LAW OF GEORGIA
ON THE QUALITY AND SAFETY OF HUMAN BLOOD AND ITS COMPONENTS

Chapter I – General Provisions

Article 1 – Purpose of the Law
The purpose of this Law is to ensure the protection of the quality and safety of human blood (blood) and its components regardless of their purpose.

Article 2 – Scope of the Law
1. This Law regulates the main legal, organisational and other relevant measures for the protection of the quality and safety of blood and its components, as well as issues relating to the collection, testing, processing, storage and distribution of blood and its components.
2. Only the provisions of this Law which regulate issues relating to the collection, testing and export of blood and plasma shall apply to blood and plasma as a source material for the production of therapeutic agents derived from blood or plasma.
3. Issues relating to the production, storage and transportation of plasma as a source material for the production of therapeutic agents derived from blood or plasma shall be regulated by the relevant legislation.

Article 3 – Legislation of Georgia on the quality and safety of blood and its components
1. The legislation of Georgia on the quality and safety of blood and its components comprises the Constitution of Georgia, international agreements of Georgia, this Law and other legislative and subordinate normative acts.
2. This Law shall be based on the legislation of the European Union, in particular the relevant directives of the European Parliament and of the Council, for the purpose of envisaging the requirements of these directives in the legislation of Georgia.

Article 4 – Definition of terms used in the Law
For the purposes of this Law, the terms used herein shall have the following meanings:
a) blood - whole blood taken from a donor and processed for transfusion or further production;
b) blood component - the therapeutic part of blood (red cells, white cells, thrombocytes, plasma), which can be processed via different methods;
c) blood product - any therapeutic product obtained from blood or plasma;
d) therapeutic agent derived from blood or plasma - a therapeutic agent based on a blood component that is processed by a state or private institution by means of manufacturing. Such therapeutic agents are: albumin, coagulation factors, immunoglobulins of human origin;
e) donor - a person whose health, age and medical history meet the established criteria of compliance of a donor and who voluntarily donates blood or blood components;
f) being a blood donor - voluntary donation of blood and/or its components by a donor, as well as events aiming at organising the voluntary, benevolent donation and processing of blood and its components, and ensuring their safety;
g) processing - any step of the process of preparing a blood component between the collection of blood and the issuance of the blood component;
h) donation of blood - the procedure of donating blood by a donor that is carried out in accordance with the requirements of the legislation of Georgia;
i) autologous transfusion - transfusion when the donor and the recipient are the same person and predeposited blood and its components are used;
j) autologous donation - the collection of blood and its components from a person, intended for autologous transfusion or other use only for that person;
k) allogeneic donation - taking blood or its components from a person, intended for transfusion to another person, for use in medical equipment or for its/their use as a source material or raw material for the manufacturing of a therapeutic agent;
l) transfusion - the procedure of transfusion of donor blood or its components in the circulatory system of a patient (recipient);
m) recipient - a person who undergoes transfusion;
n) manufacturer of a therapeutic agent derived from blood or plasma - a state or private institution that produces various therapeutic agents from blood or plasma;
p) hemosurveillance - a combination of organised surveillance procedures relating to serious side effects and serious side reactions observed in donors and recipients and to further the epidemiological monitoring of donors;
q) serious side effect - any undesirable event relating to the collection, testing, processing, storage and distribution of

blood or its components that may cause death or a life-threatening condition, the limitation of capabilities, hospitalisation, illness or the prolongation of hospitalisation or illness of a patient (recipient);
r) serious side reaction - an unforeseen response observed in a donor or a patient (recipient) relating to the collection or transfusion of blood or its components which may result in death, a life-threatening condition, the limitation of opportunities, hospitalisation, illness or the prolongation of hospitalisation or illness of a donor or a patient (recipient);
s) traceability - the possibility of tracing each unit of blood or its components from the donor to the place of final destination (recipient, manufacturer of a therapeutic agent derived from blood or plasma, the handling of blood and its components) and from the place of final destination to the donor;
t) Ministry - Ministry of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs of Georgia;
u) Minister - Minister of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs of Georgia;
v) competent authority - a relevant authorised state body responsible for compliance with the individual requirements of this Law and appropriate subordinate normative acts, including controlling the compliance of blood institutions with the quality and safety rules of blood and its components established by this Law and appropriate subordinate normative acts;
w) blood institution - a non-entrepreneurial (non-commercial) legal entity responsible for any aspect of collecting and testing blood and its components, regardless of their purpose, as well as for the processing, storage and issuance of blood and its components for distribution and transfusion purposes. The term blood institution does not include a blood bank of a medical institution;
x) blood bank of a medical institution - a unit of a medical institution that receives, stores and issues blood and its components, and can perform donor and recipient compatibility testing exclusively for the internal use of the medical institution, including for ongoing transfusion activities in the medical institution. It does not perform the collection and processing of blood and its components;
y) reporting institution - a blood institution, a blood bank of a medical institution or an institution that carries out transfusion and provides a competent authority with information on a serious side effect and/or a serious side reaction;
z) mobile point - a temporary or mobile station which is used for the collection of blood and its components, is located outside the territory of a blood institution, but is its unit and falls under its control;
z_1) central testing laboratory - an independent legal entity or a structural unit of a central blood institution which performs the serological testing of a donor blood group and testing for markers of infectious diseases, and the quality control of blood and its products, and may also provide other examination services and diagnostic services;
z_2) quality system - the organisational structure, responsibilities, procedures, processes and resources used for the performance of quality management;
z_3) quality management - the coordinated, quality-related activities of management and control of an organisation, which is carried out at a blood institution or at a blood bank of a medical institution, at all levels;
z_4) quality control - a part of a quality system which is focused on the fulfilment of established requirements for quality;
z_5) quality assurance - a set of activities from blood collection to its distribution, carried out to assure the quality that is necessary for the intended use of blood and its components;
z_6) inspection - formal and impartial control, performed in accordance with established procedures for the purpose of assessing compliance with the requirements of this Law and appropriate subordinate acts, and for the purpose of identifying problems;
z_7) electronic system - an electronic system of the entry and processing of data, and the release of information which is used for reporting, traceability, automatic control or documentation;
z_8) release of blood or its component - a process by means of which blood or its component is released from quarantine via procedures which ensure compliance with the characteristics of the release of final products from quarantine;
z_9) quarantine - the physical isolation of blood or its components, as well as incoming materials/reagents for different amounts of time, during which blood or its components, as well as incoming materials/reagents, are in a waiting mode for receiving, issuing or confirming defects;
z_{10}) distribution - the supply of blood and its components to other blood institutions, blood banks of medical institutions and manufacturers of therapeutic agents derived from blood or plasma. Distribution does not include issuing blood and its components for transfusion;
z_{11}) issuance - supplying blood and its components for the purpose of transfusion to a recipient by a blood institution or a blood bank of a medical institution;
z_{12}) rejection of a donor - temporary or permanent suspension of a person's right to be a blood donor.

