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PROVISIONAL INSTITUTIONS OF SELF GOVERNMENT

KUVENDI I KOSOVËS
СКУПШТИНА КОСОВА
ASSEMBLY OF KOSOVO

LAW No: 02/L-101

FOR BLOOD TRANSFUSION, BLOOD CONTROL AND ITS PRODUCTS

The Assembly of Kosovo,

Based on Chapter 5.1. (h) and 9.1.26(a) of the Constitution Frame for Provisional Self-government in Kosovo.

Hereby adopted the following:

LAW FOR BLOOD TRANSFUSION, BLOOD CONTROL AND ITS PRODUCTS

Chapter I
GENERAL DISPOSITIONS

Article 1
Purpose of Law

This Law regulates the activities relating to blood donation, test, processing, safeguard, transfusion and quality control and its components.

Article 2
Definitions

For this law purpose the following definitions are valid:

"Autologous transfusion" is a procedure of providing blood in which the donor and the taker is the same person".

"Citafereza" is a procedure by which the specific cells are divided using the respective device assistance.

“Blood donor” is a person having a good health, good medical anamnesis, and suitable according to medical professional criteria and who voluntary donates blood, plasmas or blood cells for therapeutic use.

“Oriented blood donor” is a person who donates blood or blood components for a specific patient, family member or his/her acquaintance.

“Blood donation” is an activity which is based on voluntary blood donation policies, without pay and in anonymous manner.

“Fraction of blood plasmas” is a procedure by which are divided the special plasmas protein components as therapeutic products.

“Blood for transfusion” is a tissue in a liquid state taken from the donor in anticoagulant bags.

“Full blood” is the received and processed blood either for transfusion or for further processing.

“KRC” Kosovo Red Cross.

“Blood component” is a therapeutic fraction (erythrocytes, leucocytes, trombocytes, and plasmas) acquired from complete blood with a conventional methodology in the Blood Transfusion.

“Transfusion Medicine” is a medical field dealing with blood donation, collection, testing, storing, processing, and blood transfusion and its components

“One blood unit-dose” is the blood amount taken from a single.

“Plasma-fereza” is a procedure by which the blood plasmas is collected from the blood donor.

“Good Clinical Practice” in the field of transfusion medicine means the blood optimal use and its products in clinical practice.

“Blood product” is any therapeutic product gained from the human blood and includes all blood components and the blood therapeutic.

“Promotion of blood donation” includes all activities concerning to motivation, organization, education, recruitment and donors’ appeal for national blood supply.

“NCBTK” – National Center of Blood Transfusion of Kosovo.

“Register of blood donors” is the integral personal and medical data, important for security reasons in blood supply.

“Transfusion” is the blood or its components transmission from the donors into the recipient.

“Self-sufficiency” is a supply principle with blood or its components which ensures that all needs for blood and blood components in the specific region or country are covered by their own sources.

Chapter II
BLOOD DONATION AND COLLECTION

Article 3
Establishing the quality Standards for obtaining and storing the blood

3.1 The Ministry of Health, by means of a sub-legal act determines the criteria for establishing a quality system, which should be provided in each center where the blood i donated.

3.2 This sub-legal act should include the standards determined by Direction 2005/65.

Article 4
Needs for blood

Blood collection will provide the Kosovo self-sufficiency for blood according to conformity with determined and foreseen needs as well the unexpected needs increase for blood.

Article 5
National Center for Blood Transfusion of Kosovo

5.1 National Center for Blood Transfusion of Kosovo is a Tertiary Public Health Institution where the blood transfusion services are offered and applied as well as educational and research-scientific activities.

5.2 NCBTK realizes the rights, obligations, duties and its aims in the field of supplying the citizens with blood and its components, doing:

a) planning the needs for curing the sick persons with blood components;
b) stimulating the policies of self-sufficiency in supplying the citizens with blood components through donors without payment;
c) providing the conditions for increasing the conscience of citizens for the need of collecting blood for curing the patients in need for it;
d) providing the conditions for storing the collected blood, testing it as well as producing, storing and delivering the components, in accordance with the technological scientific development;
e) establishing and providing the development of the information-health system on the field of the transfusion medicine;
f) providing the development of the health activities in the field of transfusion medicine;
g) providing conditions for educating the health workers in the field of the transfusion medicine.

5.3 Organizing, functioning and the activity of NCBTK will be determined by the statute of NCBTK, based on the provisions of this Law and Kosovo Law on Health.

Article 6
Blood Collection

6.1 In order to provide the donors of blood and its components, for all health institutions, which in their work use the blood and its components, QKTGJK establishes its branches in all hospitals.

6.2 The blood transfusion activity can be exercised by the authorized branches that have at least one specialist doctor from the transfusion medicine.

Article 7
Actions planning for blood collection

7.1 The foreseen needs for blood are projected by annual plan prepared by NCBTK. Unexpected needs increase for blood and blood products will be covered by additional actions for blood collection and with other measures in coordination with MH.

