BLOOD, BLOOD DONATION, AND BLOOD TRANSFUSION ACT

Prom. SG. 102/21 Nov 2003, amend. SG. 70/10 Aug 2004, amend. SG. 30/11 Apr 2006, amend. SG. 65/11 Aug 2006, amend. SG. 31/13 Apr 2007, amend. SG. 41/2 Jun 2009, amend. SG. 74/15 Sep 2009, amend. SG. 59/31 Jul 2010, amend. SG. 98/14 Dec 2010, amend. SG. 60/5 Aug 2011, amend. SG. 38/18 May 2012, amend. SG. 54/17 Jul 2012, amend. SG. 68/2 Aug 2013, suppl. SG. 77/18 Sep 2018, amend. SG. 102/11 Dec 2018, amend. and suppl. SG. 54/16 Jun 2020

Chapter one.
GENERAL PROVISIONS

Art. 1. (1) This Act shall regulate the social relationships related to donation, taking, diagnostics, processing, transportation, conservation and use of blood and blood components and ensuring their good quality and safety.

(2) Subject to planning shall be the type and the quantities of blood and blood components required for meeting the needs of the medical institutions and for production of drugs obtained from blood plasma.

(3) The tracing out of blood and blood components from donor to recipient and back shall be guaranteed by exercising transfusion surveillance as a system of registration and analysis of the information and of control on ensuring the good quality and safety of blood and blood components.

(4) The activities under para 1 shall be carried out according to a medical standard of transfusion technology approved by a regulation of the Minister of Health care.

Art. 2. The provisions of the Act shall not apply to the transplantation of haematopoietic stem cells.

Art. 3 (1) The activities under this Act shall be carried out in compliance with the principles of:

1. voluntary and free donation of blood and blood components;
2. protection of donorsâ€™ and recipientsâ€™ rights and health;
3. equality of donors and recipients;
4. rational use of blood and blood components;
5. self-sufficiency of the country with blood and blood components.

(2) Blood and blood components shall be used for medical needs according to medical indications or where other methods of treatment are inefficient.

Art. 4. Blood and blood components may not be subject of onerous transaction, save in the cases provided for in this Act.

Art. 5. (1) (amend. â€“ SG 65/06, in force from 11.08. 2006) The multi-profile hospitals for active treatment, which have in their structure a ward of transfusion haematology shall supply each unit of blood, taken by them, to the centres for transfusion haematology against payment for the expenses for its taking.

(2) (amend., - SG 98/10, in force from 01.01.2011) The centres for transfusion haematology shall supply free of charge diagnosed and processed blood and blood components to the medical institutions for hospital aid and the comprehensive cancer centres within the limits of the approved quantities under Art. 26, item 1.

(3) (amend., - SG 98/10, in force from 01.01.2011) Apart from the cases under para 2, the centres for transfusion haematology may also supply the medical institutions for hospital aid and the comprehensive cancer centres with blood and blood components against payment for the costs for the diagnostics and processing.

(4) The conditions and procedure of the payment under paras 1 and 3 and of evaluation of the costs shall be determined by a regulation of the Council of Ministers.

(5) The centres for transfusion haematology shall supply plasma to the producers of drugs at prices, under terms and procedure determined by a regulation of the Council of Ministers.

(6) The conditions and procedure of the stimulation, organization and implementation of the activities, related to blood donation, shall be specified by the ordinance under para 4.

(7) (amend. â€“ SG 38/12, in force from 01.07.2012) The funds under para 3 and 5 enter in the Ministry of Health and shall be included in the budgets of the centres for transfusion haematology.

Art. 5a. (New â€“ SG 65/06, in force from 11.08. 2006) (1) The Military Academy of Medicine shall supply non-diagnosed blood and blood components to the centres for transfusion haematology in case the quantities, gathered at blood donation, exceed the quantities, necessary for satisfying the needs of the medicinal institution.

(2) In the cases under para 1 the Military Academy of Medicine shall supply the centres for transfusion haematology with blood and blood components for free.

(3) The centres for transfusion haematology may supply the medical institution with blood exceeding the quantities, approved for the Military Academy of Medicine under art. 26, item 1, against payment of the expenses for diagnostics and processing.

(4) The terms and the manner for the payment under para 3, as well as for costing the expenses, shall be determined by the ordinance under art. 5, para 4.

(5) The Military Academy of Medicine shall supply plasma to the producers of medicines at prices, under conditions and following a procedure, established by the ordinance under art. 5, para 5.

Art. 6. (1) The medical institutions under Art. 15 shall be allowed to receive blood against payment in the following cases:

1. in emergency cases and in case of lack of available quantities of the needed blood group at the respective centre for transfusion haematology;

2. for production of vaccines, serums and immunoglobulins;

3. for research and diagnostic purposes in medicine;

(2) The medical institutions under Art. 15 may cover the direct costs of blood donors and stimulate them with symbolic gifts and by other means compatible with the principle of voluntary donation of blood.

(3) The payment of the blood and blood components in the cases under para 1 shall be made according to a procedure and at prices specified in the regulation under Art. 5, para 4.

Art. 7. (1) Blood and blood components shall only be exported beyond the territory of this country by a decision of the Council of Ministers, where they are meant for:

1. rendering humanitarian aid;

2. production of drugs for this countryâ€™s needs.

(2) The Minister of Health shall organise the export of blood and blood components in the cases under para 1, item 2.

Art. 8. (1) (suppl. â€“ SG 41/09, in force from 02.06.2009) Blood and blood components shall only be imported in the territory of this country with the permission of the Minister of Health or of an authorized by him/her Deputy Minister in case of emergencies where the available quantities of blood and blood components in the country are not sufficient for the protection of peopleâ€™s health.

(2) The import under para 1 shall be allowed in case the blood and blood components have been diagnosed, processed, labelled and provided by an institution legally recognised by the respective state and shall be accompanied by documentation making possible the identification of every unit of blood or blood components and by information about laboratory examinations mad and about the methods of diagnosis and processing.