Article 5 – Availability of blood and its components

1. Everyone shall have the right to receive quality and safe blood and its components, when required.
2. The State shall promote voluntary, benevolent donation and ensure sustainable conditions for the quality and safety of blood and its components.
3. The State shall be obliged to ensure the existence of a sufficient number of blood institutions in the country for the uninterrupted availability of blood and its components.

Article 6 – Principles of being a blood donor

1. Blood donation shall be based on the principles of voluntariness, benevolence and anonymity.
2. The principle of voluntariness implies a right of a person to donate blood or its components by his/her own free will, without coercion.
3. The principle of benevolence implies that a person gives away blood or its components selflessly, without an expectation of monetary payment and/or benefits equivalent thereto.
4. It shall be impermissible to accept monetary payment and/or benefits equal thereto by a donor or another person in exchange for blood or its components, as well as to offer/give to him/her monetary payment and/or benefits equivalent thereto. It shall also be impermissible to trade in blood or its components in violation of the requirements of the legislation of Georgia.
5. The remuneration given to a donor during the time off provided for by Article 7(11) of this Law, a one-time monetary payment given to an honorary donor, a symbolic sign, souvenir or gift presented to a donor, the value of which cannot become an incentive to violate the principle of benevolence, but which will help encourage donation, shall not be regarded as a benefit equivalent to monetary payment.
6. The principle of anonymity implies the right of a donor and a recipient to donate anonymously, which includes the protection of personal data about the donor and the recipient (including genetic data) and the impossibility of their identification by a third party under the legislation of Georgia.
7. In order to achieve high standards of safety of blood and its components, the State shall promote the performance of donation in compliance with the principles of voluntariness, benevolence and anonymity.

Article 7 – Rights and obligations of a donor

1. The State shall provide donors with legal guarantees, including their health guarantees, and establish relief for donors.
2. The State shall ensure the equality of donors, regardless of their race, skin colour, gender, origin, ethnicity, language, religion, political or other views, social affiliation, property or titular status, or any other grounds.
3. A donor shall have the right to donate blood and its components on a voluntary basis, benevolently.
4. A donor shall have the right to receive comprehensive and easy-to-understand information on being a blood donor and the donation of blood (including written information) in accordance with Article 24(1) of this Law. On the basis of the above information, before each donation of blood and its components, a donor shall give written informed consent on the voluntary donation and confirm it with a signature.
5. Under the legislation of Georgia, a donor shall have the right to receive free medical assistance in accordance with the established norms, in the event of the deterioration of his/her health condition, or serious side effects or serious side reactions relating to the performance of the donor's function.
6. A donor shall have the right, in the case of temporary or permanent rejection of a donor by a blood institution, to receive notification thereof and take appropriate consultation, as well as a referral to a relevant medical institution for further examination and treatment at his/her own and/or the State's expense, if necessary.
7. A donor shall have the right to have his/her confidentiality maintained:
a) during an interview, or a consultation, and in the processing of any information relating to his/her health provided to authorised personnel;
b) when processing the results of an examination relating to a blood donation, as well as information relating to the traceability of blood and its components;
c) when receiving medical care.
8. A donor shall have the right to request the provision of safe conditions during the collection of blood and its components.
9. A donor shall have the right to receive incentives under Article 6(5) of this Law. Incentive mechanisms for donors shall be determined by an ordinance of the government of Georgia.
10. A donor shall have the right to receive a title of honorary donor in accordance with the procedure established by the government of Georgia. The procedure for awarding the title of honorary donor and the amount of one-time monetary payment shall be determined by an ordinance of the government of Georgia.
11. A donor shall have the right to be released from work when donating blood and its components. An employer shall be obliged to send the employee, with a prior agreement, to donate blood or its components without delay.
12. On the day of donation of blood or its components, a military service person shall be released from detail, watch and other duties of military service.
13. A donor shall be obliged to provide a blood institution with complete information on his/her identity, identification data, health status (including performed medical procedures, vaccinations, medications taken) and behaviour involving

the risk of infection, as well as other information required by the blood institution to assess the donor's compatibility.

Article 8 – Rights of a recipient and the informed consent thereof

1. Every precaution shall be taken to protect the health and safety of a recipient.
2. Transfusion may be performed only on the basis of the informed consent of a recipient, except for the cases provided for by paragraph 3 of this article.
3. If a recipient is a minor or is not able to make an informed decision, informed consent shall be obtained from the recipient's relative or legal representative. Where a recipient is underage, the consent of the recipient's legal representative shall be obtained along with the recipient's informed consent. If such consent cannot be obtained, a decision on transfusion shall be made by a medical service provider taking into consideration the health interests of the recipient.
4. The Law of Georgia on Patient Rights shall apply to issues relating to the protection of the recipient's health and safety, as well as to informed consent as provided for by this article.
5. The methodology of the performance of transfusion and the clinical indications thereof shall be approved by an order of the Minister.

Chapter II – Managing the Field of the Quality and Safety of Blood and Its Components

Article 9 – Obligations of the State in the field of the protection of the quality and safety of blood and its components

1. The State shall be obliged to ensure the determination and implementation of state policy in the field of the quality and safety protection of blood and its components, the development and implementation of appropriate procedures for quality and safety protection, and control over the implementation of these procedures.
2. In order to ensure the quality and safety protection of blood and its components, the State shall be obliged to:
a) ensure the determination of the requirements of the country for blood and its components, as well as blood products as products of strategic importance, and the determination and creation of safe/strategic supplies to satisfy the above requirements;
b) ensure the establishment and maintenance of a continuous and efficient supply system of quality and safe blood, its components, and blood products based on voluntary, benevolent donation;
c) encourage sustainable educational and social campaigns promoting voluntary, benevolent and regular donation;
d) ensure the support of the processes of collection, testing, processing, storage and distribution of blood and its components in accordance with the development of transfusion medicine and scientific and technical progress;
e) create hemosurveillance and traceability systems and ensure their operation;
f) provide appropriate conditions for the training of qualified personnel in the field of transfusion medicine;
g) ensure the operation of a unified data base/system for blood and its components with a view to the development of the safety of blood and its components and their donation;
h) ensure the functioning of the competent authority (authorities) provided for by Article 10 of this Law;
i) perform other functions as determined by the legislation of Georgia.
3. The State shall provide control of the implementation of state policy and the appropriate procedures in the field of the quality and safety protection of blood and its components through the competent authority (authorities).

