

Blood, Blood Donation, and Blood Transfusion Act

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Text in Bulgarian: Закон за кръвта, кръводаряването и кръвопреливането

Chapter One GENERAL PROVISIONS

Article 1. (1) This Act shall regulate the social relationships related to donation, collecting, 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-treatment facilities 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 Paragraph 1 above shall be carried out according to a medical standard of a transfusion technology approved by a Regulation of the Minister of Health.

Article 2. The provisions of this Act shall not apply to the transplantation of haemopoietic stem cells.

Article 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 donors' and recipients' 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.

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

Article 5. (Amended, SG No. 65/2006) (1) The multiprofile hospitals for active treatment, which have in their structure a ward of transfusion haematology shall supply an unit taken from their blood to the centres for transfusion haematology against payment for taking it.

(2) (Amended, SG No. 98/2010, effective 14.12.2010) The centres for transfusion haematology shall supply free of charge diagnosticated and processed blood and blood components to the medical-treatment facilities for inpatient treatment and to the comprehensive cancer centres within the limits of the approved quantities under Item 1 of Article 26.

(3) (Amended, SG No. 98/2010, effective 14.12.2010) Apart from the cases under Paragraph 2 above, the centres for transfusion haematology may also supply the medical treatment facilities for inpatient care and the comprehensive cancer centres with blood and blood components against payment for the costs for the diagnostics and processing thereof.

(4) The conditions and procedure of the payment under Paragraphs 1 and 2 above of and the 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 the order of the stimulation, organization and implementation of the activities, linked to the blood donation shall be determined by the regulation under Article 4.

(7) (Amended, SG No. 38/2012, effective 1.07.2012) The means under Articles 3 and 5 shall be transferred to the Ministry of Health and included into the budgets of the transfusion haematology centres.

Article 5a. (New, SG No. 65/2006) (1) The Military Medical Academy supplies the transfusion haematology centres undiagnosed blood and blood components, when the quantities, obtained during the blood donation are more than the quantities necessary to the satisfaction of the needs of the medical institution.

(2) In the cases under Paragraph 1 the Military Medical Academy supplies the transfusion haematology centres with blood and blood components without any payment in return.

(3) Over the determined quantities under Item 1 of Article 26 for the Military Medical Academy the transfusion haematology centres can supply the medical institution with blood

against payment for the diagnostics and the processing.

(4) The conditions and the order for the payment under Paragraph 3, as well as for the evaluation of the costs are determined with the regulation under Article 5, Paragraph 4.

(5) The Military Medical Academy supplies plasma to the pharmaceutical producers under prices, conditions and order such as stipulated in the regulation under Article 5, Paragraph 5.

Article 6. (1) The medical-treatment facilities under Article 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 immunoglobulin's;

3. for research and diagnostic purposes in medicine;

(2) The medical institutions under Article 15 may cover the direct costs of blood donors and encourage 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 Paragraph 1 above shall be made according to a procedure and at prices specified in the Regulation under Paragraph 4 of Article 5 above.

Article 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 country's needs.

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

Article 8. (1) (Supplemented, SG No. 41/2009, effective 2.06.2009) Blood and blood components shall only be imported in the territory of this country with the permission of the Minister of Health or a Deputy Minister authorized by the Minister in case of emergencies where the available quantities of blood and blood components in the country are not sufficient for the protection of people's health.

(2) The import under Paragraph 1 above shall be allowed in case the blood and blood components have been diagnosticated, 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 testing performed and about the methods of diagnostics and processing.

(3) The requirements, which the quality of blood and blood components under Paragraph 1 above should meet, shall be determined by the Regulation under Paragraph 2 of Article 20 of this Act.

(4) (Amended, SG No. 31/2007) Drugs made of plasma shall be imported by the procedures, set forth with the Medicinal Products in Human Medicine Act.

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

Chapter Two

DONATION, COLLECTING, DIAGNOSTICS, PROCESSING AND CONSERVATION OF BLOOD AND BLOOD COMPONENTS

Article 10. Donation is a humane and voluntary act by which free of charge blood and blood components are collected from the donor.