(3) The conditions, which the quality of blood and blood components under para 1 should meet, shall be determined by the regulation under Art. 20, para 2.

(4) (amend. â€“ SG 31/07, in force from 13.04.2007) Drugs made of plasma shall be imported under the order of the Medicinal Products in Human Medicine Act.

Art. 9. Advertising blood or blood components shall be prohibited.

Chapter two.
DONATION, TAKING, DIAGNOSTICATION, PROCESSING AND CONSERVATION OF BLOOD AND BLOOD COMPONENTS

Art. 10. Donation is a human and voluntary act by which free of charge blood and blood components are taken from the donor.

Art. 11. (1) (amend. â€“ SG 74/09, in force from 15.09.2009; amend. â€“ SG 68/13, in force from 02.08.2013) The Minister of Health, the Minister of Education and Science, the Minister of Defence, the Bulgarian Red Cross and the medical and health institutions shall organise and promote the donation of blood or blood components.

(2) Mass media, non-government organisations and religious institutions registered by order of the Religions Act may also take part in the promotion under para 1.

(3) The bodies of the central and local governments, the juridical and physical persons shall be obliged to contribute to the carrying out of the promotion and to render assistance in the taking of blood.

Art. 12. (1) Donors of blood or blood components may be legally capable persons of 18 to 65 years of age, who show no contraindication to do so.

(2) The interval of time between two standard takings of blood shall not be less than 60 days.

(3) The circumstance under para 2 shall be established by making a check in the register under Art. 36.

Art. 13. (1) The donor shall give informed consent in writing and shall fill in a declaration about his or her state of health.

(2) For receiving the consent under para 1, the donor shall be given information in accessible language about the procedure of taking blood or blood components, about the physiological changes which take place in the organism as a result of that and about the safety measures and the potential risks.

Art. 14. (1) Blood or blood components shall be taken after a medical examination performed by a physician or under his or her control.

(2) The person taking blood or blood components shall label them and shall prepare and indicate a satellite blood sample and prepare a set of documentation containing a filled in form about:

1. informed consent;

2. declaration on the state of health;

3. the results from the medical examination and from the laboratory examinations;

4. identification of the taken unit of blood or blood components;

(4) The donor shall be entitled to receive information about his or her state of health established upon the examination under para 1 and about the results from the performed laboratory examinations.

Art. 15. The taking of blood or blood components shall be arranged and carried out by:

1. the centres for transfusion haematology;

2. the multi-profile hospitals for active treatment, in whose structure there is a ward for transfusion haematology;

3. the Military Academy of Medicine.

Art. 16. (1) The medical institutions under Art. 15 shall issue each donor a card.

(2) In the card under para 1 shall be stated the unique identification number, the full name, UCN1, the constant address, the blood group, the date and the quantity of the taken blood or blood components.

Art. 17. The medical institutions under Art. 15 shall ensure conditions for protection of the donorsâ€™ health.

Art. 18. (amend. â€“ SG 65/06, in force from 11.08. 2006) (1) (amend. â€“ SG 54/12) The National Centre for Transfusion Haematology shall supply the medicinal articles for taking, diagnosis, processing and conservation of blood and blood components required by the medical establishments under Art. 15, Items 1 and 2 and shall provide them free of charge under conditions and order determined in an ordinance of the minister of Health.

(2) (new â€“ SG 54/12) The required funds for carrying out the activities under Para 1 shall be provided for such purposes by the National Centre for Transfusion Haematology through the budget of the Ministry of Health.

(3) (prev. text of Para 02, amend. â€“ SG 54/12) The medical articles for the activities related to taking, diagnosis, processing and conservation of blood and blood components, carried out by the Military Academy of Medicine, shall be paid by the Ministry of Defence.

Art. 19. The medical institution under Art. 15, items 2 and 3 shall submit the taken blood and blood components, together with the satellite blood samples, a copy of the documentation under Art. 14, para 2 and a protocol for delivery to the centre for transfusion haematology.

Art. 20. (1) The diagnostics, processing and conservation of each unit of blood or blood components shall be effected by the centres for transfusion haematology in compliance with the rules of Good Laboratory Practice and Good Production Practice.

(2) The terms and procedure of effecting diagnostics, processing and conservation of blood and blood components shall be determined by a regulation of the Minister of Health.

(3) (New â€“ SG 65/06, in force from 11.08. 2006) The Military Academy of Medicine shall diagnose, process and preserve blood and blood components for its own necessities only, within the scope of the approved quantities under art. 26, item 1.

Art. 21. (revoked - SG 102/18, in force from 01.01.2019)

Art. 22. (1) The persons engaged in taking, diagnostics, processing and conservation of blood and blood components shall pass a compulsory training course at least once in two years.

(2) (amend. â€“ SG 60/11) The training shall be done according to a programme approved by the Minister of Health on a proposal of the Director of the National Centre for Transfusion Haematology.

Art. 23. Distribution of data allowing the identification of the donors shall be prohibited.

Chapter three.
PLANNING AND PROVISION OF BLOOD AND BLOOD COMPONENTS

Art. 24. (1) Every year the Director of the centre for transfusion haematology shall analyse and plan for the needs of the served district:

1. the activities for promoting voluntary and free donation of blood;

2. the quantities of blood and blood components for satisfying the planned and emergency needs and their distribution by regions;

3. the quantity of plasmas for production of drugs;

4. (suppl. â€“ SG 65/06, in force from 11.08. 2006) the medical devices necessary for taking, diagnostics, processing and conservation of blood and blood components;

5. the expected number of blood donations and the schedule of their performance;

6. the expected number of paid takings of blood.

(2) The analysis shall be based on:

1. information received from the medical institutions using blood and blood components;

2. the possibilities of the centre for providing blood and blood components.

Art. 24a. (New â€“ SG 65/06, in force from 11.08. 2006) (1) The head of the Military Academy of Medicine shall analyse and plan the necessities of the medical institution annually:

1. the quantities of blood and blood components for satisfying the planned and the emergency needs and their distribution by structures;

2. the quantity of plasma for production of medicines;

3. the expected number of blood donations and the schedule of their performance;

4. the expected number of paid blood takings.