Article 10 – Competent authority (authorities)

1. A competent authority (authorities) in the field of the quality and safety protection of blood and its components within the scope of powers granted to it by the legislation of Georgia shall be responsible for observing the requirements of this Law and relevant subordinate normative acts, including controlling the compliance of blood institutions with procedures for the quality and safety protection of blood and its components established by this Law and relevant subordinate normative acts.
2. A relevant competent authority shall be a licence/permit issuing body as provided for by Article 13 of this Law.
3. A relevant competent authority shall be authorised to perform measures provided for by legislation relating to the inspection and proper control of blood institutions and blood banks of medical institutions.
4. Within its powers, a relevant competent authority shall ensure the performance of traceability and hemosurveillance of blood and its components in the country, and exercise other powers granted to it by this Law and subordinate normative acts.

Article 11 – Blood institution

1. A blood institution shall be created in the organisational and legal form of a non-entrepreneurial (non-commercial) legal entity, in accordance with the procedure established by the legislation of Georgia.
2. A blood institution shall carry out its activities in accordance with a licence issued by a competent authority, this Law and other legal acts.
3. For the purpose of creation and management of safe supplies to ensure uninterrupted access to high standard blood and its components for recipients and medical institutions, to determine the requirement of the country for blood and its components, as well as blood products as the products of strategic importance, and to satisfy the requirements of medical

institutions, the central blood institution established by the State shall operate in the country, that ensures the exercise of powers provided for by this Law and other legislative and subordinate normative acts of Georgia.
4. The central blood institution provided for by paragraph 3 of this article shall be established by the government of Georgia on behalf of the State, and after its establishment the Ministry shall exercise all the powers of a founder.
5. A blood institution shall be authorised to:
a) attract and select donors, collect blood and its components, test, process and store blood in the central testing laboratory, distribute it according to the terms and procedures established under an order of the Minister or agreed upon with the central blood institution, as well as issue blood for transfusion purposes;
b) develop and submit to the Ministry information on the requirement for blood, its products and intermediate products for the next year for the approval of the plan for the corresponding year, on the basis of the analysis of information on the annual requirement reported from blood banks of medical institutions;
c) ensure the implementation of activities necessary for the adequate traceability and hemosurveillance of blood and its components;
d) ensure the attraction of benevolent donors and their maintenance as regular donors;
e) exercise other powers as provided for by this Law, subordinate normative acts issued on the basis of this Law, other legislative and subordinate normative acts, and the statute of the blood institution.
6. A blood institution shall be obliged to carry out its activities in accordance with the requirements of this Law and the licence conditions established for the above activities.
7. The organisational structure of a blood institution, the procedure for establishing a management body (electing a director) and the term of office, as well as the procedure for approving the budget and plan of activities of a blood institution, shall be determined by the statute of the blood institution.
8. A blood institution shall have the right to collect blood at a fixed location (permanent station) and/or through mobile points and/or mobile units located outside the territory of the blood institution.
9. A blood institution shall be obliged to sell blood products and intermediate products at marginal prices approved in advance, except in the case of the export of these products.
10. The prices of blood products and intermediate products shall be approved by the Minister.
Law of Georgia No 1471 of 1 April 2026 – website, 1.4.2026

Article 12 – Responsible person

1. When carrying out its activities, a blood institution shall be obliged to ensure the availability of a responsible person in that institution in accordance with this Law, subordinate normative acts issued on the basis of this Law, and other legal acts. Official powers, tasks, minimum qualification requirements, and the procedure for transferring authority to another relevant person shall be determined by an appropriate subordinate normative act.
2. A blood institution shall notify a competent authority of the data on the responsible person provided for by paragraph 1 of this article, and the specific tasks he/she is responsible for.
3. In the event of the suspension of the official authority of the responsible person as provided for by paragraph 1 of this article, or his/her dismissal, a blood institution shall immediately notify a competent authority of the data on a new responsible person and the date of his/her appointment.

Article 13 – Licencing/issuing permit

1. A blood institution shall collect blood and its components, and test, process, store, distribute and/or issue it/them to a central testing laboratory (industrial transfusiology activities) on the basis of a relevant licence.
2. A blood bank of a medical institution shall receive, store and test the compatibility of a donor and a recipient of blood and its components, and issue them for the purpose of transfusion for the internal use of the medical institution based on the appropriate permit issued to the relevant medical institution, provided the conditions of that permit are complied with.
3. A licence/permit to carry out the activities referred to in paragraphs 1 and 2 of this article shall be issued by the relevant competent authority on the basis of this Law, the Law of Georgia on Licences and Permits, and appropriate subordinate normative acts.
4. The procedure for issuing a licence/permit and the licence/permit conditions shall be determined by this Law, and shall be in accordance with this Law and the Law of Georgia on Licences and Permits.
5. The amount of licence/permit fees to be paid for carrying out a relevant activity shall be determined by the Law of Georgia on Licence and Permit Fees.
6. A licence shall be issued for an indefinite period.
7. The form of a licence certificate shall be determined by an order of the Minister.
8. A relevant competent authority shall have the right to refuse the issuance of a licence in accordance with Article 11 of the Law of Georgia on Licences and Permits and this Law. This refusal can be appealed in accordance with the procedure established by the law.
9. A competent licence issuing body shall be authorised to revoke the licence of a blood institution, if control measures related to the fulfilment of the licence conditions confirm that the blood institution has not fulfilled the licence

conditions and is subject to liability in the form of fines in accordance with the procedure established by this Law and the Law of Georgia on Licences and Permits.
Law of Georgia No 1471 of 1 April 2026 – website, 1.4.2026

Article 14 – Control and inspection

1. A competent authority shall control the fulfilment of licence/permit conditions in accordance with the procedure established by this Law and other legislative and subordinate normative acts. The failure to fulfil licence/permit conditions by a holder of a licence/permit shall result in liability in accordance with the procedure established by this Law.
2. A competent authority shall carry out the measures of inspection of a blood institution and a blood bank of a medical institution.
3. A competent authority shall carry out an inspection of a blood institution and a blood bank of a medical institution at least once every 2 years, and in the event of a serious side effect, a serious side reaction or a suspicion thereof, an extraordinary, special inspection shall be carried out.
4. When carrying out control and inspection measures, a relevant authorised person of a competent authority shall have the right to:
a) inspect, in accordance with the legislation of Georgia, a blood institution and a blood bank of a medical institution, any documents relating to their activities, and request them to carry out their activities in accordance with this Law, any subordinate normative acts based thereon, and the licence/permit conditions;
b) identify deficiencies, violations and/or any non-compliance with the legislation of Georgia in the operation of a blood institution and a blood bank of a medical institution;
c) take samples for inspection and analysis during the inspection process;
d) indicate to a blood institution or a blood bank of a medical institution any detected deficiencies and/or incidences of non-compliance, and request the rectification of same;
e) in the event of any violation of the requirements of the legislation of Georgia identified in the activities of a blood institution or a blood bank of a medical institution, take a decision on imposing a fine on the blood institution or medical institution in question, in accordance with Chapter V of this Law and/or the Law of Georgia on Licences and Permits;
f) if any blood, and/or its components and/or blood products do not meet the quality and safety requirements established by this Law and appropriate subordinate normative acts, ensure its/their rejection, confiscation and destruction in accordance with the procedure established by the legislation of Georgia, or ensure its/their use for the purposes provided for by Article 29(4) of this Law;
g) evaluate data on serious side effects and serious side reactions received from reporting institutions and respond in a timely manner, within the scope of powers granted to it;
h) exercise other rights granted by the legislation of Georgia and fulfil other duties assigned to them.

