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Blood Act[1]

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Amended by the following acts

Passed	Published	Entry into force
31.05.2006	RT I 2006, 27, 196	13.06.2006
15.02.2007	RT I 2007, 24, 127	01.01.2008
20.12.2007	RT I 2008, 3, 22	01.09.2008
17.12.2008	RT I 2009, 5, 35	01.07.2009
30.09.2009	RT I 2009, 49, 331	01.01.2010
22.04.2010	RT I 2010, 22, 108	01.01.2011, enters into force on the date which has been determined in the Decision of the Council of the European Union regarding the abrogation of the derogation established in respect of the Republic of Estonia on the basis provided for in Article 140 (2) of the Treaty on the Functioning of the European Union, Council Decision 2010/416/EU of 13 July 2010 (OJ L 196, 28.07.2010, p. 24 - 26).
19.02.2014	RT I, 13.03.2014, 4	01.07.2014, partially 23.03.2014

Chapter 1
GENERAL PROVISIONS

§ 1. Scope of application of Act

(1) This Act establishes, with the aim to ensure the health protection of blood donors and recipients, the requirements for handling of human blood (hereinafter blood) and the organisation for handling blood.

(2) This Act regulates the financing of handling of blood and exercise of state and administrative supervision over compliance with the requirements set by this Act and the legislation established on the basis thereof. [RT I, 13.03.2014, 4 - entry into force 01.07.2014]

(3) The Administrative Procedure Act applies to the administrative proceedings prescribed in this Act, taking account of the specifications arising from this Act.

§ 2. Blood products

(1) Blood product is a medicinal product manufactured or produced from blood, packaged and labelled as required and containing one or several blood constituents. Whole blood, blood components and plasma-derived products are blood products. The provisions of the Medicinal Products Act shall apply to blood products, taking account of the specifications arising from this Act.

(2) Whole blood is a blood product containing all blood constituents and an anticoagulant solution.

(3) Blood component is a blood product manufactured from whole blood or collected directly from a blood donor and which contains constituents from the blood of one or several blood donors.

(4) Plasma-derived product is a blood product industrially produced from the blood plasma of several blood donors and which contains a specific constituent of blood plasma.

(5) For the purposes of this Act, transfusion means a therapeutic procedure in the course of which whole blood or blood components are transfused to the recipient.

Chapter 2
HANDLING OF BLOOD

§ 3. Handling of blood

Handling of blood is the collection of blood, and the manufacture, testing, storage, distribution, use and sale of blood components.

§ 4. Blood establishment

(1) The function of a blood establishment is to collect blood, and to manufacture, examine, store, distribute and sell blood components. The objective of a blood establishment is to guarantee that blood components are available to Estonian health care providers on a twenty-four-hour basis.

(2) A blood establishment may be a legal person in private law or a state agency administered by a governmental authority which operates based on an activity licence for manufacture of medicinal products issued pursuant to the Medicinal Products Act.

§ 5. Hospital blood bank

(1) The function of a hospital blood bank is to order and store blood components, and to distribute them for use within hospital facilities, to carry out immunohaematological testing and to co-ordinate and provide consultations for use of transfusions for treatment.

(2) Hospital blood banks are permitted to collect blood only under extraordinary circumstances where the hospital, and blood establishment which usually provides the hospital with blood components, lack sufficient blood supplies, and postponement of or failure to perform a transfusion is likely to result in a patient's death or permanent damage to his or her health.

(3) A hospital blood bank is a structural unit of the operator of a hospital which operates on the basis of an activity licence for provision of health care services issued to the operator of the hospital pursuant to the Health Services Organisation Act.

§ 6. Collection of blood

(1) Blood is collected by way of voluntary donation.

(2) Blood shall not be collected from a person who refuses the testing carried out to assess the eligibility to donate, whose blood is unsuitable for use due to illnesses he or she has suffered from or medications he or she has been treated with or for other reasons, or if donation is likely to pose a threat to the person's health.

§ 7. Blood donor and recipient

(1) A blood donor is a person with active legal capacity who is 18-65 years of age and who donates blood free of charge for the purpose of treatment of other persons to a handler of blood.

(2) A blood donor has the rights and obligations of a patient as provided by the Law of Obligations Act.

