

The Parliament of the Republic of Moldova

LAW

On Blood Safety

The Parliament adopts the present organic Law.

The present Law has been developed to regulate the relations concerning the establishment of voluntary and non-remunerated donation of blood and blood components and their usage by the healthcare institutions of the Republic of Moldova, having granted compound social, legal, economic and medical rights to donors and recipients of blood and blood components.

Chapter I.

GENERAL PROVISIONS.

Article 1. The Scope of Regulation.

(1) The present Law shall regulate:

- a) The legal framework of the activity carried out by all partners oriented towards the promotion of blood/blood components donors, self-provision of Blood Banks with blood components and their efficient usage;
- b) Social relations in organizing donations of blood/blood components;
- c) The norms aimed at assuring the quality and safety of donation, human blood and blood components processing and usage, including the blood and blood components used as raw material for producing diagnosing and biomedical preparations, in order to ensure human health high-level protection.

(2) The present Law shall not regulate:

- a) Social relations for donation and transplant of human body organs;
- b) Production, stockpiling and management of diagnosis and biomedical preparations from blood;
- c) Relations of donation of insignificant quantity of blood for diagnostics purposes, production of homeopathic blood preparations and collection of some autologous blood quantity to produce preparations for stomatological treatment used in the dentistry practice based on medical norms.

Article 2. Legal Framework.

- (1) The Constitution of the Republic of Moldova constitutes the legal framework for blood/blood components donation and usage as well as the present Law, the international treaties to which the Republic of Moldova is a Party and other regulatory acts that regulate the relations relevant to this area.
- (2) In case the international treaties to which the Republic of Moldova is a Party stipulate provisions other than the ones comprised by the present Law, the provisions of international treaties shall apply.
- (3) The Ministry of Health shall establish the rules for organizing the activities in the field of blood service and blood transfusion in compliance with the provisions of the present Law.

Article 3. Principal Notions.

The following principal notions shall be defined for the purpose of the present Law:

authorization – the assessment and analysis process that conditions, from the technical and legal points of view, putting into operation and carrying out certain activities in the blood transfusion area;

license – technical and legal deed documented by the **competent** public health authority, which establishes the operation conditions and/or parameters for a blood-related activity;

self-sufficiency – providing the requisite quantity of human blood and blood components given their therapeutic reasonable usage in compliance with modern practice of transfusion therapy;

blood bank – subdivision of a healthcare institution empowered with functions to promote voluntary and non-remunerated blood donation among the patients' relatives and among population, to receive blood products from transfusion centers and units and to distribute them to the institution subunits along with mandatory immunohematological tests carried out for transfusion purposes;

blood committee – a group of specialists from a healthcare institution responsible for implementing the blood transfusion and alternative transfusion policies in the healthcare institution;

blood components – human origin blood components – erythrocytes, leucocytes, thrombocytes and plasma, which can be obtained as a result of separation through different methods or blood sample processing;

blood derivate – therapeutic product obtained through the blood component preparation;

distribution – supply of human blood and blood components to other blood transfusion centers and sections or to be processed industrially-pharmaceutically; the notion „distribution” does not refer to supply of human

blood or blood components from the blood banks of one healthcare institution to a section from the same hospital for therapeutic purposes;

autologous donation – collection of blood or blood components to be used exclusively by the person who donated them;

homologous donation - collection of blood or blood components from one person to be used therapeutically for another person or for industrial-pharmaceutical processing;

voluntary and non-remunerated **donation of blood/blood components** is the one when a person donates according to his/her choice without any remuneration either cash or valuable that may be considered as cash substitute;

donor of blood/blood components – a physical person who donates blood/blood components;

permanent voluntary donor of blood/blood components – a person who donates blood at least four times per year or blood components 20 times per year for at least five year in a row and continues to perform this activity;

blood donation – collection of venous blood from a single donor (a single physical person), into a sterile and apyrogenous device that contains anticoagulant, which is transfused or processed into blood components afterwards;

hemovigilance – ensemble of procedures for surveillance of unwanted incidents or of severe adverse health effects that may occur in both the blood donor and the blood recipient as well as for surveillance of donors through epidemiological methods;

freedom of donation – none of the persons shall encounter any constraints while donating blood/blood components, this action being a voluntary deed;

quality management – aggregate activities coordinated to direct and control an organization in terms of quality at all levels within the area of blood transfusion institutions;

biomedical blood preparation/product – a therapeutic product obtained from human blood or plasma as a result of industrial-pharmaceutical processing;

diagnostic blood preparation/product – a diagnostic product obtained through preparation of blood or blood component.