Article 11. (1) (Amended, SG No. 74/2009, effective 15.09.2009, SG No. 68/2013, effective 2.08.2013) The Minister of Health, the Minister of Education and Science, the Minister of Defence, the Bulgarian Red Cross and the medical-treatment facilities and health-care institutions shall organise and promote the donation of blood or blood components.

(2) Mass media, non-government organisations and religious institutions registered under the Religious Denominations Act may also take part in the promotion under Paragraph 1 above.

(3) The bodies of the central and local governments, the legal entities and natural persons shall be obliged to contribute to the carrying out of the promotion and to render assistance in the collecting of blood.

Article 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 collectings of blood shall not be less than 60 days.

(3) The circumstance under Paragraph 2 shall be established by checking the Register under Article 36 of this Act.

Article 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 Paragraph 1 above, the donor shall be given information in an understandable language about the procedure of collecting 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.

Article 14. (1) Blood or blood components shall be taken following a medical examination performed by a physician or under the control of a physician.

(2) The person collecting blood or blood components shall label them and shall prepare and label 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 collected unit of blood or blood components;

(3) The original documents under Paragraph 2 above shall be stored at the medical-treatment or healthcare facility, which has performed the collecting for a period of 15 years

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

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

1. the centres for transfusion haematology;
2. the multiprofile hospitals for active treatment, in whose structure a ward for transfusion haematology is established;
3. the Military Academy of Medicine.

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

(2) The card under Paragraph 1 above shall stated the unique identification number, the full name, UCN1, the permanent address, the blood group, the date and the quantity of the collected blood or blood components.

Article 17. The medical-treatment facilities under Article 15 above shall ensure the conditions for protection of the donors' health.

Article 18. (Amended, SG No. 65/2006)

(1) (Amended, SG No. 54/2012) The National Centre for Transfusion Haematology shall supply the medical devices for collecting, diagnosing, processing and storing blood and blood components needed by the medical treatment facilities under items 1 and 2 of Article 15 above,

and provide them thereto for free, subject to conditions and in accordance with a procedure provided for in a regulation by the Minister of Health.

(2) (New, SG No. 54/2012) The funds needed for the activities referred to in Paragraph 1 shall be provided to the National Centre for Transfusion Haematology in a targeted way through the budget of the Ministry of Health.

(3) (Renumbered from Paragraph 2, amended, SG No. 54/2012) Medical products for the activities related to collecting , diagnostic, processing and conservation of blood and blood components, undertaken by the Military Medical Academy, are paid for by the Ministry of Defense.

Article 19. The medical-treatment facilities under items 2 and 3 of Article 15 above shall submit the collected blood and blood components, together with the satellite blood samples, a copy of the documentation under Paragraph 2 of Article 14 above, and a protocol for delivery to the centre for transfusion haematology.

Article 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 Manufacturing 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, SG No. 65/2006) The Military Medical Academy diagnoses, processes and conserves blood and blood components only for its needs in the frame of the determined quantities under Item 1 Article 26.

Article 21. The multiprofile hospitals for active treatment with a ward of transfusion haematology, the centres for transfusion haematology and the Military Medical Academy shall be subject to accreditation by the procedures under the Medical-Treatment Facilities Act for the activities carried out by them in connection with the collecting, diagnostics, processing, conservation and distribution of blood and blood components.

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

(2) (Amended, SG No. 60/2011, effective 5.08.2011) 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.

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

Chapter Three

PLANNING AND PROVISION OF BLOOD AND BLOOD

COMPONENTS

Article 24. (1) Every year the Directors of the Centres 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 plasma for production of drugs;
4. (supplemented, SG No. 65/2006) the medical devices and supplies necessary for collecting, diagnostic, 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 collections of blood.

(2) The analysis shall be based on:

1. information received from the medical institutions using blood and blood components;
2. the capacity of the centre for providing blood and blood components.

Article 24a. (New, SG No. 65/2006) (1) The director of the Military Medical Academy analyzes and determines on a annual basis the needs of the medical facility

1. the quantities of blood and blood components necessary to satisfy the planned and urgent needs as well as dispatching them in the structures
2. the quantity of plasma necessary for the production of medicines;
3. the expected number of blood donations and the schedules for their organization
4. the expected number of paid blood takes.