(3) A blood donor has the right:
1) to receive general information on handling of blood and transfusions;
2) to receive information on potential dangers arising from donation;
3) to decline from donation at any time if he or she so decides;
4) to receive information on his or her state of health, the results of the tests conducted on his or her blood, and the suitability for treatment of the blood donated by him or her;
5) to get time off from his or her employer for the donation of blood;
[RT I 2009, 5, 35 - entry into force 01.07.2009]
6) of confidentiality of identity.

(4) A blood donor has the obligation to:
1) submit his or her personal data and contact information to the handler of blood;

2) disclose all information and circumstances to the handler of blood which, to the blood donor's best understanding are relevant to donation;
3) inform the handler of blood of circumstances which become known to him or her after donation, and of any changes which occur in his or her state of health after donation which could affect the suitability for treatment of the donated blood or blood components;
4) confirm the correctness of the submitted information by his or her signature.

(5) The criteria for eligibility for donation, conditions and procedure for assessment of eligibility, and a list of permanent or temporary deferral criteria shall be established by a regulation of the Minister of Social Affairs.

(6) For the purposes of this Act, a recipient is a person who receives a transfusion. A recipient has the rights and obligations of a patient as provided by the Law of Obligations Act.

(7) A recipient may express his or her will on transfusions by certifying it with digital signature through the Health Information System.
[RT I 2008, 3, 22 - entry into force 01.09.2008]

§ 8. Manufacture of blood components

(1) Blood components manufactured by a blood establishment shall be of high quality, safe to the recipient and clinically effective.

(2) The head of a blood establishment is responsible for the quality of the production of the blood establishment.

(3) The head of a blood establishment shall guarantee:
1) handling of blood in conformity with the requirements provided for in this Act and legislation established on the basis thereof;
2) timely application for the activity licence for manufacture of medicinal products, and compliance with the requirements provided thereby.

(4) In their operation, blood establishments and hospital blood banks shall adhere to good manufacturing practice. The Minister of Social Affairs shall establish the rules for manufacture of blood components in accordance with good manufacturing practice in force in the European Union by a regulation which provides for the requirements set for manufacture of blood products, the staff, facilities, equipment and documentation, and for the collection and testing of blood, the manufacture, labelling, storage and distribution of blood components, the settling of complaints and the withdrawal of blood components.

(5) The requirements for the quality of blood components, and the conditions and procedure for quality control and microbiological testing of blood components shall be established by a regulation of the Minister of Social Affairs.

§ 9. Transfusion

(1) Transfusions are carried out for the objective of restoration of the health of patients, to prevent the deterioration of the state of health of patients and to reduce disease-related malaise.

(2) The conditions and procedure for transfusions shall be established by a regulation of the Minister of Social Affairs.

§ 10. Use of blood and blood components for research and commercial purposes

(1) The blood and blood components collected from a blood donor shall be used for research purposes only with the written consent of the blood donor.

(2) The blood and blood components collected from a patient for the purpose of autologous transfusion shall be used for research and commercial purposes only with the written consent of the patient.

§ 11. Immunohaematological testing of blood products

(1) Donor blood products suitable for the treatment of a patient shall be determined by way of immunohaematological testing of the blood of the patient and the blood of the blood donor.

(2) The conditions and procedure for immunohaematological testing shall be established by a regulation of the Minister of Social Affairs.

§ 12. Haemovigilance

(1) Haemovigilance means the provision of information concerning any serious adverse event associated with the handling of blood and any serious adverse reaction occurring at the time or after a transfusion, and the procedure for establishing the reasons thereof.

(2) The health care provider shall inform the blood establishment which supplied the blood components of any post-donation serious adverse reaction. Information regarding post-donation suspicion of a communicable disease and diagnosis of such disease shall be provided pursuant to the procedure provided by the Communicable Diseases Prevention and Control Act.

(3) A blood establishment is required to immediately inform the State Agency of Medicines of any post-donation serious adverse reaction or serious adverse event associated with the handling of blood which become known to the establishment, and of initiation of withdrawal of the blood components. A blood establishment shall also inform the relevant health care provider and manufacturer of plasma-derived products who bought plasma from the blood establishment of any serious adverse events associated with the handling of blood and of initiation of withdrawal of the blood components.

(4) Based on the information forwarded to the State Agency of Medicines, an annual consolidated report concerning the serious adverse effects of handling of blood and the serious adverse reactions shall be prepared by the State Agency of Medicines and forwarded to the Ministry of Social Affairs, the blood establishments and relevant health care providers.