7.2 In order to ensure a consistent and secure supply with blood, the regional units Blood Transfusion Services of hospital should cooperate with the integrative system.

7.3 The Plan for blood donor actions is regulated by a sub-legal act of the Ministry of Health.

Article 8
Spaces where the blood collection or receiving is performed

Spaces where is blood collection or receiving made will meet the quality standards determined by Ministry of Health with sub-legal act.

Article 9
Actions Organizers for blood donation

9.1 NCBTK organizes and carries out the actions for blood collection. To realize this action it cooperates with Kosovo Red Cross (KRC), Association of Voluntary Blood Donors and with other organizations, which in their activity perform the promotion of blood donation.

9.2 The NCBTK relations with these organizations will be regulated by a special agreement.

Article 10
Blood donors

10.1 The donor of blood and blood components is the adult person 18 – 65 years old. It is allowed to take blood also from the age of 17 years, on condition that the doctor will ascertain meeting the criteria for blood donor and not more than twice in a year, before the age of 18 years.

10.2 Exception from paragraph 1 of this article is the autologous transfusion, where the donor of blood and its components is not necessary to be of the adult age.

10.3 The frequency of blood donor for females con not be more than three times in a year and for males not more that four times in a year.

Article 11
Anonymity

NCBTK is obliged to keep the anonymous of the blood donor.

Article 12
Compensation for the donated blood

12.1 Compensation with money for the obtained blood and its components is prohibited.

12.2 In cases when the blood donor is invited by NCBTK or Hospital Blood Transfusion Services to donate blood or blood components will be provided a meal and travel expenses payment.

12.3 Way for travel expenses payment will be regulated by a sub-legal act.

12.4 The blood donor is released from self participation for the health services in public institutions for the period of one year from the date of blood donation.

Article 13
Autologous transfusion

13.1 Collection of own blood is allowed for a specific person and for specific cells or blood plasmas-cita-fereza and plasma-fereza in such cases where based on medical criteria it is available.

13.2 During the surgical intervention, when a huge amount of blood is foreseen to be lost, the doctor who treats the patient informs him/her about the auto-transfusion possibilities.

Article 14
Promotion of blood donation

The NCBTK carries out the promotion of blood donation and it is assisted by:

a) Ministry of Health,
b) Ministry of Education,
c) Institutions for Health Insurance,
d) Kosovo Red Cross (KRK),
e) Association of voluntary blood donors,
f) Health Institutions,
g) Mass-media,
h) Schools,
i) Trade Union Organizations
j) Non-government organizations which are obliged to inform the public about the importance of blood donation and stimulate actions implementation for blood donation.

Article 15
Approval for blood donation

15.1 Blood donation is done only by the written approval of the donor, after the professional explanation offered by the professional personnel for the procedure and the possible marginal effect, need for testing and after giving the personal data, or the anamnesis details**.**

15.2 The Ministry, by a sub-legal act, determines the content of the written text with the approval of the blood donor.

15.3 Blood obtaining is made in the presence of the authorized doctor.

15.4 Only the persons that are considered to be blood donors can undergo the blood obtaining. For determination of this criteria, there should be taken into consideration the new inventions and scientific-technological information and the responsibility of this criteria falls on the doctor that allows the blood donor to donate blood

Article 16
Protection of blood donor identity

16.1 Protection of blood donor identity is secured in all blood collection procedures.

16.2 Identification of blood donor and lab tests is carried out in accordance with professional policies and medical ethics except in cases of court trials and allow cases by this law.

Article 17
Documentations and blood donor protection

17.1 NCBTK keeps the register of blood donors.

17.2 From the paragraph 1 of this Article, especially there are written the details on the register for the persons who temporarily and during all their lives should not be blood donors.

17.3 The Register of blood donors is a part of the information system of the transfusion activity.

17.4 The Register is available at all health institutions, which collect blood.

17.5 The content and form of the register is compiled by NCBTK, based on its statute

Chapter III
USE AND MANIPULATION WITH BLOOD

Article 18
Use of blood and blood components

18.1 Blood and blood components are used in accordance with good clinical Practice policies.

18.2 NCBTK supplies with blood and blood products the public and private institutions.

18.3 The Methods for preparation, using, providing the quality of blood and its components as well as the conditions of blood supply from paragraph 2, is determined by sub-legal act. This sub-legal act should be in accordance with the Directions 2002/19 of European Council and Parliament of date 27 January 2003, regarding collection, testing, processing, storing and distributing the blood and its components

Article 19
Test

19.1 The authorized institutions from Article 6.1 perform the testing of each dose or the blood components from article 18.3.

19.2 Methods and Conditions of blood testing from article 18.3, is determined by the sub-legal act.

19.3 Testing the cause of infectious diseases that can be carried over in blood during transfusion is made by QKTGJK.

19.4 Persons who make the testing, processing and storing the blood and its components are subject to continuous professional trainings every two years.

Article 20
Distribution prohibition

Blood distribution, blood and its components use is prohibited in cases when:

a) cannot be verified their origin,
b) were not tested as prescribed in article 19 paragraph 2, and
c) Doesn't exist any possibility for retest.