Article 15 – Blood bank of a medical institution

1. A blood bank of a medical institution shall be authorised to:
a) receive from blood institutions processed blood and blood components and store them for further use;
b) manage stocks of blood and its components. The procedure for the management of stocks of blood and its components shall be approved by an order of the Minister;
c) perform pretransfusion testing of blood and its components (donor and recipient compatibility testing). The procedures and rules for testing to be performed by a blood bank of a medical institution shall be determined by a subordinate normative act as provided for by Article 27(6) of this Law;
d) issue blood and its components for the purpose of transfusion;
e) carry out its activities in coordination with blood institutions;
f) implement other activities falling within the scope of its powers under this Law and any subordinate normative acts issued on the basis thereof.
2. A blood bank of a medical institution shall have a quality system created in accordance with the procedure established by this Law and any subordinate normative acts issued on the basis thereof.
3. A blood bank of a medical institution shall comply with the requirements established by this Law and any subordinate normative acts issued on the basis thereof with respect to traceability, serious side effects and serious side reactions, the storage and issuance of blood and its components, the protection of personal data about donors, as well as to the personnel of a blood institution.
4. A blood bank of a medical institution shall, at the beginning of the year, provide a blood institution with detailed information on the requirements for blood and its components for transfusions to be carried out during the year, on the basis of the data of the previous year.

Chapter III – Hemosurveillance

Article 16 – Essence of hemosurveillance

1. The State, in accordance with this Law and any subordinate normative acts issued on the basis thereof, shall ensure the organisational surveillance of the transfusion chain (complete process) via the procedures for the traceability of this process and for the reporting of serious side effects and serious side reactions.
2. The procedure for performing hemosurveillance shall be approved by an order of the Minister.

Article 17 – Traceability

1. Traceability shall be performed by means of the accurate identification of a donor and a recipient, and proper laboratory procedures and record keeping, and a proper identification system and labelling system.
2. Traceability procedures shall include activities relating to the identification of each donor, each blood donation, each tested, processed, stored, issued and/or distributed blood unit or processed blood component, each recipient, each transfusion, and all the institutions involved in this process. Traceability shall ensure the search for blood components at their locations and stages of processing.
3. In order to perform traceability procedures in the shortest possible period of time, it is necessary to have in place an electronic system support.
4. A blood institution shall be obliged to:
a) ensure the proper operation of a traceability system in accordance with the rules and procedures established by this article and any subordinate normative act issued on the basis of this Law;
b) have a unique identifier allowing connection with each collected blood unit and processed blood component of that institution;
c) have an identification system that allows an accurate identification of each blood donation, collected blood unit, and processed blood component, and thus the full traceability of each donor, each transfusion and each recipient;
d) store traceability data for at least 30 years on an appropriate, readable data carrier.
5. Any institution which may be supplied with blood or blood components shall be obliged to ensure the operation of a traceability system which records each blood unit or blood component supplied to it, regardless of whether it was transfused, rejected or returned to the blood institution.
6. In the case of an import of blood or its components, the donor identification system shall have an equivalent level of traceability.
7. Other rules and procedures of traceability shall be determined by the subordinate normative act provided for by Article 16(2) of this Law.

Article 18 – Notification of serious side effects and serious side reactions

1. A competent authority shall ensure the creation and proper operation of a unified system for monitoring serious side effects and serious side reactions.
2. The reporting institution shall, in accordance with this Law and any subordinate normative act issued on the basis thereof:
a) introduce procedures for recording serious side effects and/or serious side reactions, and keep and store the relevant records;
b) immediately provide (submit) information on any alleged serious side effect and/or alleged serious side reaction to a competent authority in the form of a proper notification, and for this purpose, ensure communication with the above authority in accordance with the procedures determined in advance;
c) carry out detailed analysis of any identified serious side effect or serious side reaction in order to determine the causes thereof;
d) in the case of the detection of a serious side effect and/or a serious side reaction, in order to fulfil the obligation provided for by subparagraph (b) of this paragraph, prepare the relevant information (notification) on the effect/reaction as soon as it is assessed;
e) introduce an accurate, effective and verifiable procedure for removing from distribution the blood and/or blood component, due to which a serious side effect and/or serious side reaction was or may be detected, and which is related to the submitting of an appropriate notification to the competent authority;
f) submit a report on serious side effects and serious side reactions annually to a competent authority;
g) perform other functions assigned to it by an appropriate subordinate normative act.
3. Other rules and procedures for the detection, monitoring and reporting of serious side effects and serious side reactions shall be determined by the subordinate normative act provided for by Article 16(2) of this Law.

Chapter IV – Quality System of a Blood Institution and a Blood Bank of a Medical Institution

Article 19 – Quality system of a blood institution and a blood bank of a medical institution

1. The State shall take all necessary measures to ensure the establishment of a quality system by each blood institution and each blood bank of a medical institution based on international standards and principles of good practice (including the guidelines of best practice developed jointly by the European Commission and the European Directorate of the Council of Europe).

2. A blood institution, and a blood bank of a medical institution, shall be obliged to introduce a quality system for blood and its components and to ensure the operation of that system based on principles of good practice. The quality system shall take into account all the elements of activities based on principles of good practice, which shall comply with characteristics determined in advance, and shall aim at the quality assurance of blood and its components.
3. A blood institution, and a blood bank of a medical institution, shall ensure a systematic approach to the quality system, and check its efficiency on a regular basis, and, if necessary, take adequate measures to improve the system.
4. Georgia selectively recognises a list of international and national guidelines and standards of good practice. This list shall be recognised by the government of Georgia. The said guidelines and standards shall be implemented gradually by the government of Georgia, and the national guidelines and standards of good practice, as well as the procedures for compliance with them, shall be approved by an order of the Minister.
5. The appropriate standards and technical requirements for the quality and safety of blood and its components shall be determined by this Law and any appropriate subordinate normative act(s).

Article 20 – Personnel of a blood institution

1. A blood institution shall be obliged to have a necessary number of personnel required for activities related to collecting, testing, processing, storing and distributing blood and its components, who shall have completed training relevant to their functions, and each of whom has a job description.
2. The personnel of a blood institution directly participating in the process of collecting, testing, processing, storing and distributing blood and its components, shall have the corresponding qualifications necessary for the performance of their functions, and shall have completed appropriate training. A blood institution shall ensure the timely, appropriate and periodic certification and retraining of its personnel.