(5) The conditions and procedure for haemovigilance and withdrawal of blood components shall be established by a regulation of the Minister of Social Affairs.

§ 13. Safety of blood products

Safety of blood products from infection upon handling of blood shall be ensured pursuant to the procedure provided in § 14 of the Communicable Diseases Prevention and Control Act.

§ 14. Removal of unused blood products

Unused blood products are deemed to be waste and such products shall be removed pursuant to the Waste Act.

§ 15. National blood information system

(1) A national blood information system (hereinafter blood information system) is established in order to guarantee that handling of blood and related treatment are carried out in conformity with the quality requirements.

(2) The provisions of the Public Information Act and Personal Data Protection Act shall be applied to the blood information system and the maintenance thereof with the specifications provided for in this Act. The blood information system unites all processes related to the handling of blood, sub-registers and other relevant documents into an integral whole.
[RT I 2007, 24, 127 - entry into force 01.01.2008]

(3) The blood information system consists of the following sub-registers:
1) sub-register of blood donors;
2) sub-register of blood products;
3) sub-register of recipients.

(4) The following are the documents related to the blood information system:
1) standards covering the entire manufacturing process;
2) standard descriptions of all processes for handling of blood;
3) descriptions of the tests prescribed for donated blood and quality requirements for blood components.

(5) The data entered in the blood information system concerning blood donors and recipients shall be processed, making reference to each person separately.

(6) [Repealed - RT I 2007, 24, 127 – entered into force 01.01.2008]

(7) The chief processor of the blood information system is the Ministry of Social Affairs.

(8) The authorised processors of the blood information system are the blood establishments and hospital blood banks.

(9) The blood information system shall be established and the statutes for the maintenance of the register shall be approved by the Government of the Republic.

Chapter 3

REFERENCE LABORATORY FOR IMMUNOHAEMATOLOGICAL TESTING

§ 16. Reference laboratory for immunohaematological testing

The reference laboratory engaged in immunohaematological testing (hereinafter reference laboratory) is a laboratory which provides reference services, including the determination of antigens and antibodies in systems of clinically significant blood groups and provides methodological guidance to other laboratories operating in the same field in Estonia. The purpose of the reference laboratory is to ensure the quality of immunohaematological testing.

§ 17. Functions of reference laboratory

In providing reference services, the reference laboratory shall:
1) co-ordinate, direct and check the diagnostics provided by relevant laboratories;
2) determine antigens and antibodies in systems of clinically significant blood groups;
3) provide routine diagnostics in the field of immunohaematology;
4) hold and apply reference methods;
5) prepare reference materials and reference panels;
6) introduce new methods of diagnostics, collect information on different new methods and compare their efficiency;
7) organise professional consultations and training, and participate in research;
8) participate in the international quality control of analyses performed in the field of immunohaematology.

§ 18. Organisation of provision of reference services

The Ministry of Social Affairs shall organise the provision of reference services. For the provision of reference services, the Minister of Social Affairs shall enter into a contract under public law with the term of five years with a blood establishment having a reference laboratory pursuant to the conditions provided for in the Administrative Cooperation Act.
[RT I 2006, 27, 196 - entry into force 13.06.2006]

Chapter 4
FINANCING OF HANDLING OF BLOOD

§ 19. Financing of handling of blood

(1) The operating costs of the reference laboratory are covered from the state budget through the Ministry of Social Affairs.

(2) Health care providers shall be compensated for the costs incurred upon purchasing of blood components by the health insurance fund based on the Health Insurance Act.

Chapter 5
STATE AND ADMINISTRATIVE SUPERVISION

[RT I, 13.03.2014, 4 - entry into force 01.07.2014]

§ 20. Authorities exercising state and administrative supervision over handling of blood
[RT I, 13.03.2014, 4 - entry into force 01.07.2014]

(1) The authorities exercising state supervision over the handling of blood are the State Agency of Medicines and the Health Board.
[RT I 2009, 49, 331 - entry into force 01.01.2010]

(2) The State Agency of Medicines shall monitor the compliance of blood establishments engaged in handling of blood with the requirements provided by this Act and legislation established on the basis thereof.

