

BLOOD AND BLOOD PRODUCTS LAW

Law Number: 5624 Date of Adoption: 11/4/2007 Official Gazette of Publication: Date: 2/5/2007 Issue: 26510 Düstur of Publication: Tertip: 5 Volume: 46

SECTION ONE Purpose, Scope and Definitions Purpose and scope

ARTICLE 1 – (1) The purpose of this Law is to regulate the procedures and principles concerning blood, blood components and products. (2) This Law covers public institutions and organizations providing blood, blood components and products services, as well as natural persons authorized by the Ministry and private legal entities operating in this field. (3) Blood stem cell practices are outside the scope of this Law.

Definitions

ARTICLE 2 – (1) In this Law; a) Apheresis: The separation of the desired blood components using a special device, b) Minister: The Minister of Health, c) Ministry: The Ministry of Health, ç) Regional blood centre: The most comprehensive unit where all operations and procedures related to blood banking can be carried out, established in the regions to be determined by the Ministry, operating in cooperation with the blood donation and transfusion centres in its own region, and having the capacity to meet the blood needs of the region for which it is responsible, d) Service unit: Transfusion centre, blood donation centre and regional blood centre, e) Blood donor: The person who gives whole blood or components thereof, f) Blood donation: The procedure of giving whole blood or blood components, g) Blood donation centre: The unit that collects blood from donors and operates under the regional blood centre in terms of its operation, ğ) Blood components: Cellular blood components such as erythrocyte, platelet and granulocyte suspensions obtained from whole blood directly, by apheresis or by other methods, as well as plasma, h) Blood products: Blood components and plasma products obtained from blood, ı) Plasma products: All therapeutic products obtained by processing human plasma, i) Plasma products manufacturing facility: The facility where the proteins needed for therapeutic purposes are separated from fresh frozen plasma and made available for use, manufacturing in compliance with national and international standards, j) Whole blood: Human blood taken from a blood donor for transfusion or for processing to obtain new products, mixed with a suitable anticoagulant substance and not subjected to any separation procedure, k) Transfusion: The transfer of whole blood or a blood component to a patient in need due to a health problem, 1) Transfusion centre: The unit that is not authorized to collect blood from blood donors except in emergencies, and that prepares the blood or component obtained for use on patients by performing cross-matching and other required tests for transfusion, express.

SECTION TWO General Principles, Blood and Blood Products Council General principles

ARTICLE 3 – (1) The general principles concerning blood, blood components and products are as follows: a) The Ministry is exclusively authorized and responsible for the planning, execution and supervision of the services covered by this Law. b) Unpaid and voluntary donation is the fundamental basis in the provision of blood, blood components and products. However, practices that encourage blood donors, which do not constitute financial compensation, are exempt. c) In the collection and administration of blood, blood components and products, it is mandatory that the health of the donor and the recipient is not endangered, that they are protected against medical risks, that the transfusion is performed safely, and that the donor and recipient are monitored after the transfusion. The reporting of complications that may arise in the recipient and the donor is mandatory. All data relating to blood donation, the blood donor, the preparing institution, the place of use and the recipient, concerning the collection, recording, analysis, processing, storage, preparation for use, distribution and use of blood, blood components and products, must be recorded in written or electronic form and retained for thirty years. The originals of the blood request form and donor screening forms, together with the witness samples of blood samples taken from the blood donor, shall be retained for the period to be determined by

the Ministry, which shall not be less than one year. ç) The collection or transfusion of blood, blood components and products is performed under the responsibility and supervision of a physician. d) The processing of plasma collected within the country for product manufacturing, whether within the country or abroad, is possible only with the permission of the Ministry. The importation of plasma from abroad for product manufacturing is also subject to the permission of the Ministry. e) Those who establish and operate service units are required to carry out their activities covered by this Law within the framework of national and international quality assurance programmes. f) Those providing blood, blood components and products services are obligated to protect the personal information relating to the donor, not to disclose it to third parties or the press. This information may only be provided to the Ministry. g) In cases of emergency, as well as (...) 1 mobilization and state of war, the regional blood centres organize the provision and nationwide stockpiling of the blood, blood products and the materials required therefor within the framework of the Ministry's planning.

Blood and Blood Products Council

ARTICLE 4 – (1) A Blood and Blood Products Council, composed of seven members selected by the Minister from among expert physicians who have distinguished themselves in the field through their work on blood, blood products and blood banking, or persons who have completed postgraduate education in these subjects, is established under the chairmanship of the head of the relevant unit of the Ministry in order to provide the scientific support that may be required in the work to be carried out by the Ministry concerning blood, blood components and products. (2) The term of office of the members of the Blood and Blood Products Council is two years. A member whose term of office has expired may be re-elected.

SECTION THREE Service Units for the Provision and Use of Blood Service units, persons authorized to establish service units

ARTICLE 5 – (1) Transfusion centres, blood donation centres and regional blood centres are established for the provision and use of blood. (2) Of the service units covered by this Law; a) The regional blood centre and blood donation centre may be established and operated by public institutions and organizations and the Turkish Red Crescent Society; b) The transfusion centre may be established and operated by, in addition to those listed in paragraph (a) of this subsection, natural persons and private legal entities, provided that they are private healthcare institutions possessing emergency intervention facilities; c) The plasma products manufacturing facility may be established and operated by public institutions and organizations, natural persons and private legal entities.