(2) The analysis shall be based on information, received from the structures of the Military Academy of Medicine, using blood and blood components.

Art. 25. (suppl. â€“ SG 65/06, in force from 11.08. 2006; amend., - SG 98/10, in force from 01.01.2011; amend. â€“ SG 60/11) The results from the performed analysis and planning under Art. 24 and Art. 24a shall be submitted to the Director of the National Centre for Transfusion Haematology and to the directors of the regional health inspectorates.

Art. 26. (amend. â€“ SG 60/11) Every year the Director of the National Institute for Transfusion Haematology shall analyse, summarise and submit for approval by the Minister of Health the planned:

1. quantities of blood and blood components for satisfying the medical needs in this country;

2. quantity of plasma for production of drugs;

3. (suppl. â€“ SG 65/06, in force from 11.08. 2006) medical devices for taking, diagnostics, processing and conservation of blood and blood components.

Art. 27. (1) (amend., - SG 98/10, in force from 01.01.2011) The medical institutions for hospital aid and the comprehensive cancer centres available on the territory of a region, in which there is an established centre for transfusion haematology, shall be supplied with diagnosed and processed blood and blood components by that centre.

(2) (amend., - SG 98/10, in force from 01.01.2011) The medical institutions for hospital aid and the comprehensive cancer centres available on the territory of a region, in which there is no established centre for transfusion haematology but there is a regional multi-profile hospital for active treatment with a transfusion haematology ward, shall be supplied with diagnosed and processed blood and blood components from such hospital.

(3) (amend., - SG 98/10, in force from 01.01.2011) The medical institutions for hospital aid and the comprehensive cancer centres available on the territory of a region, in which there is no established centre for transfusion haematology and no regional multi-profile hospital for active treatment with a transfusion haematology ward shall be supplied with diagnosed and processed blood and blood components from the centres for transfusion haematology or from the nearest regional multi-profile hospital for active treatment with a transfusion haematology ward .

(4) The centres for transfusion haematology shall provide with diagnosed and processed blood and blood components the situated in their district of service regional hospitals under para 2.

(5) The regional hospitals under para 2 shall safe-keep the provided to them blood and blood components for their own needs and for the needs of the medical institutions supplied by them.

(6) In case of temporary shortage of blood and blood components, the centres for transfusion haematology shall supply the medical institutions with blood and blood components according to clinical criteria.

Art. 28. (1) The centres for transfusion haematology shall provide specialised transportation of blood and blood components to the regional hospitals under Art. 27, para 2 situated in their district of service.

(2) The transportation of blood and blood components from the centres for transfusion haematology or from the regional hospitals to the medical institutions using blood and blood components shall be provided for by the medical institutions.

(3) In case of lack of blood or blood components for a patient in a state of emergency, the transportation shall be provided for by a centre for emergency medical care.

(4) In the cases under para 3, blood and blood components shall be delivered from the nearest medical institution where they are available.

Chapter four.
BLOOD AND BLOOD COMPONENTS TRANSFUSION

Art. 29. Transfusion of blood or blood components shall be assigned by a certified physician, who shall determine and enter into the medical documentation the type, the quantity and the method of applying them.

Art. 30. The transfusion of blood and blood components shall be carried out under the control of a certified physician.

Art. 31. (1) Transfusion of blood or blood components shall be carried out in compliance with the patientâ€™s rights and after receiving his or her informed

consent in writing, for which purpose the patient shall be given information in accessible language about:

1. the reasons for transfusion of blood or blood components;

2. the purpose of the transfusion and the expected result;

3. the possible unwanted reactions and the potential risks in connection with the transfusion of blood or blood components;

4. the existing alternatives and the risks arising therefrom.

(2) Where the patient is legally incapable, the informed consent under para 1 shall be given by his or her legal representative or custodian.

Art. 32. (1) Transfusion of blood or blood components without receiving informed consent may be carried out when the patientâ€™s life is endangered and:

1. his or her physical or mental state do not allow for receiving an informed consent;

2. the patient is legally incapable and receiving in due time consent from his or her legal representative or custodian is impossible.

(2) the decision and the reasons under para 1 shall be reflected in the patientâ€™s medical documentation by the physician having assigned the transfusion.

Art. 33. (1) The patient, respectively his or her legal representative or custodian, may refuse transfusion of blood or blood components at any time of the treatment.

(2) The refusal under para 1 shall be certified by signatures of the person and the attending physician, and of a witness, if the person refuses to sign.

Art. 34a. (new, SG 70/04) (1) (amend. â€“ SG 59/10, in force from 31.07.2010) All medical establishments for hospital care and centres for transfusion haematology may take blood for autohaemotransfusion in observance of the requirements of art. 12, para 2 where there are no medical counter indications and upon obtaining a written informed consent.

(2) When the person is underage written informed consent shall be taken from the legal representative or guardian of the underage.

Art. 34a. (new, SG 70/04) (1) All medical establishments for hospital care and dispensaries with beds may take blood for autohaemotransfusion in observance of the requirements of art. 12, para 2 where there are no medical counter indications and upon obtaining a written informed consent.

(2) When the person is underage written informed consent shall be taken from the legal representative or guardian of the underage.

Art. 35. Prohibited shall be the circulation of data allowing for the identification of the recipient.

Chapter five.
TRANSFUSION CONTROL

Art. 36. (1) (amend. â€“ SG 60/11) The National Centre for Transfusion Haematology shall establish a register, which shall include information about:

2. the results of the carried out laboratory examinations;

3. every unit of taken blood and blood components;

4. the activities of taking, diagnostics, processing, labelling, documenting, distribution, conservation and use of blood and blood components;

5. the destruction of every unit of blood and the reasons therefor.

