REGISTER AND CONTROL (title suppl. - SG 71/06, in force from 01.01.2007)

Art. 39. (1) (Amend. – SG 102/18, in force from 01.04.2019) The Executive Agency "Medical Supervision" shall create and maintain:

1. a public register;

2. (suppl. - SG 71/06, in force from 01.01.2007) an official register, in which shall be entered the names of the persons, who have expressed dissent for taking organs, tissues and cells.

(2) The circumstances and the data entered in the registers under para 1, the order of entry and using of the information shall be determined by the Minister of Health. The public register under para 1, item 1 shall not contain personal data.

(3) The data of the public register shall be accessible to all persons under the conditions and by the order of the Access to public information Act.

(4) (amend. - SG 71/06, in force from 01.01.2007) The data of the official register shall be kept for a period of 30 years. The citizens shall have the right to check up whether the expressed dissent for taking organs, tissues and cells has been correctly expressed in the official register.

(5) (amend. - SG 71/06, in force from 01.01.2007) Health related information from the official register shall be provided by the manner of Art. 28 of the Health Act.

Art. 39a. (New - SG 71/06, in force from 01.01.2007) (1) (amend. - SG 36/09, amend. – SG 102/18, in force from 01.04.2019) The Executive Agency "Medical Supervision" shall implement checks of the medical establishments, carrying out activities under this act and under Section III "Assisted reproduction" of Chapter four of the Health Act at least once every two years.

(2) (Amend. – SG 102/18, in force from 01.04.2019) Checks shall be held whenever serious adverse reaction, or serious incident occurs, as well as upon request by a competent authority of another state.

(3) (Amend. – SG 102/18, in force from 01.04.2019) The checks under para 1 and 2 shall be carried out by qualified employees of the Executive Agency "Medical Supervision" under terms and by manner, established by the ordinance under Art. 7c, Para. 4 of the Medical establishments Act.

(4) The persons under para 3 shall pass obligatory training course at least once a year according to the terms and the manner, established by the ordinance under para 3.

Chapter seven.
ADMINISTRATIVE PENAL PROVISIONS. ENFORCEMENT ADMINISTRATIVE MEASURES (TITLE AMEND. - SG 36/09)

Art. 40. (1) (amend. - SG 36/09; suppl. – SG 60/12) Who carries out activity related to extraction, examination, provision, characterization, processing, treatment, storing, transportation, provision or implanting organs, tissues or cells, or spreads information in violation of the provisions of this act or of the normative acts for its implementation, shall be punished by a fine of 10 000 to 30 000 levs, inasmuch as the act does not constitute a crime.

(2) Where the offence under para 1 has been committed by a corporate body a proprietary sanction of 20 000 to 50 000 levs shall be imposed.

Art. 40a. (New - SG 71/06, in force from 01.01.2007) (1) Who violates the prohibitions under Art. 6 or under Art. 24, para 8, shall be punished by a fine of 20 000 to 40 000 levs.

(2) Where the offence under para 1 has been committed by a legal entity, a proprietary sanction of 30 000 to 50 000 levs shall be imposed.

Art. 40b. (New - SG 71/06, in force from 01.01.2007) A medical establishment, which violates the provisions under Art. 13, para 4 and 5, Art. 15a, 15b, 15c, 15d, 15e or 29, shall be imposed a proprietary sanction of 30 000 to 50 000 levs.

Art. 41. (1) (amend. - SG 36/09; suppl. – SG 60/12) Who carries out an activity of import and export of organs, tissues and cells and exchange of organs in violation of the provisions of this act or of the normative acts for its implementation, shall be punished by a fine of 100 000 to 500 000 BGN, unless subject to a more severe punishment.

(2) Where the offence under para 1 has been committed by a corporate body a proprietary sanction of 750 000 to 2 000 000 BGN shall be imposed.

Art. 41a. (new - SG 36/09) (1) Whoever violates the provisions of this Act or the normative acts on its implementation, except in the cases of Art. 40 - 41, shall be fined from BGN 5000 to 10 000.