Article 21 – Relevant facilities of a blood institution and a blood bank of a medical institution and the spaces thereof; equipment, materials and reagents

1. The relevant facilities of a blood institution and a blood bank of a medical institution and the spaces thereof, including mobile stations and permanent stations, shall be adapted and maintained in a manner that allows them to perform their functions and carry out their activities. These facilities and spaces shall enable the performance of work in a logical order to minimise the risk of errors. In addition, the efficient cleaning and maintenance of such facilities and spaces shall be ensured to minimise the risk of contamination.
2. The relevant facilities of a blood institution and a blood bank of a medical institution shall be planned and equipped in accordance with the requirements of an appropriate subordinate normative act.
3. The relevant units of equipment in a blood institution and a blood bank of a medical institution shall be subject to validation and calibration. They shall be technically sound and provided with regular servicing. In addition, instructions for equipment shall be available in the official language of the State and appropriate records on the condition of equipment shall be kept.
4. Equipment shall be selected so as to minimise the risk to a donor, the personnel, or a blood component.
5. All equipment, materials and reagents shall comply with the relevant regulation of the European Parliament and of the Council on medical devices, and in the case of the collection of blood and its components in another country, with an equivalent standard.
6. Records on the inventory of the equipment shall be kept for the term agreed upon with the competent authority.
7. In the case of using an electronic system, the relevant software and hardware, and the backup procedure, shall be subject to validation before use, and afterwards they shall be inspected regularly to ensure their reliability, at intervals agreed upon with the competent authority. Software and hardware shall be protected from unauthorised use or unauthorised modification. Additionally, the availability of backup procedures shall prevent the loss or damage of data in the event of an expected or unexpected interruption or functional failure of the electronic system.

Article 22 – Documentation and records

1. A blood institution and a blood bank of a medical institution shall, in accordance with the procedure established by a relevant subordinate normative act, keep the documentation that describes characteristics, procedures and records relating to each of the activities they carry out. In addition, the records shall be kept in accordance with the procedure established by this Law and a relevant subordinate normative act. A blood institution and a blood bank of a medical institution shall keep the medical documentation on the activities carried out in accordance with the procedure established, and shall document the appropriate instructions, training and reference manuals and reporting forms.
2. The documentation referred to in paragraph 1 of this article shall be available to the competent authority in the process of carrying out an inspection and control in accordance with the procedure established by Law.

Article 23 – Donor compatibility

1. The right to donate blood shall be granted to a person who meets the donor compatibility criteria established by this Law and a subordinate normative act issued on the basis of this Law, and who has completed the procedures for donor selection and compatibility assessment.

2. A donor can be a person from 18 to 65 years of age. Taking blood and its components from a minor between 17 and 18 years of age shall be allowed only on the basis of the informed consent from him/her and his/her parent(s) or other legal representative, as a matter of urgency and in the absence of an option for alternative treatment.
3. The procedures for donor selection and compatibility assessment (including the examination of donor blood and its components) provided for by paragraph 1 of this article shall be carried out with respect to all donors of blood and its components (including autologous donors). A blood institution shall ensure that a donor meets the donor compatibility criteria provided for by this Law.
4. Donor compatibility shall be assessed and a donor shall be interviewed before each donation. The authorised medical personnel shall be obliged to receive from a donor the information necessary for the assessment of his/her compatibility, and a donor shall be obliged to provide the authorised medical personnel with accurate information. A donor compatibility record and final assessment document shall be signed by an authorised qualified person.
5. The results of donor selection and compatibility assessment, as well as the results of laboratory testing of blood and its components, shall be documented; the results of donor rejection shall be notified to the donor by an authorised person of a blood institution. The criteria for rejection of a donor according to the results of the assessment of the donor compatibility shall be determined by the subordinate normative act provided for by paragraph 6 of this article, and in the case of rejection of a donor as a result of the laboratory testing of blood and its components, the manner and the procedures for notifying this to the donor shall be determined in accordance with the subordinate normative act provided for by Article 27(6) of this Law.
6. The procedure for donor selection and compatibility assessment shall be approved by an order of the Minister.

Article 24 – Information to be provided to and received from a donor

1. A blood institution shall be obliged to provide a donor with comprehensive and easy-to-understand information (including written information) on being a blood donor and the donation of blood (including the amount of blood and blood components to be collected from a donor), as well as the risks of donation, potential reactions and other potential implications for the donor's health, the potential results of laboratory testing, the protection of personal data about the donor, and his/her rights and obligations. In addition, a blood institution shall be obliged to receive from a donor the information provided for by Article 7(13) of this Law and the written informed consent provided for by paragraph 4 of the same article.
2. A blood institution, and a blood bank of a medical institution, shall take all necessary measures to ensure the protection of the personal data available to it concerning a donor and a recipient.
3. The types of information to be provided to and received from a donor considered by paragraph 1 of this article, as well as the procedure for their provision and receipt, shall be determined by the subordinate normative act provided for by Article 23(6) of this Law.

Article 25 – Autologous donation

1. Autologous blood and blood components, as well as blood components collected and processed for special purposes, shall be accurately identified and stored, and transported and distributed separately from blood and blood components received through allogeneic donation.
2. Autologous donor compatibility shall be assessed in accordance with the procedure established by the subordinate normative act provided for by Article 23(6) of this Law, and other issues relating to autologous donation shall be determined by an appropriate subordinate normative act.

Article 26 – Collection of blood and its components

1. In the process of blood collection, donation shall be carried out in accordance with the procedure established by this Law and a relevant subordinate normative act.
2. When collecting blood and its components, the identity of a donor shall be verified and adequately registered. The relationship between a donor on the one hand, and the blood, its components and blood samples on the other, shall be clearly established.
3. The sterile blood bag systems used during the collection and processing of blood and its components shall be CE marked; if blood and its components are collected in another country, they shall comply with equivalent standards. The batch number of each blood component indicated on the blood bag shall be traceable.
4. Procedures for blood collection shall be performed so as to minimise the risk of bacterial contamination.
5. Procedures for record keeping, and marking blood bags and laboratory samples with donation numbers for their complete identification, shall be carried out in accordance with this Law and the subordinate normative act provided for by paragraph 7 of this article.
6. In order to ensure the quality of blood before and after blood collection, the conditions for handling and storing a blood bag shall be observed as much as possible.
7. Other procedures for the collection of blood and its components shall be approved by an order of the Minister.