(2) The analysis is based on the information received from the structures of the Military Medical Academy using blood and blood components.

Article 25. (Supplemented, SG No. 65/2006, amended, SG No. 98/2010, effective 1.01.2011, SG No. 60/2011, effective 5.08.2011) The results from the performed analysis and planning under Article 24 and 24a above shall be submitted to the Director of the National Centre for Transfusion Haematology and to the directors of the regional health inspections.

Article 26. (Amended, SG No. 60/2011, effective 5.08.2011) Every year the Director of the

National Centre 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. the quantity of plasma for production of drugs;
3. (supplemented, SG No. 65/2006) medical devices and supplies for collecting diagnostic, processing and conservation of blood and blood components.

Article 27. (1) (Amended, SG No. 98/2010, effective 14.12.2010) The medical-treatment facilities for hospital care and the comprehensive cancer centres within on the territory of a given region, in which there is an established centre for transfusion haematology, shall be supplied with diagnosticated and processed blood and blood components by that centre.

(2) (Amended, SG No. 98/2010, effective 14.12.2010) The medical-treatment facilities for hospital care and the comprehensive cancer centres within the territory of a given region, where no established centre for transfusion haematology is found, but which have a regional multiprofile hospital for active treatment with a ward for transfusion haematology, shall be supplied with diagnosticated and processed blood and blood components from the said hospital.

(3) (Amended, SG No. 98/2010, effective 14.12.2010) The medical-treatment facilities for hospital care and the comprehensive cancer centres available on the territory of a region, where no established centre for transfusion haematology and no regional multiprofile hospital for active treatment with a ward for transfusion haematology are found, shall be supplied with diagnosticated and processed blood and blood components from the centres for transfusion haematology or from the nearest regional multiprofile hospital for active treatment with a ward for transfusion haematology.

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

(5) The regional hospitals under Paragraph 2 above shall safe keep the blood and blood components provided thereto for their own needs and for the needs of the medical-treatment facilities they are responsible for the supply of.

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

Article 28. (1) The centres for transfusion haematology shall provide specialised transportation of blood and blood components to the regional hospitals under Paragraph 2 of Article. 27 above, 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-treatment facilities using blood and

blood components shall be provided for by the respective medical-treatment facility.

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

(4) In the cases under Paragraph 3 above, blood and blood components shall be delivered from the nearest medical treatment facility where they are available.

Chapter Four

BLOOD AND BLOOD COMPONENTS TRANSFUSION

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

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

Article 31. (1) Transfusion of blood or blood components shall be carried out in compliance with the patient's rights and after receiving his or her informed consent in writing, for which purpose the patient shall be given information in an understandable 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 associated 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 Paragraph 1 above shall be given by his or her legal representative or custodian.

Article 32. (1) Transfusion of blood or blood components without receiving informed consent may be carried out when the patient'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 the consent from his or her legal representative or custodian in due time is impossible.

(2) the decision and the reasons under Paragraph 1 above shall be recorded in the patient's medical documentation by the physician having administered the transfusion.

Article 33. (1) The patient, respectively his or her legal representative or custodian, may

refuse to have the transfusion of blood or blood components at any time of treatment.

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

Article 34. Prohibited shall be the transfusion of:

1. non-diagnosticated blood and blood components, unless in case of self haemo-transfusion;
2. blood and blood components with expired date.

Article 34a. (New, SG No. 70/2004 - effective of 1.01.2005) (1) (Amended, SG No. 59/2010, effective 31.07.2010) All medical treatment facilities for inpatient care and centres for transfusion haematology may collect blood for the purpose of autohaemotransfusuion in compliance with the requirements under Paragraph 2 of Article 12 of this Act, provided that no medical contraindications exist, and having received an informed consent in writing.

(2) In the event of minors, or underaged persons, the informed consent in writing shall be sought from the legal representative or from the custodian of the said minor or underaged.