(2) Where the violations under Para 1 are committed by a legal person, a proprietary sanction shall be imposed amounting to BGN 7000 to 12 000.

Art. 42. (1) (suppl. - SG 71/06, in force from 01.01.2007; amend. - SG 36/09, amend. – SG 102/18, in force from 01.04.2019) The offences under art. 40, 40a, 40b and 41a shall be established with acts drawn up by officials, appointed by the Executive Director of the executive Agency "Medical Supervision".

(2) (suppl. - SG 71/06, in force from 01.01.2007; amend. - SG 36/09, amend. – SG 102/18, in force from 01.04.2019) The penal provisions for the offences under art. 40, 40a, 40b and 41a shall be issued by the Executive Director of the Executive Agency "Medical Supervision".

Art. 43. (1) (Amend. – SG 102/18, in force from 01.04.2019) The offences under art. 41 shall be established by acts issued by the customs bodies or by officials appointed by the Executive Director of the Executive Agency "Medical Supervision".

(2) (Amend. – SG 102/18, in force from 01.04.2019) The penal provisions for the offences under art. 41 shall be issued by the Director of Agency "Customs" or by officials authorised by him, respectively by the Executive Director of the Executive Agency "Medical Supervision".

Art. 44. The establishment of the offences, the issuance, the appeal and the fulfilment of the penal provisions shall be carried out by the order of the Administrative Violations and Penalties Act.

Art. 45. (new - SG 36/09) The income from fines and property sanctions for violations established under this act or the secondary legislative acts on its implementation shall be transferred to

the budget of the authority that has issued the penal provision.

Art. 46. (new - SG 36/09) (1) (Amend. – SG 102/18, in force from 01.04.2019) The Executive Director of the Executive Agency "Medical Supervision" may suspend in an order transplantation activities for up to 6 months, if a medical establishment does not meet the requirements of the medical standard for transplantations of organs, tissues and cells.

(2) (Amend. – SG 102/18, in force from 01.01.2019) For the medical establishments under Art. 13, Para 3, a copy of the suspension order under Para. 1 shall be sent to the respective primary budget spending unit, to whom the director of the medical establishments is a secondary budget spender.

(3) (Amend. – SG 102/18, in force from 01.04.2019) If after the expiration of the term under Para 1 the medical establishment still fails to meet the requirements of the medical standard for transplantations of organs, tissues and cells, the Executive Director of the Executive Agency "Medical Supervision" may:

1. (amend. – SG 102/18, in force from 01.04.2019) cancel the transplantation activities from the permit for medical activities of the respective medical establishment - for the medical establishments under Art. 13, Para 1;

2. (amend. – SG 98/10, in force from 01.01.2011, amend. – SG 102/18, in force from 01.04.2019) cancel the transplantation activities from the activity certificate of the respective medical establishment - for the medical establishments under Art. 13, Para 2;

3. (amend. and suppl. – SG 102/18, in force from 01.04.2019) withdraw the certificate for transplantations of the medical establishments under Art. 13, Para 3, whereby informing about that the respective primary budget spending unit, to whon the Director of the medical establishment is a secondary budget spender.

(4) The orders under Para 1 and Para 3, Item 3 shall be subject to appeal under the order of the Administrative Procedure Code.

(5) The appeal of the orders shall not suspend their enforcement.

Additional provisions

§ 1. In the meaning of this act:

1. "Cell" is the smallest functional unit of which the tissues and organs consist.

2. "Tissue" is a group of body cells, homogeneous of their structure and functions, which is a composite part of an organ or which can regenerate.

3. (amend. – SG 60/12) "Organ" is a part of the human body consisting of different tissues, maintaining its structure and vascular system and may fulfill physiological functions. Organs are also parts of organs where they are intended to be used for the same purpose like the entire organ in the human body with maintaining of its structure and vascular system.

an integrated, morphologically and functionally separate group of tissues fulfilling a definite function of the body.

4. "Hemopoietic truncal cells" are the cells generating all cells of the blood.