(2) The information under para 1 shall also be entered into the register in the cases where the blood and the blood components have been entered into in accordance with the procedure under Art. 8, para 1

(3) (amend. â€“ SG 60/11) The medical institutions and the persons carrying out activities of taking, diagnostics, processing, labelling, documenting, distribution, conservation and use of blood and blood components shall be obliged to reflect in the register the information under para 1. In the cases of Art. 8, para 1, the information shall be reflected in the register by the National Centre for Transfusion Haematology .

(4) (amend. â€“ SG 60/11) The centres for transfusion haematology shall process and analyse the information and shall submit summarised data to the National Centre for Transfusion Haematology.

(5) The information under para 1 shall constitute official secret and shall be kept for a period of 30 years.

Art. 37. The terms and procedure for drafting, processing, keeping and submission of the information from the register, the forms and the documentation regarding donation, taking, diagnostics, processing, distribution, use and destruction of blood and blood components and for announcing the serious unwanted reactions and serious incidents, shall be determined by a regulation of the Minister of Health.

Art. 38. (amend. â€“ SG 65/06, in force from 11.08. 2006) (1) The Executive director of the Bulgarian Drug Agency shall function as a competent body with regards to the activity of the medical institutions for taking, diagnosing, processing, preserving, using, distributing, ensuring quality and safety of the blood and blood components and with regards to the transfusion supervision, for observing the requirements of the law, the standard under Art. 1, para 4 and the rules for Good laboratory and Good production practice.

(2) The Executive director of the Bulgarian Drug Agency shall exercise the immediate control through officials authorised by him/her.

Art. 39. (1) (amend. â€“ SG 65/06, in force from 11.08. 2006) In execution of his or her control powers, the Executive director of the Bulgarian Drug Agency shall organise the performance of inspections in the medical institutions.

(2) (amend. â€“ SG 65/06, in force from 11.08. 2006) The inspections shall be conducted at least once a year. The inspections may be conducted in any case of serious accident or serious unwanted reaction or in case of doubt of serious incident or serious unwanted reactions.

(3) (amend. â€“ SG 65/06, in force from 11.08. 2006) The persons under Art. 38, para 2 shall be entitled to free access to the inspected medical institutions, right of access to the documentation related to the subject of the inspection, and right to take samples.

(4) (New â€“ SG 65/06, in force from 11.08. 2006) The Bulgarian Drug Agency shall provide the Ministry of Health with information about the inspections carried out and the results thereof in every 6 months.

(5) (New â€“ SG 65/06, in force from 11.08. 2006; amend., - SG 98/10, in force from 01.01.2011) The directors of the regional health inspectorates shall provide the Bulgarian Drug Agency with information on the penal decrees, issued by them for offences under Art. 50, 51 and 53 in every three months.

(6) (Prev. Text of para 4, amend. â€“ SG 65/06, in force from 11.08. 2006) The terms and procedure for carrying out the inspections shall be determined by a regulation of the Minister of Health.

Art. 40. (1) (amend. â€“ SG 65/06, in force from 11.08. 2006) With the Ministry of Health shall be established a register of the medical institutions carrying out activities of taking, diagnostics, processing, conservation and distribution of blood and blood components.

(2) (amend. â€“ SG 65/06, in force from 11.08. 2006) The register under para 1 shall include data about:

1. the medical institution and its managing bodies;

2. the inspections under Art. 39 carried out with regard to the medical institution.

(3) (New â€“ SG 65/06, in force from 11.08. 2006) The Bulgarian Drug Agency shall create and maintain a register of the serious incidents and the serious unwanted reactions, related to taking and using blood and blood components.

(4) (prev. text of para 3 â€“ SG 65/06, in force from 11.08. 2006) The terms and procedure for establishing and keeping the registers shall be determined by a regulation of the Minister of Health.

(5) (prev. text of para 4, suppl. â€“ SG 65/06, in force from 11.08. 2006) The information under para 1 and 3 shall constitute official secret and shall be kept safe for a period of 30 years.

Art. 41. (1) (amend., - SG 98/10, in force from 01.01.2011) Commissions for control on the quality, safety and rational use of blood and blood components shall established to the medical institutions for hospital care and the comprehensive cancer centres.

(2) The commission shall be a consultative body to the manager of the medical institution, which shall:

1. oversee the prescription, safe-keeping and rational use of blood and blood components and the compliance with the standard under Art. 1, para 4.:

2. analyse the serious unwanted reactions, incidents and faults;

3. give proposals for improvement of the work with blood and blood components.

(3) The composition of the commission shall be determined by an order of the manager of the medical institution.

Art. 42. (1) (amend. and suppl. â€“ SG 65/06, in force from 11.08. 2006) Persons engaged in taking, diagnostics, processing, transfusion and conservation of blood or blood components, shall immediately inform the Bulgarian Drug Agency of arising serious incidents or unwanted reactions or of doubts of serious incidents or serious unwanted reactions.

(2) (amend. â€“ SG 65/06, in force from 11.08. 2006) The Executive director of the Bulgarian Drug Agency, through authorised persons shall analyse and summarise the information about the serious incidents and the serious unwanted reactions and shall take measures for preventing them.

Art. 43. (1) (suppl. â€“ SG 41/09, in force from 02.06.2009, amend. - SG 54/20, in force from 16.06.2020) Blood and blood components, which do not meet the standard under Art. 1, para 4, shall be withdrawn from use, destroyed or given for training or scientific and research needs with the permission of the Minister of Health or of an authorized by him/her Deputy Minister, subject to terms and conditions determined by an ordinance.