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

Chapter Five

TRANSFUSION CONTROL

Article 36. (1) (Amended, SG No. 60/2011, effective 5.08.2011) The National Centre for Transfusion Haematology shall establish a register, which shall include information about:

1. the donors and the recipients;
2. the results of the carried out laboratory testing;
3. every unit of blood and blood components collected;
4. the activities of collecting, diagnostics, processing, labelling, documenting, distribution, conservation and use of blood and blood components;
5. the destruction of every unit of blood and the reasons therefore.

(2) The information under the preceding Paragraph 1 shall also be recorded into the register in the cases where the blood and the blood components have been imported in accordance with the procedure under Paragraph 1 of Article 8 of this Act.

(3) (Amended, SG No. 60/2011, effective 5.08.2011) The medical-treatment facilities and the persons carrying out the activities of collecting, diagnostics, processing, labelling,

documenting, distribution, conservation and use of blood and blood components shall be obliged to record in the register the information under the above Paragraph 1. In the cases under Paragraph 1 of Article 8 of this Act, the information shall be recorded in the register by the National Centre for Transfusion Haematology.

(4) (Amended, SG No. 60/2011, effective 5.08.2011) The centres for transfusion haematology shall process and analyse the information and shall submit summarized data to the National Centre for Transfusion Haematology.

(5) The information under Paragraph 1 above shall be regarded as an official secret and shall be stored for a period of 30 years.

Article 37. The terms and procedure for drafting, processing, keeping and submission of the information from the register, the forms and the documentation regarding donation, collection, 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.

Article 38. (Amended, SG No. 65/2006) (1) The executive director of the Bulgarian Drug Agency shall function as a competent body with regard to the activity of the medical-treatment facilities concerning the collection, diagnostics, processing, conservation, use distribution and guarantee for quality and safety of the blood and blood components as well as for the transfusion supervising, respecting the law and the standards under Article 1 Paragraph 4 and the rules for Good laboratory and production practice.

(2) The executive director of the Bulgarian Drug Agency shall exercise direct control through officials designed by him:

Article 39. (1) (Amended, SG No. 65/2006) In execution of his or her control powers, the the executive director of the Executive agency for medicines shall organise on site inspections in the medical-treatment facilities.

(2) (Amended, SG No. 65/2006) The inspections shall take place at least once a year. Inspections shall be conducted in each case of a serious incident or unwanted event or in doubt of a serious incidents or serious unwanted events.

(3) (Amended, SG No. 65/2006) The persons under Paragraph 2 of Article 38 of this Act shall be entitled to free access to the medical-treatment facility under inspection, as well as to the right of access to the documentation related to the subject of the inspection, and to the right to take specimens.

(4) (New, SG No. 65/2006) The Bulgarian Drug Agency provides to the Ministry of health information concerning the conducted inspections and their results on a six-month basis.

(5) (New, SG No. 65/2006, amended, SG No. 98/2010, effective 1.01.2011) The directors of the regional health inspections provide on a three-month basis to the Bulgarian Drug Agency information concerning the decisions they took against the violations under Articles 50, 51 and

53.

(6) (Renumbered from Paragraph 4, amended, SG No. 65/2006) The terms and procedure for carrying out the inspections shall be determined by a Regulation of the Minister of Health.

Article 40. (1) (Amended, SG No. 65/2006) With the Ministry of Health shall be established a register of the medical-treatment institutions implementing activities of collecting, diagnostics, processing, conservation and distribution of blood and blood components;

(2) (Amended, SG No. 65/2006) The register under Paragraph 1 above shall include data about:

1. the medical-treatment facility and the managing bodies thereof;
2. the inspections under Article 39 carried out with regard to the medical-treatment facility.

(3) (New, SG No. 65/2006) The Bulgarian Drug Agency creates and holds a register of the serious incidents and serious unwanted events, linked to the collection and use of blood and blood components.

(4) (Renumbered from Paragraph 3, SG No. 65/2006) The terms and procedure for establishing and keeping the registers shall be determined by a Regulation of the Minister of Health.

(5) (Renumbered from Paragraph 4, supplemented, SG No. 65/2006) The information under Paragraph 1 above shall constitute official secret and shall be stored for a period of 30 years.