Article 27 – Testing and processing of blood and its components

1. A blood institution shall be obliged to perform the testing of blood and its components during each donation of blood and its components.
2. Donor's blood shall be tested by the central testing laboratory.
3. The following types of testing of the whole blood, apheresis and autologous blood shall be mandatory:
a) determination of ABO group (except for plasma determined for fractionation);
b) determination of Rh D-group (except for plasma determined for fractionation);
c) testing for HIV infection;
d) testing for hepatitis C;
e) testing for hepatitis B;
f) testing for syphilis;
g) other additional testing for specific components or donors, or due to the epidemiological situation (if necessary).
4. Laboratory blood sampling shall be performed at the time of donation. Proper conditions for the processing and storage of examination materials shall be strictly observed.
5. The procedure for assessing the quality of laboratory examinations shall be determined by a corresponding subordinate normative act.
6. The requirements and procedures relating to the testing of blood and its components (including the requirements and procedures relating to serological, molecular, immunohematological and other laboratory testing for infections transmitted through transfusion), and the description of the requirements for providing laboratory diagnostic services, as well as the requirements for processing and quality assurance of blood and its components, shall be approved by an order of the Minister.
7. Blood and its components shall be processed by means of relevant, validated procedures. These procedures shall also include measures necessary for avoiding the risk of bacterial contamination of processed blood components.
8. In the case of the import of blood or its components, it shall be confirmed that the blood and its components have been tested in accordance with the procedure established by the normative act provided for by paragraph 6 of this article.

Article 28 – Labelling

1. The labelling system of blood and its components collected, tested, processed, stored, issued and/or distributed in the territory of Georgia shall comply with the identification system and procedures provided for by Articles 17(1) and (2) of this Law, as well as the requirements established by paragraph 7 of the same article and the subordinate normative acts provided for by paragraph 4 of this article.
2. Labels used at all stages of the production of blood or its components shall contain the relevant identification information.
3. The labelling system for collected blood, intermediate and processed blood components, and samples, shall identify the type of contents without an error.
4. The labelling procedures, including the labelling procedures for autologous blood and its components, shall be approved by an order of the Minister.

Article 29 – Release, storage, transportation and distribution of blood and its components

1. If quarantined blood or blood components, after being subject to compatibility assessment (testing) procedures, comply with the characteristics of release from quarantine and with all the quality and safety criteria, and at the same time the document records which confirm this are available, an authorised person shall officially release each unit from quarantine by an act of release from quarantine.
2. Quarantine blood and its components shall be stored separately from blood and its components released from quarantine. The status of release from quarantine shall be indicated on the label of the blood or its components in accordance with Article 28(2) of this Law.
3. If the final unit of blood or its components cannot be released from quarantine based on the results of testing performed in accordance with Article 27 of this Law, traceability shall be carried out to ensure the identification of other components of the same donation, and the components processed during the previous donation from the same donor, and the records of the relevant donor shall be immediately updated.
4. Blood or its components which do not comply with the quality and safety standards of blood and its components established by the appropriate subordinate normative act shall be rejected and destroyed or, on the basis of the prior consent of a donor, shall be used for future scientific research.
5. Storage areas shall provide the possibility to safely and separately store different categories of blood, blood components and materials/reagents (including quarantined materials/reagents and materials/reagents released from quarantine), as well as blood and blood components collected for special purposes (for example, autologous blood). In addition, in order to avoid the contamination of blood and its components during the entire period of storage, the procedures for their storage and distribution shall be validated and then inspected on a regular basis.
6. Other requirements for the release, storage, transportation and distribution of blood and its components shall be determined by a relevant subordinate normative act.

Article 30 – Withdrawing blood and its components

1. Any complaint and/or information (including on serious side effects or serious side reactions) that provides grounds for assuming that a defective/low quality blood component was issued shall be documented and examined for the purpose of determining the reason why the blood component is defective/of low quality. If necessary, the blood component shall be withdrawn and appropriate measures shall be taken to prevent recurrence. In addition, a notification of a serious side effect or serious side reaction (if any) shall be submitted to a competent authority.
2. A blood institution shall have appropriate personnel who will assess the necessity of withdrawing blood or its components, and take relevant measures.
3. The procedure for withdrawing blood or its components shall be determined by a relevant subordinate normative act.

Article 31 – Other rules and procedures relating to the quality system

1. Activities relating to the quality system, which are to be carried out outside the territory of a blood institution, shall be carried out on the basis of a corresponding written agreement.
2. In the process of managing the quality system, a blood institution shall:
a) have a system required to ensure the prevention and solution of problems relating to the compatibility and quality of blood components;
b) carry out systematic analysis of data on blood quality in order to reveal such quality related problems for the solution of which appropriate measures need to be taken, as well as to identify undesirable trends whose avoidance requires the implementation of appropriate measures;
c) examine all errors and cases, and document them in order to identify systemic problems.
3. In order to inspect compliance with the procedures relating to the quality system, a blood institution shall have internal inspection and audit systems for all components of operation. The said internal inspection and audit shall be performed regularly, by competent persons trained for this purpose, in accordance with an appropriate subordinate normative act.
4. A blood institution, and a blood bank of a medical institution, shall prevent the illegal processing of personal data so as to guarantee the traceability of donation.

Article 32 – Export and import of blood and its components

1. It shall be impermissible to export and import blood and its components from and to Georgia, except for the cases provided for by paragraphs 2 and 3 of this article.
2. During a state of emergency or martial law, and also in the case of a lack of blood and its components in the country, when it is justified by the extraordinary and urgent nature of the situation, the Minister shall have the right to take a decision on the export or import of blood and its components, for which the country shall have a properly functioning logistics scheme and a list of partner countries, from which blood and its components may be exported, when necessary.
3. A blood institution shall be authorised to export plasma produced in excess of the amount determined by the requirement plan provided for by Article 11(5)(b) of this Law, which can be used for the production of therapeutic agents.
4. A blood institution shall carry out activities provided for by paragraph 3 of this article on the basis of an appropriate licence issued by a competent authority in accordance with the legislation of Georgia.
5. The procedure for issuing a licence provided for by paragraph 4 of this article and the licence conditions shall be determined by this Law, and also in accordance with this Law and the Law of Georgia on Licences and Permits, and the amount of licence fees shall be determined by the Law of Georgia on Licence and Permit Fees. A licence shall be issued for an indefinite period.
6. Blood and its components imported from other countries (including blood and blood components used as a source material or raw materials for the production of therapeutic agents derived from blood or plasma) which are to be distributed within the country, shall comply with the standards and specifications equivalent to those of the quality system of the blood institution as determined by this Law (including traceability requirements).
7. Other rules and procedures for the export and import of blood and its components shall be approved by an order of the Minister.

Chapter V – Responsibility

Article 33 – Grounds for liability

1. Liability for the violation of requirements in the field of the quality and safety protection of blood and its components shall be determined by the legislation of Georgia, including this Law.
2. Criminal liability for the violation of requirements established in the field of the quality and safety protection of blood and its components shall be determined by law.
3. The right to draft an administrative offence report as provided for by this Law shall be granted to an authorised person of a competent authority, and the relevant case shall be reviewed by a court.
4. The form of an administrative offence report as provided for by this Law, as well as the procedure for its filling and submission shall be approved by an order of the Minister.