legal representative of the recipient of blood/blood component – a person who can represent, under the law provisions, without any power of attorney, the recipient's interests who does not have full motion capacity or who has been declared incapable or with limited motion capacity;

close relative – a person who is a patient's relative (parent, children, brother, sister, grand-parent), including the spouse, who has been utmost in contact with the patient or has been identified by the recipient when the latter had limited motion capacity to represent his/her interests in relations established by the present Law;

quality system – the organizational structure, procedures, processes and resources necessary to implement the quality management;

blood service – a public health system unit that comprises institutions – blood transfusion centers and sections habilitated with functions to promote voluntary and non-remunerated blood donation, being responsible for collecting and testing human blood and blood components, whatever the proposed goal is, and for their processing, preparation and distribution when they are intended for transfusion or for industrial-pharmaceutical procedure;

blood transfusion service – a unit within the healthcare institutions that includes the blood bank habilitated with functions to promote voluntary and non-remunerated blood donation among the patients' relatives as well as among population, receives blood products from the transfusion centers and sections and distributes them to the institution subunits along with mandatory immunohematological tests carried out for transfusion purposes, keeps records on and monitors the blood traceability and hemovigilance in the institution;

transfusion of allogenic blood – management of blood or blood components collected from the donor to be used therapeutically for other persons;

transfusion of autologous blood - management of blood or blood components collected from a person to be used therapeutically for the same person;

traceability – the ensemble of information recorded and of measures that allow to track down and identify each stage of activity, starting from the admission of a person to donate blood and ending with blood and blood components therapeutic usage; traceability enables to establish a link between the donor and one or more recipients and between the recipient and the donor based on a single national system for identification of blood samples and persons;

validation – establishing documented and objective proofs that particular requirements set up for specific usage can be observed in full.

Article 4. Principles of blood safety.

The present Law promotes observance of the following principles:

- a) Blood is a national resource, included in the country security and public health;
- b) The Blood Service units have public status;
- c) The freedom of donation;
- d) Ensuring health protection and equality of rights of donors and recipients;
- e) Blood/blood components donation is a person's prerogative not a right; donation is voluntary and non-remunerated;
- f) Ensuring a high level of safety and quality of blood and its components;
- g) Availability of blood components and its derivatives based on self-provision;

h) Reasonable usage of blood products in the health system.

Chapter II.

STATE POLICY IN THE FIELD OF BLOOD/BLOOD COMPONENTS DONATION AND BLOOD TRANSFUSION.

Article 5. The Policy of Public Authorities in the blood-related area.

- (1) The State supports the Blood Service, as one of the important areas of the national security, through managerial and economic leverages and through actions for ensuring technical and material basis and specific technologies in conformity shall will ensure the quality and safety of blood and blood components transfusions.
- (2) The blood transfusion practices are based on principles of donors' voluntary blood services, anonymity of both the donor and the recipient, no remuneration for the donor and non-profit for medical units involved in blood transfusion services.
- (3) The State encourages voluntary and non-remunerated blood donations, which are deemed as a measure to ensure blood transfusion safety.
- (4) The Government:
 - a) Established the State policy in the field of blood transfusion safety and of blood components and derivates as well;
 - b) Approves the field-related national strategy and national programs;
 - c) Ensures sustainable development of blood service;
 - d) Promotes through the mediation of public services voluntary and non-remunerated blood donations as a factor that contributes to building high-level standards of blood and blood components safety and, as a result, to protection of human health;
 - e) Undertakes incentive actions for voluntary and non-remunerated blood donations through adequate measures and initiatives, through enhanced public recognition of donors;
 - f) Delegates to the Ministry of Health, as the competent authority, to organize and control the production of blood components and derivates and their transfusion.

Article 6. Authorities' accountability.