Article 41. (1) (Amended, SG No. 98/2010, effective 14.12.2010) Committees on control on the quality, safety and rational use of blood and blood components shall be established at the medical-treatment facilities for hospital care and at the comprehensive cancer centres.

(2) The Committees shall be a consultative body to the manager of the medical-treatment facility, which shall:

1. oversee the administration, storage and rational use of blood and blood components and the compliance with the standard under Paragraph 4 of Article 1 of this Act.

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

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

(3) The composition of the committee shall be determined by an order of the manager of the medical-treatment facility.

Article 42. (1) (Amended and supplemented, SG No. 65/2006) Persons engaged in collecting, diagnostics, processing, transfusion and conservation of blood or blood components, shall immediately inform the Bulgarian Drug Agency of all serious incidents or unwanted

reactions or suspicion for serious incidents or unwanted reactions, taken place.

(2) (Amended, SG No. 65/2006) The executive director of the Bulgarian Drug Agency through authorised persons shall analyze and summarize the information about the serious incidents and the serious unwanted reactions and shall take measures for preventing them.

Article 43. (1) (Supplemented, SG No. 41/2009, effective 2.06.2009) Blood and blood components, which do not meet the standard under Paragraph 4 of Article 1 of this Act shall be withdrawn from use, and destroyed or given for training or scientific and research needs with the permission of the Minister of Health or a Deputy Minister authorized by the Minister, subject to the terms and conditions determined by a regulation.

(2) The medical-treatment facilities shall provide the Ministry of Health with information about every destroyed unit of blood or blood components by announcing their identification data and the reasons for destruction.

(3) (Amended, SG No. 60/2011, effective 5.08.2011) Information about every destroyed unit of blood or blood components shall also be provided to the Director of the National Centre for Transfusion Haematology to be recorded into the register.

Article 43a. (New, SG No. 65/2006, effective 1.01.2007) (1) (Amended, SG No. 60/2011, effective 5.08.2011) The Minister of health according the annual reports of the director of the National Centre for Transfusion Haematology prepares a report on the undertaken measures for the encouragement of the voluntary and free blood donation.

(2) The executive director of the Bulgarian Drug Agency prepares a report concerning the activity of the agency as a competent institution under this Act, including a report on the taken measures linked to the inspection and the control.

(3) A copy of the report under Paragraph 1 will be sent to the European Commission once every three years and a copy of the report under Paragraph 2 - once every two years.

Chapter Six

COMPULSORY ADMINISTRATIVE MEASURES. ADMINISTRATIVE AND PUNITIVE PROVISIONS

Article 44. (1) (Supplemented, SG No. 65/2006) The Minister of Health upon proposal by the executive director of the Bulgarian Drug Agency may prohibit the practicing of activities related to the collection and conservation of blood and blood components and transfusion surveillance in case of violation of the standard of transfusion haematology.

(2) (Amended, SG No. 65/2006) The Minister of Health shall prohibit the practicing of the activities under paragraph 1 by a substantiated order stating the date of delisting of the said activities in the permit under Article 48 of the Medical Treatment Facilities Act.

(3) (Amended, SG No. 30/2006) The order under Paragraph 2 above shall be subject to appeal under the procedure, provided by the Administrative Procedure Code.

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

Article 45. Whoever, in violation of Chapter Two or Four of this Act, commits collection 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 BGN 2,000, and in case of a second violation - with a fine of BGN 5,000.

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

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

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

Article 48. A medical-treatment facility, which happens to violate the requirements of Article 19 of this Act shall be subject to a pecuniary sanction amounting to BGN 1,000, and in case of a second violation - to a pecuniary sanction amounting to BGN 5,000.

Article 49. (1) In case of failure to fulfil an obligation under Paragraph 2 of Article 14, or under Paragraph 3 of Article 36 the person responsible shall be punished with a fine of BGN 300, and in case of a second violation - with a fine of BGN 700.