(3) The Health Board shall monitor the compliance of hospital blood banks with the requirements provided by this Act and legislation established on the basis thereof applicable to the ordering, storage, distribution for use within hospital facilities, and immunohaematological testing of blood components, to the use of transfusions for treatment and to collection of blood under extraordinary circumstances.
[RT I 2009, 49, 331 - entry into force 01.01.2010]

§ 20[1]. Special state supervision measures

For the execution of state supervision provided for in this Act, the law enforcement agency may apply the special state supervision measures provided for in §§ 30, 31, 32, 49 and 50 of the Law Enforcement Act on the basis of and pursuant to the procedure provided for in the Law Enforcement Act.
[RT I, 13.03.2014, 4 - entry into force 01.07.2014]

§ 21. Rights and obligations of officials exercising administrative supervision
[RT I, 13.03.2014, 4 - entry into force 01.07.2014]

(1) An official exercising administrative supervision has the right, for performance of his or her duties, to:
[RT I, 13.03.2014, 4 - entry into force 01.07.2014]
1) enter the place of business of the person being monitored in the presence thereof, including without giving prior notice, as necessary;
2) inspect the handling of blood;
3) take samples and analyses for checking, as necessary;
4) examine documents related to the handling of blood, or copies thereof, and to obtain extracts of such documents;
5) obtain explanations from the management bodies of the person being inspected;
6) submit proposals to the person being inspected in order to improve the activities thereof;
7) issue, within the limits of his or her competence, precepts to terminate a violation of the requirements of this Act or legislation established on the basis thereof, to eliminate the consequences of the violation or to perform other acts.

(2) Administrative supervision over compliance with the requirements provided by this Act and legislation established on the basis thereof shall be exercised at least once every two years.
[RT I, 13.03.2014, 4 - entry into force 01.07.2014]

(3) Before commencing the performance of his or her duties, a supervisory official must present identification.
[RT I, 13.03.2014, 4 - entry into force 01.07.2014]

§ 22. Precepts
[Repealed -RT I, 13.03.2014, 4 - entry into force 01.07.2014]

§ 23. Contestation of precept
[Repealed -RT I, 13.03.2014, 4 - entry into force 01.07.2014]

Chapter 6
LIABILITY

§ 24. Knowing entry of incorrect information in blood information system

Knowing entry, by a legal person, of incorrect information in the blood information system is punishable by a fine of 770 euros.
[RT I 2010, 22, 108 - entry into force 01.01.2011]

§ 25. Interference with exercise of state supervision

A legal person who obstructs state supervision, refuses to submit documents or information necessary for supervision or fails to submit such documents or information on time, submits false information or submits documents or information in a manner which does not permit supervision to be exercised shall be punished by a fine of up to 3200 euros.
[RT I 2010, 22, 108 - entry into force 01.01.2011]

§ 26. Proceedings

(1) The General Part of the Penal Code and the Code of Misdemeanour Procedure apply to the misdemeanours provided for in §§ 24 and 25 of this Act.

(2) The Ministry of Social Affairs shall conduct extra-judicial proceedings in the matters of the misdemeanours provided for in § 24 of this Act.

(3) The State Agency of Medicines and the Health Board shall conduct extra-judicial proceedings in the matters of the misdemeanours provided for in § 25 of this Act.
[RT I 2009, 49, 331 - entry into force 01.01.2010]

Chapter 7

IMPLEMENTING PROVISIONS

§ 27. Notifying European Commission

The Ministry of Social Affairs shall notify the European Commission of:
1) measures for promoting voluntary and unpaid donation, once every three years as of the entry into force of this Act;
2) measures related to the handling of blood, including supervisory measures, by 31 December 2006 and after that, once every three years.

§ 28. Application of good manufacturing practice

Blood establishments and hospital blood banks shall bring the handling of blood into conformity with the requirements provided on the basis of subsection 8 (4) of this Act not later than by 1 January 2006.

§ 29.–§ 32.[Omitted from this text.]

§ 33. Entry into force of Act

(1) This Act enters into force on 1 May 2005.

(2) Sections 15 and 24 of this Act enter into force on 1 January 2008.

[1]Directive 2002/98/EC of the European Parliament and of the Council setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC (OJ L 033, 08.02.2003, pp. 30–40); Commission Directive 2003/94/EC laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use (OJ L 262, 14.10.2003, pp. 22–26); Commission Directive 2004/33/EC implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components (OJ L 091, 30.03.2004, pp. 25–39).