- (1) Ministries, other bodies of central and local public authorities, cultural institutions, mass-media, are accountable, according to their competences, to support the actions for promoting human blood and blood components donation.
- (2) Local public administration bodies:
 - a) Plan and organize blood donation days within the administrative territory in order to contribute to sufficient self-provision of blood

- components and derivatives to cover the medical needs and cases of emergency;
- b) Foster without constraints and in all possible formats the spirit of civic importance to be voluntary non-remunerated blood donor and promote healthy life style in the community;
 - c) Offer social motivation to blood donors to make them faithful to the blood donation act.
- (3) Promotion of blood donation through newspapers, radio and TV station is free of charge with the right to broadcast **for the last 30 minutes** on a monthly basis.

Chapter III. COMPETENT AUTHORITY.

Article 7. Functions of the Competent Authority.

The Ministry of Health, as the Competent Authority, exercises the following functions:

- a) Develops the leverages for organizing, co-operating, monitoring and controlling the activity performed by the blood and blood transfusion services, regardless of the status of institutions;
- b) Ensures the safety of health of donors and recipients of blood and blood components;
- c) Develops regulations for conducting autologous donations with their stockpiling in blood banks;
- d) Creates the Hemovigilance Committee, which is a monitoring and notifying body about different incidents in the field, which have an impact on blood transfusion quality and safety;
- e) Develops and approves national programs on education and training for blood products efficient usage in healthcare institutions;
- f) Plans the blood service budgeting from the state budget and other investments;
- g) Provides the blood service with the equipment and consumables necessary for a sound production practice;
- h) Creates the commission and approves the regulation on the manner and situations of authorization of imports and/or exports of blood, blood components, blood diagnostics and biomedical preparations;
- i) Coordinates and offers methodical recommendations to all partners in terms of promoting and recruiting blood donors;
- j) Concludes cooperation agreements/contracts with the Red Cross Society and with other non-governmental entities in order to promote and recruit voluntary donors;

- k) Establishes collaboration relationships with filed-related international structures.

Article 8. Subordinated Authorities.

- (1) The Ministry of Health exercises its prerogatives as the Competent Authority in the blood service area through the following entities:
 - a) The Blood Service with its territorial units responsible for blood and blood components collection, processing, screening and stockpiling;
 - b) The Drug Agency;
 - c) Preventive Medicine Services/Units;
- (2) The Blood Service represented by the National Blood Transfusion Center, based on its mandate:
 - a) Develops and offers methodical recommendations in the field of blood safety in the country and manages the blood service activity;
 - b) Gives written authorization in advance to changes and reorganizations related to activities performed by the transfusion sections from the territory;
 - c) Carries out the functions of a national level blood bank, managing the territorial blood banks.
- (3) The Drug Agency supervises and assures quality control in the course of blood components and derivatives processing.
- (4) The Preventive Medicine Services carry out activities aimed at preventing and ensuring the sanitary and epidemiological regime in the course of blood transfusion process from the donor till the recipient.

Chapter IV.

DONATION OF BLOOD AND BLOOD COMPONENTS.

Article 9. Donation of blood and blood components.

- (1) Donation of blood and blood components is a voluntary deed.
 - a) Donation of blood and blood components is a voluntary and non-remunerated deed;
 - b) The blood donor, after having donated blood/blood components – raw material for obtaining blood components/derivates, shall not get cash payment or any other type or remuneration that may be considered as cash substitute;
 - c) After having donated blood or blood components, the donor shall benefit from meals in order to replenish the caloric potential he/she has lost as a result of blood donation.

Article 10. Eligibility of donors of blood and blood components.

- (1) Eligibility of donors will be performed in compliance with the donor selection rules approved by the act issued by the Ministry of Health.
- (2) Examination of donors and collection of blood shall be performed under the responsibility of authorized medical personnel in conformity with the technical and medical science norms.
- (3) Collection of blood or blood components shall be performed only after the confirmation of the donor's consent. The donor will be trained this way about the blood collection substance, importance and procedure, confirmed by his/her signature.

Article 11. Rights of Donors of blood and blood components.