5. "Recipient" is a person of whom organs, tissues and cells have been implanted for therapeutic purposes.

6. "Live donor" is an individual of whom organs, tissues or cells are taken for the purpose of their implanting on other person for therapeutic purposes.

7. "Taking" is the taking out, by medical methods, of organs, tissues and cells from the body of a donor when it is done for the purpose of implantation or other therapeutic, scientific and educational

needs of the medicine.

8. "Implantation" is the placement, by medical methods, of organs, tissues and cells in the body of a recipient.

9. "Embryo organs, tissues and cells" are organs, tissues and cells taken from a human embryo.

10. "Reproductive organs" are the testes and ovaries used for the purpose of creating posterity and reproduction of the individuals.

11. "Ovary" is a female reproductive cell.

12. "Spermatozoids" are the male reproductive cells.

13. "Informed consent" is a voluntary written consent for carrying out a definite medical activity. The person, giving the consent, shall have received the whole necessary information regarding the activity and the results expected thereof, as well as explanations for the existing alternative means of resolving the medical problem.

14. "Biological products" are all substances, cellular cultures and Art.s, obtained by the order of this act, from processed organs, tissues and cells of human or animal origin, which are not medicine products.

15. "Biological compatibility" is the established, by medical methods, possibility of the implanted organs, tissues and cells from one individual to another, to fulfil their functions without causing a severe reaction of rejection of the implanted organs, tissues or cells.

16. "Amniotic tissue" is a membrane consisting of epithelioid and retiform tissues surrounding the embryo and forming the amniotic chamber.

17. (amend. - SG 36/09) "Auto-transplantation (autologous transplantation)" is taking tissues and cells from one person and their implantation in another place of the body of the same person.

18. "Implantation of artificial organs and tissues" is the placing, by medical methods, in the body of a person, of artificial organs and tissues for therapeutic purposes.

19. "Advertising" is every announcement made in the mass media, or in any other way, for submitting organs, tissues and cells for implanting.

20. "Placenta cells" are the cells of the organ through which the foetus, during its uterine development, receives oxygen and nutrition and secretes carbon dioxide and other waste products.

21. "Self-regenerating organ" is an organ which can regenerate completely its mass and function after removal of a part of it.

22. "Self-regenerating tissue" is a tissue which may regenerate its mass after a removal of a part of it.

23. "Human corpse" is the body of a person after his/her death.

24. (new - SG 71/06, in force from 01.01.2007) "Serious adverse reaction" shall be unexpected reaction in a donor or a recipient, related to expertise, taking, treatment, processing, storing, transportation and implantation of organs, tissues and cells, which has lead to death, state posing danger to life, or to spreading of contagious disease, to permanent inability to work or illness causing an extension of the stay in hospital.

25. (new - SG 71/06, in force from 01.01.2007) "Serious incident" shall be any adverse event related to expertise, taking, treatment, processing, storing, transportation and implantation of organs, tissues and cells, which may lead to death, state posing danger to life, or to spreading of contagious disease, to permanent inability to work or illness causing an extension of the stay in hospital.

26. (new - SG 71/06, in force from 01.01.2007) "Donor" shall be any source of organs, tissues and cells of human origin.

26a. (new – SG 60/12) "Donation" is donation of organs, tissues and cells for transplantation.

27. (new - SG 71/06, in force from 01.01.2007) "Invasive procedure" shall be any disruption of the skin or the mucous by way of surgical instruments, where for the purpose of taking and implanting organs, tissues and/or cells, access into the human body is provided.

28. (new - SG 71/06, in force from 01.01.2007) "Expertise" shall be activity, related to research

for assessment of the condition of organ, tissue or cells, as well as to ascertainment of: immune status, presence of disease organisms, chemical or biological substances through which illness, infection or intoxication may be transferred.

29. (new - SG 71/06, in force from 01.01.2007) "Treatment" shall be activity for preparation of removed organs, tissues and cells intended for implantation by applying physical, chemical or biological methods during their removal or immediately after that, including their packing, without affecting their integrity or physiological condition.