(2) (New - SG 54/20, in force from 16.06.2020) Blood and blood components that do not meet the standard under Art. 1, para. 4, are those in which it is established or there is a suspicion of:

1. damaged packaging integrity;

2. improper storage or transportation;

3. broken integrity of the label and / or lack or illegibility of the necessary data on it;

4. presence of coagulum, hemolysis or unusual color

5. expired date;

6. transfusion of a blood component through which a transmissible infection has been transmitted, which can also be transmitted with the current blood component obtained from the same unit of blood;

7. the possibility of transmitting a disease or intoxication to the recipient because the donor was a carrier of a viral or bacterial transmission infection, suffering from a malignant disease or one of unknown origin or has been exposed to toxic substances;

8. non-compliance of the volume of the unit of blood or blood components with the ones specified in the medical standard in transfusion hematology;

9. incomplete or incorrectly completed accompanying documentation;

10. positive markers for transmissible infections;

11. discrepancy between the tentative and definitive blood group, except when a new blood sample can be taken to identify the donor;

12. discrepancy between the blood group indicated on the label and the content of the unit of blood or erythrocyte concentrate;

13. positive direct antiglobulin test;

14. non-compliance with the requirements for quality and safety, established by conducted laboratory tests;

15. other non-compliances with quality and safety requirements.

(3) (New - SG 54/20, in force from 16.06.2020) For obtaining a permit for withdrawal from use, destruction or provision for educational or scientific-medical needs of blood or blood components that do not meet the standard under Art. 1, para. 4, the heads of the medical establishments shall submit an application to the Minister of Health.

(4) (New - SG 54/20, in force from 16.06.2020) The Minister of Health or a Deputy Minister authorized by him shall issue a written permit for withdrawal from use, destruction or provision for educational or scientific-medical needs of blood or blood components or shall make a motivated refusal within three days of receiving the application under para. 3.

(5) (New - SG 54/20, in force from 16.06.2020) Within the term under par. 4, the Minister of Health or a Deputy Minister authorized by him may request additional information from the head of the medical establishment.

(6) (New - SG 54/20, in force from 16.06.2020) The application under para. 3 may also be submitted electronically, signed with an advanced electronic signature, an advanced electronic signature based on a qualified electronic signature certificate, or a qualified electronic signature in accordance with the requirements of Regulation (EU) No 910/2014 of the European Parliament and of the Council of 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC (ĐžĐ', L 257/73 of 28 August 2014) and of Electronic Document and Electronic Trust Services Act and Electronic Government Act.

(7) (Prev. para. 2 - SG 54/20, in force from 16.06.2020) The medical institutions shall provide the Ministry of Health with information about every unit of destroyed blood or blood components by announcing their identification data and the reasons for destruction.

(8) (amend. â€“ SG 60/11, prev. para. 3 - SG 54/20, in force from 16.06.2020) Information about every unit of destroyed blood or blood components shall also be provided to the Director of the National Centre for Transfusion Haematology to be entered into the register.

Art. 43a. (New â€“ SG 65/06, in force from the date of entry into effect of the Treaty concerning the Accession of the Republic of Bulgaria to the European Union) (1) (amend. â€“ SG 60/11) On the ground of annual reports by the director of the National Centre for Transfusion Haematology, the Minister of Health shall compile a report on the measures undertaken for stimulation of the voluntary and gratuitous blood donation.

(2) The Executive director of the Bulgarian Drug Agency shall draw up a report on the activity of the agency as a competent body under this Act, including an account on the undertaken measures, concerning inspection and control.

(3) A copy of the report under para 1 shall be sent to the European commission once in three years, and of the report under para 2 â€“ once in two years.

Chapter six.
COMPULSORY ADMINISTRATIVE MEASURES. ADMINSITRATIVE AN PUNITIVE PROVISIONS

Art. 44. (1) (suppl. â€“ SG 65/06, in force from 11.08. 2006, suppl. - SG 77/18, in force from 01.01.2019) Upon proposal by the Executive director of the Bulgarian Drug Agency, the Minister of Health or an official appointed from the staff of the ministry may prohibit the carrying out of activities in connection with taking and conservation of blood and blood components and transfusion surveillance in case of violation of the standard of transfusion haematology.

(2) (amend. â€“ SG 65/06, in force from 11.08. 2006, suppl. - SG 77/18, in force from 01.01.2019) The Minister of Health or an official appointed from the staff of the ministry shall prohibit the activities under para 1 by a reasoned order stating the date of delisting the activities in the permission under Art. 48 of the Medical Establishments Act.

(3) (amend. - SG 30/06, in force from 12.07.2006) The order under par 2 shall be subject to appeal by order of the Administrative procedure code.

(4) The appeal against the order shall not suspend its implementation.

Art. 45. Whoever, in violation of Chapter Two or Four, commits taking or transfusion of blood or blood components, if he or she is not subject to heavier punishment, shall be punished with a fine amounting to 2,000 levs, and in case of a second violation â€“ with a fine of 5,000 levs.

Art. 46. Whoever, in violation of the provisions under this Act, performs a transaction, including for import or export of blood or blood components, where it is not subject to heavier punishment, shall be punished with a fine of 1,000 levs, and in case of a second violation â€“ with a fine of 10,000 levs.

Art. 47. (1) Whoever advertises blood or blood components in violation of this Act, shall be punished with a fine from 1,000 to 10,000 levs.

(2) The punishments under para 1 shall also be imposed on the persons having allowed the broadcasting or the publication of advertisement in the mass media.

Art. 48. A medical institution, which happens to violate the requirements of Art. 19 shall be subject to a pecuniary sanction amounting to 1,000 levs, and in case of a second violation â€“ to a pecuniary sanction amounting to 5,000 levs.

Art. 49. (1) In case of failure to fulfil an obligation under Art. 14, para 2 or Art. 36, para 3, the respective person shall be punished with a fine of 300 levs, and in case of a second violation â€“ with a fine of 700 levs.

(2) In case of failure to fulfil the obligation under Art. 36, para 3, the medical institutions shall be imposed a fine amounting to 1,000 levs, and in case of a second violation â€“ a fine amounting to 5,000 levs.

Art. 50. Whoever fails to supply the information under Art. 14, para 4, shall be punished with a fine of 50 levs, and in case of a second violation â€“ with a fine of 100 levs.

Art. 51. The managers of the medical institutions, who fail to comply with the provision of Art. 17, shall be punished with a fine of 500 levs, and in case of a second violation â€“ with a fine of 2,000 levs.