SECTION FOUR Licensing, Inspection and Penal Provisions Requirement to obtain a licence, inspection and penal provisions

ARTICLE 6 – (1) Natural and legal persons who are to operate within the scope of this Law are obliged, before commencing their activities, to obtain a licence from the Ministry or, where the Ministry has delegated authority, from the governorships, and to keep separate accounts and records for each activity subject to the licence. Natural and legal persons are obliged to pay the licence issuance, licence amendment, licence copy issuance and annual licence fees determined by the Ministry to the accounting unit to be determined by the Ministry of Finance.

1 By Article 62 of Decree Law No. 698 dated 2/7/2018, the phrase "martial law," in this paragraph has been removed from the text of the article.

(2) The Ministry supervises or has supervised all activities of service units. Licence holders are obliged to keep their facilities, legal books and records ready and open for Ministry inspection, and to submit to the Ministry in due time all kinds of information and documents the Ministry may require.

(3) The obtaining of a licence does not eliminate the obligation to fulfil the requirements of this Law and other legislation. The service units within the scope of this Law are also obliged to comply with subsequent regulations to be issued by the Ministry regarding standards and working

procedures and principles.

(4) The remedying of deficiencies identified as a result of inspections carried out, or the taking of necessary measures, is requested either by granting a period of time depending on the nature of the matter, or immediately. Where deficiencies that must be remedied as required by the service are not remedied, the Ministry shall, if necessary, take the required measures ex officio, provided that the costs are collected from the person concerned. The remedying of the deficiency within this period does not preclude the Ministry's authority to impose sanctions.

(5) The licences of those who lose the licence requirements during their activities shall be revoked by the Ministry.

(6) (Amended: 15/11/2018-7151/Art. 30) Those operating without a licence shall be prohibited from operating by the governorship and shall be punished with an administrative fine of ten thousand Turkish liras. An administrative fine of ten thousand Turkish liras shall be imposed on those who are found not to have kept the documents and copies whose retention is mandatory under paragraph (c) of the first paragraph of Article 3, and on those operating outside the scope of their existing licence; in the event of repetition of these violations within two years, the administrative fine shall be imposed at twice the amount; upon the third repetition, an increased administrative fine shall be imposed and the activity shall be suspended for up to ten days; upon the fourth repetition, they shall be prohibited from operating.

(7) In the inspections carried out: a) An administrative fine of one thousand New Turkish Liras shall be imposed by the Ministry or the relevant governorship on those who fail to provide the requested information in due time. In the event of repetition of the same act, an administrative fine of five thousand New Turkish Liras shall be imposed. b) An administrative fine of five thousand New Turkish Liras shall be imposed by the Ministry or the relevant governorship on those who are found not to employ personnel of appropriate qualifications.

(8) Those operating within the scope of the services covered by this Law in a manner endangering the lives and health of persons shall be immediately prohibited from operating and shall be punished with imprisonment from one year to five years and a judicial fine of up to one thousand five hundred days. No licence shall be granted to such persons for five years. Furthermore, the confiscation of blood and blood products found to lack the required technical and medical conditions shall be ordered.

(9) Regional blood centres and blood donation centres whose licence has been revoked or which have been prohibited from operating shall, where necessary, be seized and operated by the Ministry, with the necessary measures being taken by the Ministry.

(10) Those who, knowing that they have a disease transmissible through blood or carry the risk of such a disease, donate blood while concealing this condition shall be sentenced to imprisonment from one year to three years and a judicial fine of five hundred days.

FIFTH CHAPTER Miscellaneous Provisions Regulation

ARTICLE 7 – (1) The establishment of transfusion centres, blood donation centres and regional blood centres envisaged under this Law, the determination of equipment, material and personnel standards, the determination of their relations with one another and their working procedures and principles, the procedures and principles regarding the quality assurance programmes they will implement, the procedures and principles regarding the obtaining of licences, their fees and their revocation, the establishment and operating principles of plasma products manufacturing facilities and other matters, and the working procedures and principles of the Blood and Blood Products Council shall be determined by a regulation to be issued by the Ministry.

Repealed provisions

ARTICLE 8 – (1) Law No. 2857 dated 23/6/1983 on Blood and Blood Products has been repealed.

Entry into force of the Regulation and licensing of existing units PROVISIONAL ARTICLE 1 –
(1) The regulation envisaged under this Law shall be put into force by the Ministry within six months. Until the Regulation enters into force, the continued application of the provisions of the existing regulations that are not contrary to this Law shall be ensured.

(2) Type A and Type B blood centres, blood stations and other service units operating until the date of entry into force of this Law are obliged to remedy their deficiencies within one year of the entry into force of the Regulation, to obtain a licence in accordance with the type of their activities and to ensure their compliance with this Law. Within this period, no new unit within the scope of this Law may be opened without the permission of the Ministry.

Entry into force

ARTICLE 9 – (1) This Law shall enter into force on the date of its publication.

Execution

ARTICLE 10 – (1) The Council of Ministers shall execute the provisions of this Law.

TABLE SHOWING THE DATES OF ENTRY INTO FORCE OF LEGISLATION AMENDING AND SUPPLEMENTING LAW NO. 5624 OR OF CONSTITUTIONAL COURT DECISIONS

Number of the Amending Law / Decree Law or the Annuling Constitutional Court Decision
Amended or Annulled Articles of Law No. 5624 Date of Entry into Force Decree Law/698 3 On the date on which the President took office upon being sworn in, following the Turkish Grand National Assembly and Presidential elections held together on 24/6/2018 7151 6 5/12/2018