30. (new - SG 71/06, in force from 01.01.2007) "Processing" shall be activity for preparation of removed organs, tissues and cells intended for implantation or extraction of therapeutic substances by applying physical, chemical or biological methods, including their packing, without affecting their integrity or physiological condition.

31. (new - SG 71/06, in force from 01.01.2007; amend. – SG 60/12) "Storing" means the activity for use of chemical and physical agents, changes in the environment or of other means for prevention or delay the biological or physical injury of the organs, tissues and cells until securing of their transplantation.

32. (new - SG 71/06, in force from 01.01.2007) "Reasonably short term" shall be the time period, within which the organs, tissues and cells retain their vitality and may can be used for transplantation.

33. (new - SG 71/06, in force from 01.01.2007) "Labelling" shall mean activity of marking the package of organs, tissues and cells with the purpose of their identification.

34. (new - SG 71/06, in force from 01.01.2007) "Packing" shall mean isolation by way of appropriate materials of organs, tissues and cells from the environment in order their contamination or injury to be prevented.

35. (new - SG 36/09) "Third countries" shall mean countries, which are not members of the European Union, the European Economic Area and Switzerland.

36. (new - SG 36/09) "Quality system" means a number of written rules, defining the sequence of the procedures and processes, the type and quantity of the resources and the responsibility of every participant in the organisational structure, carrying out transplantation activities. The rules shall apply to the performance of quality management on every stage and to all activities directly or indirectly related to it.

37. (new - SG 36/09) "Provision" shall mean a process of distribution, supply and delivery of organs, tissues and cells, intended for transplantation, from one medical establishment to another.

38. (new - SG 36/09) "Alogeneic transplantation" shall mean the extraction of cells and tissues from one person and their transplantation to another person.

39. (new – SG 60/12) "Donor's characterization" is an activity for gathering of information regarding a potential donor of organs, tissues and cells, required for making an assessment whether he/she is suitable for donation of organs, tissues and cells in order to survive and reduce the risk for the patient, and also for optimization of the process of distribution of organs.

40. (new – SG 60/12) "Organs characterization" is an activity for gathering of information regarding an organ for transplantation, required for making an assessment whether it is suitable for transplantation, in order to assess and reduce the risk for the recipient, and also for optimization of the process of organs distribution.

41. (new – SG 60/12) "European Organ Exchange Organization" is a public or private non-profit organization, intended for national or international exchange of organs, whereby the majority of its members are European Union Member States.

42. (new – SG 60/12) "Destruction" is the end purpose of use of an organ, where it is not used for transplantation.

43. (new – SG 60/12) "Provision" is a process, in which the donors' organs, tissues and cells become available.

§ 1a. (new - SG 71/06, in force from 01.01.2007; suppl. - SG 36/09; suppl. – SG 60/12) This act incorporates the provisions of Directive 2004/23EC of the European parliament and the Council on setting standards of quality and safety for donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells and Commission Directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells and also of 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).

Concluding provisions

§ 2. Within one month from the enactment of the act the Council of Ministers shall adopt, and the Minister of Health shall issue the normative acts for its implementation.

§ 3. The following amendments and supplements are introduced to the national Health Act (Prom. SG 88/6 Nov 1973, corr. SG 92/20 Nov 1973, amend. SG 63/6 Aug 1976, amend. SG 28/8 Apr 1983, amend. SG 66/23 Aug 1985, amend. SG 27/4 Apr 1986, amend. SG 89/25 Nov 1988, amend. SG 87/10 Oct 1989, amend. SG 99/22 Dec 1989, amend. SG 15/22 Feb 1991, corr. SG 24/26 Mar 1991, amend. SG 64/27 Jul 1993, amend. SG 31/12 Apr 1994, amend. SG 36/18 Apr 1995, amend. SG 12/7 Feb 1997, amend. SG 87/1 Oct 1997, amend. SG 124/23 Dec 1997, suppl. SG 21/20 Feb 1998, amend. SG 70/19 Jun 1998, amend. SG 71/23 Jun 1998, amend. SG 93/11 Aug 1998, amend. SG 30/2 Apr 1999, amend. SG 62/9 Jul 1999, amend. SG 67/27 Jul 1999, amend. SG 90/15 Oct 1999, suppl. SG 113/28 Dec 1999, amend. SG 10/4 Feb 2000, amend. SG 36/2 May 2000, amend. SG 63/28 Jun 2002):

1. Item 16 is created in art. 3a:

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

Articles 33, 33a, 34 and 35 are revoked.