Art. 52. Whoever violates the provisions of Arts. 23 or 35, shall be punished with a fine of 1,000 levs for each identified person.

Art. 53. (1) A director of a centre for emergency medical care, who violates the provision of Art. 28, para 3, shall be punished with a fine of 300 levs.

(2) The managers of the medical institutions, who violate the provision of Art. 28, para 4, shall be punished with a fine of 500 levs.

Art. 54. (amend. â€“ SG 65/06, in force from 11.08. 2006) (1) A person, exercising medical profession, who allows violation of the standard under Art. 1, para 4, shall be punished with a fine of 1,500 levs.

(2) (suppl. - SG 77/18, in force from 01.01.2019) In case of repeated violation, upon proposal by the Executive director of the Bulgarian Drug Agency and following the procedure under Art. 193, para 1, item 1 of the Health Act, the Minister of Health or an official appointed from the staff of the ministry may deprive the person of his or her rights to practice medical profession.

Art. 55. (1) (amend. â€“ SG 65/06, in force from 11.08. 2006) Where the violations under Arts. 45 - 47 have been committed by juridical entities or sole traders, pecuniary sanctions shall be imposed. The amount of the pecuniary sanction shall be threefold the amount of the fines accordingly provided for.

(2) The imposition of a pecuniary sanction shall not preclude the imposition of a fine on the officials at fault.

Art. 56. (1) (amend. â€“ SG 65/06, in force from 11.08. 2006) The violations under this Act shall be established by acts executed by officials at the Bulgarian Drug Agency, appointed by the director of the agency.

(2) (amend. â€“ SG 65/06, in force from 11.08. 2006) The writs of punishment shall be issued by the Executive director of the Bulgarian Drug Agency.

Art. 57. (1) (amend., - SG 98/10, in force from 01.01.2011) The violations under Arts. 50, 51 and 53 shall be established by acts executed by officials from the regional health inspectorates, appointed by the director.

(2) (amend., - SG 98/10, in force from 01.01.2011) The writs of punishment shall be issued by the director of the regional health inspectorates.

Art. 58. (1) (amend. â€“ SG 65/06, in force from 11.08. 2006) The violation under Art. 46 shall be established by an act executed by officials appointed by the Executive director of the Bulgarian Drug Agency.

(2) (amend. â€“ SG 65/06, in force from 11.08. 2006) The writ of punishment shall be issued by the Executive director of the Bulgarian Drug Agency.

(3) The violations under Art. 46 regarding the import or export of blood or blood components shall be established by an act executed by the customs authorities, while the writ of punishment shall be issued by the director of the Customs Agency or by officials appointed by him or her.

Art. 59. (1) (amend. and suppl. â€“ SG 65/06, in force from 11.08. 2006) The violation under Art. 54 shall be established by an act executed by officials appointed by the Executive director of the Bulgarian Drug Agency.

(2) The writ of punishment shall be issued by the Executive director of the Bulgarian Drug Agency.

Art. 60. The establishment of administrative violations, the rendering, the appeal against and the enforcement of the writs of punishment shall be effected by order of the Administrative Violations and Sanctions Act

Art. 61. The funds from fines and pecuniary sanctions for established violations under this Act shall go in as budget receipts to the Ministry of Health.

Additional provisions

§ 1. Within the meaning of this Act:

1. A "Donor" shall be a person, from who blood and blood components are taken for transfusion to another person for therapeutic purpose.

2. "Informed consent in writing" shall be consent given on oneâ€™s own free will, after acquaintance with certain information.

3. A "Serious incident" shall be any unwanted event having to do with the taking, diagnostics, processing, conservation and distribution of blood and blood components, which may cause death, a state dangerous for life, incapability or illness causing extension of the hospitalisation of a recipient.

4. "Blood" shall be human tissue, containing all blood components.

5. "Blood components" shall be the cellular elements (leucocytes, erythrocytes and thrombocytes) and plasma, which are extracted through the use of standard methods of processing blood, with the exception of the stem cells.

6. A "Serious unwanted reaction" shall be an unexpected reaction in a donor or a recipient, having to do with the taking or transfusion of blood or blood components, which has caused death, a state posing danger to life, incapability or illness causing an extension of the stay in hospital.

7. A "Recipient" shall be a person, to whom blood or blood components have been transfused for therapeutic purpose.

8. "Satellite blood test" shall be a quantity of 0,002 to 0,007 litres of blood taken from the person from whom a standard taking of blood has been effected.

9. "Standard taking of blood" shall be taking between 0,400 and 0,500 litres of blood.

10. "Transfusion haematology" shall be activity of health care based on the medical science of the same name for taking, diagnostics, processing and use of blood and blood components.

11. "Haemopoietic stem cells" shall be the cells, which all blood cells originate from.

12. A "Blood donor" shall be a donor, from whom blood or blood components are taken free of charge.

13. (new, SG 70/04) "Autohaemotransfusion" is a method whereby blood taken from a patient previously is transfused to him.

14. (New â€“ SG 65/06, in force from 11.08. 2006) "Doubt of serious incident or serious unwanted reaction" is a presence of suspicion of cause-consequence connection between the incident or the reaction and the taking and/or the use of blood and blood components.

15. (New â€“ SG 65/06, in force from 11.08. 2006) "Inspection" is activity of exercising objective control according to the approved standards in order to be assessed whether the requirements of this Act and the normative acts for its implementation have been met, and for founding possible problems.

16. (New â€“ SG 65/06, in force from 11.08. 2006) "Repeated violation" is the offence, committed in one year period from entry into force of the penal decree, with which a punishment for the same violation has been imposed on the violator.

Transitional and concluding provisions

§ 2. Within nine-month period from the entry into force of this Act, the existing multi-profile hospitals for active treatment with a transfusion haematology ward, the centres for transfusion haematology and the Military Academy of Medicine shall bring their activities in compliance with the bylaws applicable thereto.