(2) In case of failure to fulfil the obligation under Paragraph 3 of Article 36 of this Act the medical-treatment facility shall be imposed a fine amounting to BGN 1,000, and in case of a second violation - a fine amounting to BGN 5,000.

Article 50. Whoever fails to supply the information under Paragraph 4 of Article 14 of this Act, shall be punished with a fine of BGN 50, and in case of a second violation - with a fine of BGN 100.

Article 51. The managers of the medical-treatment facilities, who fail to comply with the provision of Article 17 of this Act, shall be punished with a fine of BGN 500, and in case of a second violation - with a fine of BGN 2,000.

Article 52. Whoever violates the provisions of Articles 23 or 35 of this Act, shall be punished with a fine of BGN 1,000 for each identified person.

Article 53. (1) A director of a centre for emergency medical care, who violates the provision of Paragraph 3 under Article 28 of this Act, shall be punished with a fine of BGN 300.

(2) The managers of the medical-treatment facilities, who violate the provision under Paragraph 4 of Article 28, of this Act, shall be punished with a fine of BGN 500.

Article 54. (Amended, SG No. 65/2006) (1) A person practicing the medical profession , who allows violation of the standard under Paragraph 4 of Article 1 of this Act, shall be punished with a fine of BGN 1,500, and he or she shall be deprived of his or her rights to practice as a physician for a period of one year.

(2) In case of a second violation, the minister of health upon proposal by the executive director of the Bulgarian Drug Agency may deprive that person of the right to practice the medical profession per article 193 (1) item 1 of the Health Act .

Article 55. (1) (Amended, SG No. 65/2006) Where the violations under Articles 45 and 47 of this Act 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.

Article 56. (1) (Amended, SG No. 65/2006) The violations under this Act shall be established by acts executed by officials with the Bulgarian Drug Agency, appointed by the director of the said agency.

(2) (Amended, SG No. 65/2006) The writs of punishment shall be issued by the executive director of the Bulgarian Drug Agency.

Article 57. (1) (Amended, SG No. 98/2010, effective 1.01.2011) The violations under Articles. 50, 51 and 53 of this Act shall be established by acts executed by officials from the regional health inspection, appointed by the director.

(2) (Amended, SG No. 98/2010, effective 1.01.2011) The writs of punishment shall be issued by the director of the regional health inspection.

Article 58. (1) (Amended, SG No. 65/2006) The violation under Article. 46 of this Act shall be established by an act executed by officials appointed by the executive director of the Bulgarian Drug Agency.

(2) (Amended, SG No. 65/2006) The writ of punishment shall be issued by the executive director of the Bulgarian Drug Agency.

(3) The violations under Article 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.

Article 59. (1) (Amended and supplemented, SG No. 65/2006) The violation under Article

54 (1) shall be established by an act executed by officials appointed by the executive director of the Bulgarian Drug Agency.

(2) (Amended, SG No. 65/2006) The writ of punishment shall be issued by the executive director of the Bulgarian Drug Agency.

Article 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.

Article 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. For the purposes of this Act

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

2. "Informed consent in writing" shall be consent given on one's own free will, after understanding certain information.

3. A "Serious incident" shall be any unwanted event associated with the collection, diagnostics, processing, conservation and distribution of blood and blood components, which may lead to death, a life-threatening condition, a disability or a disorder causing extension of the hospital stay of a recipient.

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

5. "Blood components" shall be the cellular elements (leukocytes, erythrocytes and thrombocytes) and plasma, which can be extracted by the standard methods for 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 collecting or transfusion of blood or blood components, which has caused death, a life-threatening condition, disability or disorder causing an extension of the hospital stay.

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

8. "Satellite blood sample" shall be a quantity of 0.002 to 0.007 litres of the blood taken from the person from whom a standard collecting of blood has been effected.

9. "Standard collecting of blood" shall be the collecting of between 0.400 and 0.500 litres of blood.

10. "Transfusion haematology" shall be a healthcare activity based on the medical science of the same name on the collecting, 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 collected free of charge.

13. (New, SG No. 70/2004 - effective of 1.01.2005) Autohaemotransfusion, for the purposes of this Act, shall be a method whereby the patient is given a transfusion of blood, collected beforehand from that same patient.