§ 4. The following amendments and supplements are introduced to the Medical Sstablishments Act (prom., SG 62/1999; amend., SG 88 and 113 of 1999; corr., SG 114 of 1999; amend., SG 36, 65 and 108 of 2000, SG 51 of 2001 – Decision No 11 of the Constitutional Court of 2001; amend., SG 28 and 62 of 2002):

1. Item 6 is created in art. 2, para 1:

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

2. Item 7 is created in art. 10:

"7. tissue bank."

3. Item 4a is created in art. 19:

"4a. transplantation of organs, tissues and cells;"

4. Created is art. 28b:

"Art. 28b. (1) The tissue bank is a medical establishment where a physician, with the assistance of other specialists, takes, studies, stores and process organs, tissues and cells for medical purposes.

(2) The tissue banks may take only tissues and cells for implantation or processing, and organs

– only for processing.

(3) The activity of the tissue bank shall be carried out according to a regulation for the structure, activity and internal order, approved by the head of the medical establishment."

5. Created is art. 36a.:

" Art. 36a. (1) The tissue bank shall be established as a limited liability company or as a joint-stock company, and it shall carry out activity upon receipt of a permit by the order of art. 51a.

(2) Included in the subject of activity of the tissue bank shall obligatorily be only the activities under art. 28b.

(3) The court registration of the company shall obligatorily contain the full name of the medical establishment."

6. item 11 is created in art. 40, para 1:

"11. a certificate issued by the Executive Agency for the Transplantations that the medical establishment may carry out taking and implantation of tissues and cells in compliance with the established medical standards in the cases when the medical establishment will carry out such an activity."

7. item 12 is created in art. 47:

"12. a certificate issued by the Executive Agency for the Transplantations that the medical establishment may carry out taking and implantation of tissues and cells in compliance with the established medical standards in the cases when the medical establishment will carry out such an activity."

8. Created is art. 51a:

"Art. 51a. (1) The tissue banks shall carry out activity upon obtaining a permit by the Director of the Executive Agency for the Transplantations.

(2) A permit under para 1 shall be issued on the grounds of an application accompanied by:

1. the court decision for registration, a certificate for current status, a certificate for tax registration and single identification code;

2. the basic instrument of the company and the regulation for the structure, activity and internal order of the medical establishment;

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

4. the certificates of conviction of the persons representing the medical establishment;

5. the hygiene conclusion for the site by the bodies of the Hygiene and Epidemiological Inspection.

(3) For incompleteness of the presented documents under para 2 the Director of the Executive Agency for the Transplantations shall, within 15 days, notify about that the applicant and shall determine a period for its rectification.

(4) Within three months from filing the documents under para 2 the Director of the Executive Agency for the Transplantations shall issue a permit for carrying out the activity of the tissue bank, indicating the types of activities it will carry out, or shall issue a motivated refusal for its issuance.

(5) The refusal under para 4 shall be subject to appeal by the order of the Administrative Proceedings Act.

(6) The Director of the Executive Agency for the Transplantations may withdraw by an order the issued permit in the following cases:

1. if the tissue bank carries out an activity in violation of this act and of the normative acts for its implementation, or carries out activities other than those for which the permit has been issued;

2. at a request of the tissue bank;

3. upon dissolution of the tissue bank.

(7) The order of the Director of the Executive Agency for the Transplantations under para 6, item 1 shall be subject to appeal by the order of the Administrative Proceedings Act.

(8) The appeal of the order shall not stop its fulfilment.