§ 3. Following the bringing of their activities in compliance with the requirements of this Act and of the bylaws applicable thereto, within the term under § 2, the multi-profile hospitals for active treatment with a transfusion haematology ward shall file an application for amendment to the permission for medical activities under Art. 48 of the Medical Establishments Act.

§ 4. The following amendments and supplements shall be made to the Medical Establishments Act (Prom., SG, No. 62/1999; amend., No. 88 and 113/1999; revised, No. 114/1999; amend., No. 36, 65 and 108/2000, No. 51/2001 â€“ Decision No. 11 of the Constitutional Court of 2001; amend., No. 28 and 62/2003, No. 82/2003)

1. In Art. 19, item 4b shall be created:

"4b. Taking, conservation, supply of blood and blood components and transfusion surveillance;".

2. Art. 25 shall be amended as follows:

"Art. 25. (1) A centre for transfusion haematology shall be a medical institution, in which physicians with the assistance of other staff:

1. take blood and blood components;

2. diagnose, process, conserve and provide blood and blood components;

3. produce, conserve and provide blood bio-preparations;

4. perform activities of transfusion surveillance.

(2) The centres under para 1 shall carry out their activities in compliance with the requirements of this Act and of the Blood, Blood Donation and Blood Transfusion Act".

(3) The Minister of Health may make a proposal for the closing down of a centre for transfusion haematology, which is carrying out activities in contravention of para 2. "

3. In Art. 86, para 1, after the words "the centres for dialysis", the words "the centres for transfusion haematology" shall be added.

§ 5. The following supplements shall be made to the Act on Peopleâ€™s Health (Prom., SG, No. 88/1973; revised, No. 92/1973; amend. and suppl., No. 63/1976, No. 28/1983, No. 66/1983, No. 66/1985, No. 27/1986, No. 89/1988, Nos. 87 and 99/1989, No. 15/1991; revised, No. 24/1991; amend., No. 64/1993, No. 31/1994, No. 36/1995, Nos. 12, 87 and 124/1997, Nos. 21, 70, 71 and 93/1998, Nos. 30, 62, 67, 90 and 113/1999, Nos. 10 and 36/2000, No. 63/2002, No. 83/2003):

1. Art. 32a shall be created:

"Art. 32a. (1) All medical institutions for hospital care and dispensaries with beds may take blood for self-haemotransfusion in compliance with the requirements of Art. 12, para 2 of the Blood, Blood Donation and Blood Transfusion Ac, where there are no medical contraindications thereto and following the receipt of informed consent in writing.

(2) Where the person is under-age, informed consent in writing shall be taken from the young personâ€™s legal representative or custodian."

2. § 8a shall be created in the supplementary provisions:

"§ 8a. "Self-haemotransfusion" shall be a method by which a patient shall be transfused blood to, which has preliminarily been taken from him or her."

§ 6. Within one-month period from the entry into force of this Act, the Council of Ministers shall make amendments to the Rules on the Structure of the Bulgarian Drug Agency in accordance with this Act.

§ 7. Within three-month period from the entry into force of this Act, the Council of Ministers and the Minister of Health shall issue the bylaws for its application.

§ 8. This Act shall repeal the Blood, Blood Donation and Blood Transfusion Act (SG, No. 31/1994).

§ 9. The implementation of the Act shall be assigned to the Minister of Health. The Act was adopted by the 39th National Assembly on November 6, 2003 and was affixed with official seal of the National Assembly.

Transitional and concluding provisions TO THE ADMINISTRATIVE PROCEDURE CODE

(PROM. â€“ SG 30/06, IN FORCE FROM 12.07.2006)

§ 142. The code shall enter into force three months after its promulgation in State Gazette, with the exception of:

1. division three, § 2, item 1 and § 2, item 2 â€“ with regards to the repeal of chapter third, section II "Appeal by court order", § 9, item 1 and 2, § 15 and § 44, item 1 and 2, § 51, item 1, § 53, item 1, § 61, item 1, § 66, item 3, § 76, items 1 â€“ 3, § 78, § 79, § 83, item 1, § 84, item 1 and 2, § 89, items 1 - 4§ 101, item 1, § 102, item 1, § 107, § 117, items 1 and 2, § 125, § 128, items 1 and 2, § 132, item 2 and § 136, item 1, as well as § 34, § 35, item 2, § 43, item 2, § 62, item 1, § 66, items 2 and 4, § 97, item 2 and § 125, item 1 â€“ with regard to the replacement of the word "the regional" with the "administrative" and the replacement of the word "the Sofia City Court" with "the Administrative court - Sofia", which shall enter into force from the 1st of May 2007;

2. paragraph 120, which shall enter into force from the 1st of January 2007;

3. paragraph 3, which shall enter into force from the day of the promulgation of the code in State Gazette.

Concluding provisions TO THE ACT AMNEDING AND SUPPLEMENTING THE BLOOD, BLOOD DONATION AND BLOOD TRANSFUSION ACT

(PROM.â€“ SG 65/06, IN FORCE FROM 11.08. 2006)

§ 21. Within one term from the entry into force of the Act the Council of Ministers, upon proposal by the Minister of Health, shall accomplish the necessary amendments in the Structural regulations of the Bulgarian Drug Agency in conformity with this Act.

§ 22. In six months term from the entry into force of the Act the Council of Ministers and the Minister of Health shall accomplish the necessary amendments in the normative acts for the implementation of the law.

§ 23. The Act shall enter into force from the date of its promulgation in State Gazette, with the exception of § 13, which shall enter into force date of entry into effect of the Treaty concerning the Accession of the Republic of Bulgaria to the European Union.

Transitional and concluding provisions TO THE MEDICINAL PRODUCTS IN HUMAN MEDICINE ACT

(PROM. â€“ SG 31/07, IN FORCE FROM 13.04.2007)

§ 37. The Act shall enter in force from the day of its promulgation in State Gazette, except for § 22, which shall enter in force one year after entry into force of this Act.

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

(PROM. â€“ 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:

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.