5. In the event of a commission of an administrative offence as provided for by this Law, proceedings shall be carried out in accordance with the Administrative Offences Code of Georgia.

Article 34 – Collection, processing, storage, distribution and/or issuance of blood or its components (industrial transfusiology activities) without a proper licence

1. The collection, processing, storage, distribution and/or issuance of blood or its components by a person (industrial transfusiology activities) without a proper licence shall result in the imposition of a fine of not more than GEL 50 000.
2. The act provided for by the paragraph 1 of this article, if committed repeatedly, shall result in the imposition of a fine of not more than GEL 100 000.

Article 35 – Failure of a blood institution to fulfil licence conditions for the collection, processing, storage, distribution and/or issuance of blood and its components (industrial transfusiology activities)

The failure to fulfil the licence conditions for the collection, processing, storage, distribution and/or issuance of blood and its components (industrial transfusiology activities) shall result in the imposition of a fine on a blood institution in accordance with the violation of licence conditions, but of not more than GEL 10 000.

Article 36 – Failure to report on a serious side effect and/or serious side reaction

1. The failure of a reporting institution to submit information (adequate notification) as provided for by Articles 18(2)(b) and (d) of this Law to a competent authority shall result in the imposition of a fine of GEL 5 000 on the reporting institution.
2. The act provided for by the paragraph 1 of this article, if committed repeatedly, shall result in the imposition of a fine of GEL 10 000 on the reporting institution.
3. The failure of a reporting institution to submit to a competent authority a report as provided for by Article 18(2)(f) of this Law shall result in the imposition of a fine of GEL 5 000 on the reporting institution.
4. The failure to eliminate the grounds for a relevant offence within 30 calendar days from the imposition of the fine as provided for by paragraph 3 of this article shall result in the imposition of a fine of GEL 10 000 on the reporting institution.

Article 37 – Violation of the right to donate

1. The failure of a donor to provide a blood institution with information on his/her identity, identification data, health status (including the performed medical procedures, vaccination, medications taken) and behaviour involving the risk of infection, as well as other information required to assess donor compatibility, or the provision of incorrect information, shall result in the imposition of a fine of GEL 1 000.
2. The act provided for by the paragraph 1 of this article, if committed repeatedly, shall result in the imposition of a fine of GEL 2 000.
3. The failure of a blood institution to provide a donor with information on being a blood donor and the donation of blood, and/or the failure to obtain from the donor his/her identity, identification data, information on health status and behaviour involving the risk of infection, as well as other information required to assess donor compatibility, shall result in the imposition of a fine of GEL 5 000.
4. The act provided for by paragraph 3 of this article, if committed repeatedly, shall result in the imposition of a fine of GEL 10 000.
5. The violation of other rules and procedures for being a blood donor, as established by this Law, shall result in the imposition of a fine of GEL 5 000.
6. The act provided for by paragraph 5 of this article, if committed repeatedly, shall result in the imposition of a fine of GEL 10 000.

Article 38 – Illegal trade in blood or its components, illegal export or import of blood or its components

1. Accepting monetary payment and/or benefits equivalent to monetary payment by a donor or another person in exchange for donated blood or its components shall result in the imposition of a fine of GEL 1 000.
2. Offering/giving monetary payment and/or benefits equivalent to monetary payment to a donor in exchange for donating blood or its components shall result in the imposition of a fine of GEL 5 000.
3. Trading in blood or its components in violation of the requirements of the legislation of Georgia, if not in any relevant case as provided for by this chapter, shall result in the imposition of a fine of GEL 20 000.
4. The export or import of blood and its components, except for the cases provided for by Articles 32(2) and (3) of this Law, shall result in the imposition of a fine of GEL 10 000, along with the confiscation of the subject of the relevant offence.

Note: When imposing the confiscation provided for by this paragraph, the enforcement officer shall execute the corresponding ordinance.

5. The violation of licence conditions for the export of blood and its components shall result in the imposition of a fine of GEL 10 000.

6. The act provided for by paragraph 5 of this article, if committed repeatedly, shall result in the imposition of a fine of GEL 20 000.

Article 39 – Failure to draft a document on activities carried out or failure to fulfil the obligation to keep records

1. The failure to draft a document or failure to fulfil the obligation to keep records concerning the activities carried out by a blood institution/blood bank of a medical institution shall result in the imposition of a fine of GEL 10 000.
2. The act provided for by paragraph 1 of this article, if committed repeatedly, shall result in the imposition of a fine of GEL 20 000.

Article 40 – Violation of appropriate standards and technical requirements for the quality and safety of blood and its components

1. The violation of appropriate standards and technical requirements for the quality and safety of blood and its components (if it is not a licence/permit condition or any other relevant case as provided for by this chapter) shall result in the imposition of a fine of GEL 10 000, along with the confiscation of the object (blood or its component) of the relevant offence.
2. The act provided for by paragraph 1 of this article, if committed repeatedly, shall result in the imposition of a fine of GEL 20 000, along with the confiscation of the object (blood or its component) of the relevant offence.

Note: When imposing the confiscation provided for by this paragraph, the enforcement officer shall execute the corresponding ordinance.

Chapter VI – Transitional Provisions

Article 41 – Regulation of the activities of an operating blood institution (blood transfusion institution/blood bank) in the transitional period

1. A blood institution (blood transfusion institution/blood bank) operating before the entry into force of this Law, which operates in accordance with the Law of Georgia of 21 March 1995 on the Donation of Blood and Its Components, and the appropriate legal acts, shall be obliged to:
a) register, by 1 September 2025, in the organisational and legal form of a non-entrepreneurial (non-commercial) legal entity as provided for by this Law;
b) provide a body issuing a licence to the blood institution with an appropriate extract from the Registry of Entrepreneurial and Non-entrepreneurial (Non-commercial) Legal Persons within 7 days after being registered as a non-entrepreneurial (non-commercial) legal person for the purpose of making changes to the licence, based on subparagraph (a) of this paragraph. In case of the violation of the requirements of this subparagraph and subparagraph (a) of this paragraph, a relevant licence issuing body shall be authorised to use the liability forms provided for by the same law based on Article 21(1) of the Law of Georgia on Licences and Permits;
c) in accordance with the determined stages but not later than 1 April 2030, ensure compliance with the principle of benevolence in accordance with the requirements of Articles 6(3) and (4) of this Law. The above stages shall be determined in accordance with the licence conditions established under sub-paragraph (d) of this paragraph, indicating the percentage ratio of the benevolent donation;
d) in accordance with the determined stages but not later than 1 October 2030, ensure compliance with the procedures established under this Law and subordinate normative acts adopted/issued on its basis, as well as licence conditions determined by this Law, the procedures established under subordinate normative acts adopted/issued on its basis and the Law of Georgia on Licences and Permits under the terms and procedures determined by an ordinance/relevant normative act of the Government of Georgia, in compliance with the following procedure:
d.a) by 1 October 2026, ensure compliance with the licence conditions of the first stage. In the case of detection of non-compliance with the licence conditions by the licence issuing body until 1 January 2027, the issued licence shall be revoked and the blood institution shall terminate operation;
d.b) by 1 October 2028, ensure compliance with the licence conditions of the second stage. In the case of detection of non-compliance with the licence conditions by the licence issuing body until 1 January 2029, the issued licence shall be revoked and the blood institution shall terminate operation;
d.c) by 1 October 2030, ensure compliance with the licence conditions of the third stage. In the case of detection of non-compliance with the licence conditions by the licence issuing body until 1 January 2031, the issued licence shall be revoked and the blood institution shall terminate operation.
2. (Deleted – 1.4.2026, No 1471)
3. By 1 April 2030, a person shall have the right to donate blood or blood components in exchange for monetary payment and/or benefits equivalent to monetary payment, in accordance with the procedure established by the legislation of Georgia.
3^1. From 1 April 2026, a licence for industrial transfusiology activities shall not be issued to new entities and new branches of operating blood institutions shall not be registered.
3^2. By 2 April 2026, the operating blood institution registered in the organisational and legal form of a non-