14. (New, SG No. 65/2006) "Doubt of serious incident or serious unwanted reaction" means the presence of a suspicion for a cause-and-effect relationship between the incident or reaction and the collection and/or the use of blood and blood components.

15. (New, SG No. 65/2006) "Inspection" represents an activity related to the execution of objective control in accordance with adopted standards in order to make a judgment whether the provisions of this Act and relevant secondary legislation were followed and to pinpoint potential problems.

16. (New, SG No. 65/2006) "Second violation" is a violation committed within one year after effecting the respective writ of punishment which was imposed upon the defaulting person for the same type of violation.

TRANSITIONAL AND CONCLUDING PROVISIONS

§ 2. Within a nine-month period from the entry into force of this Act, the existing multiprofile hospitals for active treatment with a ward for transfusion haematology, the centres for transfusion haematology and the Military Medical Academy 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 time term under § 2 above, the multiprofile hospitals for active treatment with a ward for transfusion haematology shall file an application for amendment to the permission for the medical activities under Article 48 of the Medical Treatment Facilities Act

§ 4. The following amendments and supplements shall be made to the Medical Treatment Facilities Act for (Promulgated, SG, No. 62/1999; amended, No. 88 and 113/1999; revised, No. 114/1999; amended, No. 36, 65 and 108/2000, No. 51/2001 - Decision No. 11 of the Constitutional Court of 2001; amended, No. 28 and 62/2003, No. 82/2003)

1. The item 4b under Article 19 shall be created:

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

2. Article 25 shall be amended as follows:

"Article 25. (1) A centre for transfusion haematology shall be a medical-treatment facility, where at physicians with the assistance of other staff:

1. collect blood and blood components;
2. diagnosticate, process, conserve and provide blood and blood components;
3. produce, conserve and provide blood derived bio preparations;
4. perform the activities of transfusion surveillance.

(2) The centres under Paragraph 1 above 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 centre carried out activities in violation of the provisions under Paragraph 2 above."

3. In Paragraph 1 of Article 86, 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 Public Health Act (Promulgated, SG, No. 88/1973; corrected, No. 92/1973; amended and supplemented, 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; corrected, No. 24/1991; amended, 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. Article 32a shall be created:

"Article 32a. (1) All medical-treatment facilities for hospital care and inpatient dispensaries may collect blood for self haemotransfusion in compliance with the requirements of Article 12, Paragraph 2 of the Blood, Blood Donation and Blood Transfusion Act, 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 minor's legal representative or custodian."

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

"§ 8a. "Self-haemotransfusion" shall be a method by whereby patient shall be given a blood transfusion of blood, preliminarily taken from the said patient"

§ 6. Within a 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 a 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 implementation.

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

§ 9. The enforcement of this Act shall be assigned to the Minister of Health.

This e Act was adopted by the 39th National Assembly on November 6, 2003 and was affixed with official seal of the National Assembly

FINAL PROVISIONS

to the Amendment and Supplement Act to the Blood, Blood Donation,
and Blood Transfusion Act

(SG No. 65/2006, effective 11.08.2006)

§ 21. Within one month after this Act enters into effect, the Council of Ministers upon proposal by the minister of health will effectuate the necessary changes in the By-laws of the Bulgarian Drug Agency to bring it to compliance with this Act.

§ 22. Within 6 months after this Act enters into effect the Council of Ministers and the minister of health will effectuate necessary changes in the relevant regulations pertinent to the application of this Act.

§ 23. This Act shall become effective as of the date it is published in the State Gazette with the exception of 3 13 which shall become effective on the day of entry into force of the EU Treaty of Accession of the Republic of Bulgaria.

TRANSITIONAL AND FINAL PROVISIONS

to the Medicinal Products in Human Medicine Act

(SG, No. 31/2007)

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§ 19. (1) Within a period of three months of the entry of this Act into force:

1. The Council of Ministers shall amend and supplement the Organic Rules of the Bulgarian

Drugs Agency, bringing it in line with this Act;

2. The Minister of Health shall issue the Ordinance under Article 82, Paragraph 3.

(2) Within a period of up to 6 months of the entry of this Act into force, the Council of Ministers shall adopt and the Minister of Health shall issue the other legislative instruments for the implementation of this Act.