- (1) The present Law guarantees the blood donors' equality of rights regardless of their race, nationality, ethnic origin, language, religion, gender, opinion, political membership, welfare or social origin.
- (2) The donor has got the right to:
 - a) Gratuitous medical care to the extent of medical examination before donation;
 - b) Security of personal life, physical, psychical and moral integrity, having ensured discretion in the course of rendering healthcare services;
 - c) Confidentiality of any kind of information related to his/her health status provided to the authorized personnel, of blood donation test results and of traceability of donation afterwards;
 - d) Mitigation of ailment and softening the pain caused by medical intervention to collect blood or blood components through all possible legal methods and ways, brought by the existing level of medical science and by the actual abilities of medical personnel;
 - e) Alternative medical opinion and recommendations from other specialists upon his/her personal request or upon the request of his/her legal representative (close relative);
 - f) Information about the institution that collects blood and blood components, its profile, volume, quality and manner of rendering the relevant services;
 - g) Examination and collection of blood and blood components in conditions adequate to sanitary and hygienic norms;
 - h) Exhaustive information about his/her own health status, the methods of diagnostics, treatment and rehabilitation, prevention and potential risk and their therapeutic efficiency;
 - i) Voluntary expression of approval or disapproval of medical intervention to collect blood and blood components and participation to biomedical investigation;

- j) Information about the results of considering complaints and requests in the order established by legislation;
 - k) Forensic and non-forensic appeal of illicit actions performed by the workers of blood service institutions;
 - l) Compensation of health-related damages according to legislation.
- (3) The Employer shall grant two days-off to employees for the blood donation day, having kept intact their salaries and having included them in the length of service.
- (4) Going from the fact that permanent voluntary donors of blood/plasma bring a valuable service to the community these persons shall be treated with special esteem within the public institutions.
- (5) The permanent voluntary donors of blood/plasma benefit from a broader spectrum of medical services included in the Single Package of Medical Insurance, established annually by legislation.

Article 12. Responsibilities of persons willing to donate blood or blood components.

- (1) In order to prevent transmission of diseases through blood and ensure an equal level of quality and safety, the donor is obligated:
- a) To communicate the medical personnel of the blood service institution his/her accurate personal data;
 - b) To communicate, by filling out a questionnaire, all data referring to his/her anamnesis and health status in order to contribute to effective selection of voluntary blood donors;
 - c) To comply with relevant tests conducted by the blood service institution workers in order to identify the provisos that may impede the donation of blood.

Article 13. Blood and blood components traceability and stockpiling.

- (1) Traceability of blood and blood components is ensured by the presence of a single national system aimed at identifying the blood/blood components units, the donor and the recipient.
- (2) Traceability is applied through precise procedures aimed at identifying the donor, recipient, and the laboratory by archiving the information and through an adequate system of identifying and labeling the blood and blood components units.
- (3) In case of importing/exporting blood and blood components from/to tertiary countries based on the authorization issued by the Ministry of Health, an equivalent level of traceability is ensured by the blood service at stages preceding the import and following the export.
- (4) The information necessary for a total traceability shall be kept at least for a thirty-year period.

- (5) Stockpiling of blood and blood components is performed according to the technical and sanitary norms in effect within the blood service institutions equipped with the necessary appliances.
- (6) Stockpiling and distribution of human blood intended for transfusion is performed by the healthcare institutions authorized by the Ministry of Health.

Chapter V. QUALITY ASSURANCE AND MANAGEMENT.

Article 14. Quality Management System.

- (1) The blood service is organized through the establishment and maintenance of a quality system based on the principles of best practices.
- (2) Safety and quality standards for collecting and testing human blood and blood components, processing, preserving and distribution for transfusion shall ensure a high-level protection of human life.
- (3) Blood and blood components, imported based on the respective authorization, including basic material or unprocessed material to make final derivate products from human blood and plasma, diagnostic and biomedical preparations, shall comply with standards and specifications equivalent to the national ones, including the requests to declare and monitor the adverse reactions.
- (4) Monitoring of blood and blood components shall be ensured by applying the procedure for accurate identification, and by maintaining registers and an appropriate labeling system.
- (5) The blood service shall ensure a procedure for identification and verification of blood or blood components unit from the issuance till the stockpiling in the blood bank of the healthcare institution.
- (6) The blood service, upon need, shall apply the discard procedure to blood products notified as offensive in a precise, efficient and checkable manner.
- (7) The Ministry of Health shall ensure that the consumables, medical equipment and appliances used for processing, storing and transporting guarantee the safety and quality of blood products.
- (8) Quality assurance shall be the responsibility of all persons involved in processes carried out by blood and blood transfusion services with management that ensure gradual propinquity towards implementation and maintenance of the quality system.