9. In art. 63, para 5 the words "art. 10, item 4, 5 and 6" are replaced by "art. 10, item 4, 5, 6 and 7".

10. In art. 86, para 1 the words "and the diagnostic-consultative centres" are replaced by "the diagnostic-consultative centres and tissue banks".

§ 5. The fulfilment of the act is assigned to the Minister of Health.

§ 6. The act shall enter into force on January 1, 2004.

The act was adopted by the 39th National Assembly on July 30, 2003, adopted repeatedly on September 11, 2003, and was affixed with the official seal of the National Assembly.

Transitional and concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE ACT ON TRANSPLANTATION OF ORGANS, TISSUES AND CELLS

(PROM. - SG 71/06, IN FORCE FROM 01.01.2007)

§ 26. (1) The Council of Ministers shall amend and supplement the Structural regulations of the Executive Agency for Transplantation in compliance with this act in one-month term from its coming into effect.

(2) In six-months term from coming into effect of this act, the Minister of Health shall issue the subordinate legislation related to its implementation.

§ 27. (1) The Ministry of Health shall inform the Bulgarian citizens in a reasonable manner of the terms and the procedures for taking and implantation of organs, tissues and cells by the 31st of March 2007.

(2) The informing under para 1 shall be carried out under terms and following a procedure, established in an ordinance by the Minister of Health.

§ 28. (In force from in force from the date of coming into effect of the Treaty concerning the Accession of the Republic of Bulgaria to the European Union) The first report under Art. 11, para 5, item 16 shall be presented to the European commission by the Executive Agency for Transplantation by April 7, 2007.

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§ 30. The act shall enter into force from the 1st of January 2007, except for the provisions of § 4, item 3, letter "e" – concerning the creation of items 15, 16 and § 28, which shall enter into force from the date of coming into effect of the Treaty concerning the Accession of the Republic of Bulgaria to the European Union.

Transitional and concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE HEALTH ACT

(PROM. – SG 41/09, IN FORCE FROM 02.06.2009)

§ 96. The act shall enter into force from the day of its promulgation in State Gazette, except for the following:

1. paragraphs 3, 5, 6 and 9, which shall enter into force from 1 January 2009;

2. paragraphs 26, 36, 38, 39, 40, 41, 42, 43, 44, 65, 66, 69, 70, 73, 77, 78, 79, 80, 81, 82, 83, 88, 89 and 90, which shall enter into force from 1 July 2009;

3. paragraph 21, which shall enter into force from 1 June 2010.

Transitional and concluding provisions
TO THE ACT ON THE BUDGET OF THE NATIONAL HEALTH INSURANCE FUND FOR 2011

(PROM. – SG 98/10, IN FORCE FROM 01.01.2011)

§ 15. This Act shall enter into force from 1 January 2011 except § 10, which shall enter into force from the day of its promulgation in the State Gazette.

Transitional and concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE HEALTH ACT

(PROM. – SG 98/10, IN FORCE FROM 01.01.2011)

§ 118. In the Act of the Transplantation of Organs, Tissues and Cells (prom. – SG 83/03; amend. – SG 88/05, SG 71/06 and SG 36 and 41/09) shall be made the following amendments:

……..

2. Everywhere the words "regional healthcare centre" and "regional healthcare centres" shall be substituted by "regional health inspection" and "regional health inspections".

§ 121. The act shall enter into force from 01.01.2011, except for the following:

1. paragraphs 1, 16, 20, 29, 30, 32, 33, 34, 35, 42, 44, § 56, Item 1 and 2, § 65, 68, 70, 76, 80, 81, 90, 92, 96, § 102, Item 3, 4, 5, 7 and 8, § 105, т. 1, 3 and 5, § 107, т. 1, 2, 3, 4, 6, Letter "a", Item 7, 10, 11, 13 and 15, Letter "a", § 109, 110, 112, 113, § 115, Item 5, § 116, Item 4 and 6, § 117, Item 5 and 7 and § 118, Item 1, which shall enter into force from the date of its promulgation in the State Gazette;

2. paragraph 102, Items 1, 2 and 6, which shall enter into force from 1 March 2011;

3. paragraph 22, Item 1 (regarding Art. 36, Para 1, second sentence), § 37, § 48, Item 2, § 51 and 59, which shall enter into force from 1 July 2011;

4. paragraph 107, Item 15, Letter "b", which shall enter into force from 30 September 2011.