entrepreneurial (non-commercial) legal entity, shall continue operation if it complies with the requirements established under paragraph 1(d) of this article.

3^3. A blood institution (blood transfusion institution/blood bank) operating as of 31 August 2025, functioning in accordance with the Law of Georgia of 21 March 1995 on the Donation of Blood and Its Components and the relevant legal acts, may be registered in the organisational and legal form of a non-entrepreneurial (non-commercial) legal entity as provided for by this Law and, before 1 June 2026, apply to an authorised body with the request to make changes in the licence issued for the industrial transfusiology activities.

3^4. A legal entity who, as of 31 August 2025, holds a licence for the industrial transfusiology activities along with the permit for an inpatient facility, may establish a blood institution provided for by this Law in the organisational and legal form of a non-entrepreneurial (non-commercial) legal entity and, before 1 June 2026, apply to an authorised body with the request to issue a relevant licence. A licence for the industrial transfusiology activities issued to an entity holding a permit for inpatient facility shall be deemed revoked from the moment of making a relevant decision by an authorised body or from 1 June 2026 in case the legal entity does not apply to the authorised body with the request of issuing a relevant licence before 1 June 2026.

4. The Government/Ministry of Georgia shall, by 1 July 2024, ensure the determination of a competent authority (authorities) provided for by Article 10 of this Law and, if necessary, the allocation of functions to it (them).

5. When required, issues related to the creation and management of strategic supplies of blood and its components shall be determined by the joint order of the Minister, the Minister of Defence of Georgia and the Minster of Internal Affairs of Georgia.

Law of Georgia No 4338 of 27 June 2024 – website, 28.6.2024
Law of Georgia No 135 of 13 December 2024 – website, 29.12.2024
Law of Georgia No 1471 of 1 April 2026 – website, 1.4.2026

Article 42 – Subordinate normative acts to be adopted/issued in connection with the adoption of the Law

1. By 1 October 2025, the Government of Georgia, upon the recommendation of the Ministry, shall adopt the following ordinances:

a) in accordance with Articles 7(9) and (10) of this Law, on the determination of incentive mechanisms for donors, on the procedure for awarding the title of honorary donor, and on the determination of the amount of one-time monetary payment;

b) in accordance with Article 11(10) of this Law, on the methodology for determining the marginal prices of blood products and intermediate products, and on the approval of the marginal prices recalculated annually on the basis of this methodology;

c) in accordance with Article 19(4) of this Law, on the recognition of the list of international and national guidelines and standards of good practice, and on the introduction of the guidelines and standards of good practice.

2. The Minister shall issue, by 1 October 2025:

a) an order provided for by Article 8(5) of this Law on the approval of the methodology and clinical indications for transfusion;

b) an order provided for by Article 15(1)(b) of this Law on the approval of the procedure for the management of stocks of blood and its components;

c) an order provided for by Article 16(2) of this Law on the approval of the procedure for the performance of hemosurveillance;

d) an order provided for by Article 19(4) of this Law on the approval of national guidelines and standards of good practice, as well as of the procedure for compliance with them;

e) an order provided for by Article 22(1) of this Law on the approval of the procedure for keeping documentation and records;

f) an order provided for by Article 23(6) of this Law on the approval of the procedure for donor selection and compatibility assessment;

g) an order provided for by Article 26(7) of this Law on the approval of the procedure for the collection of blood and its components;

h) an order provided for by Article 27(6) of this Law on the approval of the description of requirements for providing laboratory diagnostic services;

i) the order/orders provided for by Article 27(6) of this Law on the approval of the requirements and procedures relating to the testing of blood and its components (including the requirements and procedures relating to serological, molecular, immunohematological and other laboratory tests for infections transmitted through transfusion);

j) an order provided for by Article 27(6) of this Law on the approval of the requirements for the processing and control of the quality of blood and its components;

l) an order provided for by Article 28(4) of this Law on the approval of the labelling procedures, as well as the labelling procedures for autologous blood and its components;

m) an order provided for by Article 32(7) of this Law on the approval of the rules and procedures for the export and

import of blood and its components;
n) other, relevant subordinate normative acts necessary for the entry of this Law into force.
3. The government of Georgia, the Ministry and other relevant agencies shall ensure the compliance of the appropriate subordinate normative acts with this Law.
4. Before the adoption (issuance) of the respective legal acts in accordance with this Law, the relevant legal acts adopted (issued) before the entry of this Law into force shall maintain their legal force.
Law of Georgia No 135 of 13 December 2024 – website, 29.12.2024

Chapter VII – Final Provisions

Article 43 – Invalidated normative act

The Law of Georgia of 21 March 1995 on the Donation of Blood and Its Components (the Official Gazette of the Parliament of Georgia, 1994-1995, NN 23-26, Art. 561) shall be declared invalid.

Article 44 – Entry into force of the Law

1. This Law, except for Articles 1-9, Article 11(2)-(6) and 11(8)-(10), and Articles 12-40 and 43 of this Law, shall enter into force upon its promulgation.
2. Articles 1-9, Article 11(2)-(6) and 11(8)-(10), and Articles 12-40 and 43 of this Law shall enter into force from 1 October 2025.
3. The effect of Article 11(9) of this Law shall be suspended until 1 October 2026.
Law of Georgia No 135 of 13 December 2024 – website, 29.12.2024
Law of Georgia No 1471 of 1 April 2026 – website, 1.4.2026

President of Georgia **Salome Zourabichvili**

Tbilisi,
15 December 2022
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