Article 15. Training of Personnel.

- (1) Training of personnel, on-job training is a national education policy in the field of blood service and clinic usage organized by the authorized institutions of special secondary and university education.

- (2) Primary specialization and continuous education shall ensure acquaintance of competences and abilities specific for blood and blood transfusion services.

Chapter VI.

USAGE OF BLOOD COMPONENTS, DERIVATES AND BIOMEDICAL PREPARATIONS.

Article 16. Blood transfusion service organizes efficient clinical usage of blood derivatives and biomedical preparations:

- (1) Efficient clinical usage of blood components, derivatives and biomedical preparations shall be based on a quality management system supported by a relevant structure in order to ensure implementation of national regulations.
- (2) Implementation of a quality management system in cooperation with and commitment of all entities involved in the blood transfusion chain defines the quality of adequate usage of blood resources.

Article 17. Blood transfusion committees of healthcare institutions.

- (1) Blood transfusion committees from different areas ensure efficient usage of blood components, derivatives and biomedical preparations in the clinic.
- (2) Blood transfusion committees ensure surveillance and support for implementing and reviewing the blood transfusion and alternative transfusions management policies.
- (3) Usage of autologous blood or blood products shall be carried out according to strict necessity only based on clear proofs concerning efficiency and avoidance of useless transfusions.
- (4) Monitoring and evaluating the clinic tactics of blood components, derivatives and biomedical preparations usage in the context of assuring the quality system of secure, inoffensive and adequate blood products stockpiles received by the blood bank from blood services and their efficient use by the doctors.

Article 18. Alternative Treatment.

The national policy for clinical transfusion supports the alternative treatment for allogenic blood transfusion, building preventive strategies to diminish the losses of blood.

Article 19. Avoidance of Waste and Losses.

The Sanitary Service shall promote efficient logistics of laboratory work practices in order to avoid any waste and losses of blood due to technical reasons.

Article 20. Studies in the field of clinical blood transfusion.

The Medicine of clinical transfusion supports studies in the field of clinical usage of blood components and derivatives by collecting and comparing the usage indicators at the national and regional levels.

Chapter VII. ACCOUNTABILITY.

Article 21. Accountability.

Physical persons and legal persons guilty for the infringement of the present Law shall bear, upon case, disciplinary, material, civil, administrative or criminal responsibility based on the provisions and in the order established by the current legislation.

Article 22. Infringements in the blood transfusion area.

The following actions in the blood transfusion area shall be deemed as infringements:

- a) Deliberate non-declaration of diseases and risk-transmissible factors by the donor in the course of medical examination;
- b) Carrying out blood transfusion activities with the aim to derive profit through trading blood or its components, which are considered as gratuitous;
- c) Donation of blood or blood components with the aim to sell them and derive profit or advantages;
- d) Disclosure of information that would violate the confidentiality of the donor and the recipient of blood or blood products;
- e) Physical and moral coercion over a person to donate blood or blood components;
- f) Collection of blood without the person's consent;
- g) transfusion of blood/blood components without the consent of the person or his/her legal representative (close relative) and the doctor in charge;
- h) collection of blood from a person who has not passed medical examination in advance;
- i) usage of blood and blood components without having passed the validation process in advance;
- j) illicit distribution and/or usage of a blood product that has not been included in the list of products approved by the Ministry of Health;
- k) carrying out blood collection, controlling, stockpiling, preparation, distribution and transfusion or management activities by an institution that has not been authorized by the Ministry of Health.
- l) Illicit taking out of blood, its components or blood preparations outside the country.

Article 23.

The Government within six months:

- a) shall submit proposals to the Parliament with respect to bringing the current legislation in compliance with the present Law;
- b) shall bring its regulatory documents in compliance with the present Law.

Chapter VIII.
FINAL PROVISIONS.

Article 24.

- (1) The present Law shall enter into force on the date of its publication.
- (2) The Law on Blood Donation No. 1458-XII from May 25, 1993 (Official Monitor 1993, No. 7, Article 212) shall be abrogated.

CHAIRPERSON OF THE PARLIAMENT

Marian LUPU