§ 20. After expiry of the first two years of the term of office of the members of Commissions under Article 103, 107, 259 and 261, half of the members whose term of office will terminate shall be drawn by lot.

§ 21. Within a period of up to one year of the entry of this Act into force, the Bulgarian Drugs Agency shall take the necessary action to have its laboratory for the control of medicinal products and active substances accredited by the European Directorate for the Quality of Medicines and Healthcare.

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§ 36. Until entry into force of the instruments under § 19, legal instruments issued for the implementation of the repealed Human Medicinal Drugs and Pharmacies Act shall apply, insofar as they do not stand in contradiction hereto.

§ 37. This Act shall become effective on the day of its publication in the State Gazette with the exception of § 22, which shall enter into force one year after the entry of this Act into force.

TRANSITIONAL AND CONCLUDING PROVISIONS to the Act to Amend and

Supplement the Medicinal Products in Human Medicine Act

(SG No. 60/2011, effective 5.08.2011, effective 5.08.2011)

§ 83. In the Blood, Blood Donation, and Blood Transfusion Act (Promulgated, SG No. 102/2003, amended, SG No. 70/2004, SG No. 30 and 65/2006, SG No. 31/2007, SG No. 41 and 74/2009 and SG No. 59 and 98/2010) the words "The National Centre for Haematology and Transfusiology" wherever used, shall be replaced by the words "The National Centre for Transfusion Haematology".

Act to Amend and Supplement the Civil Servants Act

(Promulgated, SG No. 38/2012, effective 1.07.2012)

TRANSITIONAL AND FINAL PROVISIONS

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§ 84. (Effective 18.05.2012 - SG No. 38/2012) Within one month after the promulgation of

this Act in the State Gazette:

1. the Council of Ministers shall bring the Classifier of Positions in the Administration into conformity with this Act;

2. the competent authorities shall bring the organic acts of the respective administration into conformity 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 Access to and Disclosure of the Documents and Announcing the Affiliation of Bulgarian Citizens with the State Security Service and the Intelligence Services of the Bulgarian Popular Army Act , the Criminal Assets Forfeiture Act , the Conflict of Interest Prevention and Ascertainment Act , the Social Insurance Code , the Health Insurance Act , the Agricultural Producers Support Act and the Roads Act shall be settled under the terms established by § 36 of the Transitional and Final Provisions of the Act to Amend and Supplement the Civil Servants Act (State Gazette No. 24 of 2006).

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

1. award the lowest rank designated in the Classifier of Positions in the Administration for occupation of the position, unless the servant holds a higher rank;

2. fix an individual monthly basic salary.

(3) The additional resources required for social and health insurance contributions of the persons referred to in Paragraph (2) shall be provided within the limits of the expenditures on salaries, remunerations and compulsory social and health insurance contributions under the budgets of the spending units concerned.

(4) The Council of Ministers shall effect the requisite modifications under the off-budget account of State Fund Agriculture arising from this Act.

(5) The governing bodies of the National Social Security Institute and of the National Health Insurance Fund shall effect the requisite modifications under the respective budgets arising from this Act.

(6) Any unused leaves under the employment relationships shall be retained and shall not be compensated by cash compensations.

§ 86. (1) Within one month after the entry into force of this Act, the individual monthly basic salary of the servant shall be fixed in such a way that the said salary, net of the tax due and the compulsory social and health insurance contributions for the account of the insured person, if they were due, would not be lower than the gross monthly salary received theretofore, net of the compulsory social and health insurance contributions for the account of the insured person, if they were due, and the tax due.

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

1. the monthly basic salary or the monthly basic remuneration;
2. supplementary remunerations which are paid constantly together with the monthly basic salary or monthly basic remuneration due and which are contingent solely on the time worked.

§ 87. This Act shall enter into force as from the 1st day of July 2012 with the exception of § 84 herein, which shall enter into force as from the day of promulgation of the Act in the State Gazette.