Concluding provisions TO THE ACT AMNEDING AND SUPPLEMENTING THE VOCATIONAL EDUCATION AND TRAINING ACT

(PROM. â€“ SG 74/09, IN FORCE FROM 01.10.2009)

§ 48. The Act shall enter into force from the date of its promulgation in the State Gazette, except for § 1, which shall enter into force from the 15th of September 2009 and § 47, which shall enter into force from the 1st of October 2009.

Transitional and concluding provisions TO THE ACT AMNEDING AND SUPPLEMENTING THE MEDICAL ESTABLISHEMENTS ACT

(PROM. - SG 59/10, IN FORCE FROM 31.07.2010)

§ 77. This Act shall enter into force from the day of its promulgation in the State Gazette, except for:

1. paragraphs 9 (regarding Art. 19, Para 4), 53, 60 and 66 (regarding Art. 98. Para 5 and 6) which shall enter into force from 1 January 2011;
2. paragraph 75, which shall enter into force on 30 September 2011.

Transitional and concluding provisions TO THE ACT AMNEDING AND SUPPLEMENTING THE MEDICINAL PRPODUCTS IN HUMAN MEDICINE ACT

(PROM. â€“ SG 60/11, IN FORCE FROM 05.08.2011)

§ 83. In the Blood, Blood Donation and Blood Transfusion Act (prom. SG 102/2003; amend â€“ SG 70/2004; SG 30 and 65/2006; SG 31/2007; SG 41 and 74/2009 and SG 59/98/2010) words "National Centre for Transfusion Haematology and Transfusiology" shall be replaced respectively and everywhere by "National Centre for Transfusion Haematology".

§. 84. This Act shall enter into force from the date of its promulgation in the State Gazette, except for § 65, which shall enter in force from 30 September 2011.

Transitional and concluding provisions TO THE ACT AMNEDING AND SUPPLEMENTING THE CIVIL SERVANTS ACT

(PROM. - SG 38/12, IN FORCE FROM 01.07.2012)

§ 84. (In force from 18.05.2012) Within one month from the promulgation of this Act in the State Gazette:

1. the Council of Ministers shall make the Classification of Offices in the Administration compliant with this Act;
2. the competent authorities shall make the structural acts of the respective administration compliant with this Act.

§ 85. (1) The legal relationships with the persons of the administrations under the Radio and Television Act, the Independent Financial Audit Act, the Electronic Communications Act, the Financial Supervision Commission Act, the Act on Access and Disclosure of Documents and Announcing Affiliation of Bulgarian Nationals to the State Security and Intelligence Services of the Bulgarian People's Army, Confiscation by the State of Proceeds of Crime Act, the Act on Prevention and Findings of Conflict of Interests, the Code of Social Insurance, the Health Insurance Act, the Agricultural Producers Support Act and the Roads Act shall be settled under terms and conditions of § 36 of the Transitional and Concluding Provisions of the Act Amending and Supplementing the Civil Servants Act (SG 24/06).

(2) The act of appointment of the civil servant shall:

1. determine the lowest rank for the position specified in the Classification of Offices in the Administration, unless the officer holds a higher rank;

2. determine an individual basic monthly salary.

(3) The additional funds for insurance instalments for the persons referred to in Para 2 shall be made available within the limits for expenses for salaries, remunerations and insurance instalments in the budgets of the budget credit administrators.

(4) The Council of Ministers shall amend as required by this Act the non-budget account of State Fund â€œAgricultureâ€□.

(5) The governing bodies of the National Insurance Institute and the National Health Insurance Fund shall amend as required by this Act the respective budget credits.

(6) Any non-used days of leave under employment relations shall be preserved and shall not be subject to pecuniary compensation.

§ 86. (1) Within one month from entry into force of this Act the individual basic monthly salary of the officer shall be so calculated that the said salary, reduced by the due taxes and the mandatory insurance instalments due by the insured person, if available, shall not be lower than gross monthly salary received before, reduced by the mandatory insurance instalments due by the insured person, if available, and the due taxes.

(2) The gross salary referred to in Para 1 shall include:

1. the basic monthly salary or the basic monthly remuneration;

2. the additional remunerations paid on permanent basis together with the due basic monthly salary or the basic monthly remuneration and dependent only on the working time.

§ 87. This Act shall enter into force from 1 July 2012 except for § 84, which shall enter into force from the day of the promulgation of the Law in the State Gazette.

Transitional and concluding provisions TO THE ACT AMNEDING AND SUPPLEMENTING THE MEDICAL ESTABLISHMENTS ACT

(PROM. - SG 54/12)

§ 17. Within one month from entry into force of this Act the Minister of Health shall make the ordinance referred to in Art. 18, Para 1 of the Blood, Blood Donation and Blood Transfusion Act compliant with this Act.

§ 18. The National Health Map shall be made compliant with the requirements of this Act within 6 months from its entry into force.

Concluding provisions
TO THE ACT AMNEDING AND SUPPLEMENTING THE YOUTH ACT

(PROM. - SG 68/13, IN FORCE FROM 02.08.2013)

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

Transitional and concluding provisions
TO THE ACT AMENDING AND SUPPLEMENTING THE ADMINISTRATIVE PROCEDURE CODE

(PROM. - SG 77/18, IN FORCE FROM 01.01.2019)

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

1. paragraphs 4, 11, 14, 16, 20, 30, 31, 74 and § 105 item 1 on the first sentence, and item 2 which shall enter into force on 10 October 2019;

2. paragraphs 38 and 77, which shall enter into force two months after the promulgation of this Act in the State Gazette;

3. paragraph 79, items 1, 2, 3, 5, 6 and 7, § 150 and 153, which shall enter into force on the day of the promulgation of this Act in the State Gazette.

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

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

§ 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.

Transitional and concluding provisions TO THE ACT AMENDING AND SUPPLEMENTING THE MEDICAL ESTABLISHMENTS ACT

(PROM. - SG 54/20, IN FORCE FROM 16.06.2020)

§ 38. The Act shall enter into force on the day of its promulgation in the State Gazette, with the exception of § 23, which shall enter into force on January 1, 2021.