Transitional and concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE HEALTH INSURANCE ACT

(PROM. – SG 60/12, IN FORCE FROM 07.08.2012)

§ 44. The act shall enter into force from the day of its promulgation in the State Gazette.

Transitional and concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE ACT ON TRANSPLANTATION OF ORGANS, TISSUES AND CELLS

(PROM. – SG 60/12)

§ 19. Medical establishments, having obtained permits under Art. 36, 37 and 38 prior to entering of this act into force shall carry out their activity based on the granted permits.

§ 20. The first report under Art. 11, par. 5, item 16a shall be submitted to the European Commission by the Executive Agency for Transplantations by 27 August 2013.

Transitional and concluding provisions
TO THE PUBLIC FINANCE ACT

(PROM. SG 15/13, IN FORCE FROM 01.01.2014)

§ 123. This Act shall enter into force on 1 January 2014 with the exception of § 115, which enters into force on January 1, 2013, and § 18, § 114, § 120, § 121 and § 122, which came into force on 1 February in 2013.

Transitional and concluding provisions
TO THE ACT ON THE BUDGET OF THE NATIONAL HEALTH INSURANCE FUND FOR 2019

(PROM. - SG 102/18, IN FORCE FROM 01.01.2019)

§ 41. In the Act on Transplantation of Organs, Tissues and Cells (prom., SG 83/2003, amended, SG 88/2005, SG 71 of 2006, SG 36 and 41 of 2009, SG 98 of 2010, SG 9 of 2011, SG 60 of 2012 and SG 15 of 2013), the following amendments and supplements shall be made:

. . . . . .

10. (In force from 01.04.2019) In the remaining texts of the Act, the words "the Executive Agency for Transplantation" shall be replaced by "the Executive Agency "Medical Supervision".

. . . . . .

§ 43. The Act shall enter into force on 1 January 2019, with the exception of:

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

2. paragraph 28, items 6 - 12 and items 14 - 19, § 35, item 3 with the exception of Art. 7a, Para. 4 and Art. 7c, Para. 4, item 5 and 6, item 8 - 22 and items 36 - 40, § 41, items 2 - 8, item 9, letters "a" and "c" and item 10 which shall enter into force on 1 April 2019;

3. paragraph 29, item 5, letter "a" on the words "through the budget of the Ministry of Health

for the payment of medical devices, aids, devices and facilities for people with disabilities", item 9, letter "a" on the words "as well as medical devices, aids, devices and facilities for people with disabilities", item 9, letter "d" on the words "aids, devices and facilities for people with disabilities" and on the words "as well as with the persons carrying out activities related to delivery and repair of medical devices, aids, devices and facilities for people with disabilities, registered as traders and entered in the register of persons, performing activities related to delivery and repair of medical devices, aids, devices and facilities for people with disabilities", and item 9, letter "e" regarding Para. 15, item 3 and Para. 16 on the words "as well as persons carrying out activities related to delivery and repair of medical devices, aids, devices and facilities for people with disabilities, registered as traders and entered in the register of persons performing activities related to delivery and repair of medical devices, aids, devices and facilities for people with disabilities - for the payment of medical devices, aids, devices and facilities for people with disabilities", item 25, letter "a" - Para. 1, item 13 on the words "aids, devices and facilities for people with disabilities" and item 25 concerning Para. 4 on the words "persons carrying out activities related to delivery and repair of medical devices, aids, devices and facilities for people with disabilities, registered as traders and entered in the register of persons, performing activities related to delivery and repair of medical devices" and "and aids, devices and facilities for people with disabilities", § 36 and § 37 concerning Art. 14, Para. 8, item 2, letter "b", which shall enter into force from 1 January 2020.