Article 21
Import

22.1 The blood and its components cannot be imported in Kosovo.

21.2 The Minister can allow importing the blood and its components in special cases such as: natural disasters and other extraordinary conditions, or other cases dealing with emergency needs reasonable from medical point of view.

21.3 The imported blood and its components should meet the conditions foreseen with this Law and should be tested, processed and labeled by the authorized authority from Article 19, and it should be associated by the documentation regarding each blood unit and blood components as well as with the information of blood analysis.

21.4 The Criteria for determination of blood quality are determined with the sub-legal act in accordance with the Direction 2005/62 and the Direction 2002/98 of European Council and Parliament.

Article 22
Export

22.1 Blood and its components cannot be exported from Kosovo for commercial purposes.

22.2 The Minister can allow the exporting of blood and its components in special cases such as: natural disasters and other extraordinary conditions, or other cases dealing with emergency needs reasonable from medical point of view.

22.3 The Minister can allow the temporarily exporting of plasma, in order to fractionize it for the needs of Kosovo Health".

Article 23
Unused blood

23.1 The unused blood and components will be stored, transported and eliminated exceptionally in the NCBTK and Hospital blood Transfusion Services in a determined manner by a sub-legal act by Ministry of Health.

23.2 The unused blood for auto-transfusion cannot be used for other purposes, except by approval of the person who donated blood for autologous transfusion**.**

Article 24
Quality security in blood and its components usage

Doctors who use blood and its components for patients treatment, in accordance with good clinical practice will ensure:

a) a rational use and high quality,
b) keeping of the prescribed documents and requests,
c) record good-useful effects and negative effects, and
d) Undertaking other necessary measures.

Article 25
Hospital transfusion committees

25.1 Hospital institutions, based on its Statutes establish their Hospital transfusion committees.

25.2 Hospital Transfusion Committees consist of transfusion medical specialist and other clinic specialists who enable the implementation of the important transfusion activities in hospitals.

25.3 Hospital Transfusion Committees supervise and evaluate:
a) blood and its components use,
b) treatment indications and effectiveness,
c) undesirable marginal actions from blood transfusion,
d) undertaken measures in cases of blood shortage,
e) selection of recipients, and
f) Other clinical activities relating to blood and its products.

Article 26
Approval for blood receiving

26.1 Blood and its components can be given to a patient only then when the person who should receive the blood transfusion has given the written approval verifying that he/she was informed prior to transfusion and for possible undesirable marginal effects.

26.2 When the blood transfusion or its components will be given to a juvenile person under the age of 15 years, the doctor will provide a written approval by his/her parent or custodian.

26.3 When the blood transfusion or its components will be given to an adult person who does not possess activity ability or when this ability is limited, the doctor the doctor will provide a written approval by his/her custodian in accordance to Law for citizens' rights and Responsibilities for Health Care.

26.4 If the patient is not able to give the written approval which deals with paragraph 1of this article or if the doctor cannot take the written approval dealing with the second and third paragraph of this article, then the doctor will act in accordance with doctor's professional policies.

Article 27
Documentations for blood use

27.1 Documentations will provide attendance of each blood dose and its components from the donor to recipient.

27.2 The doctor who uses the blood for treatment purposes will keep the documents for each blood and its components dose including the biotechnological substitutes used for treatment.

27.3 Documents include the issued written approval by the patient or his/her parent or custodian, result of blood group determination, list lab tests, records for positive and undesirable actions during or after the transfusion process.

Article 28
Data for blood use

28.1 The doctor who uses the blood for treatment purposes in accordance with article 30 of this Law will record the following data for the used blood and its component:

a) identification number of the patient, his/her name, parent's name, surname, date of birth and address,
b) number of result for the patient's blood group,
c) unified code for blood product and its name, producer, amount and product concentration, date and hour of blood transfusion,
d) Other data prescribed by doctor.

28.2 Disposition of this Article will be also used even in cases of autologous transfusion.

Article 29
Documentations maintenance

29.1 For purposes of blood transfusion attendance, all patient data should be available immediately.

29.2 The users of data shall have access only to those data for which they are authorized.

29.3 Documentations together with electronic data processing will be kept for at least 15 years. Documentations after this period will be removed and archived. Records older than 30 years will be changed in a manner that hey will remain anonymous.

29.4 This register should include also the authorized persons by this Law.

29.5 The information about the imported blood is noted down in a special register

Article 30
Undesirable marginal effects

30.1 In cases while using the blood and its components, prepared by blood or by biotechnological procedure, initiate undesirable marginal effects, the ordinary doctor shall immediately notify the hospital person in-charge, who in accordance with good clinical practice, will be informed.

30.2 Person in-charge will immediately notify the authorized transfusion institution.

30.3 In case of suspicion that the undesirable marginal effects are connected to blood products use, the person –charge will notify the official person authorized to attend and record the undesirable marginal effects of the blood products as well as the Kosovo Agency for Medical Products.

30.4 Notification should contain these data:

a) name of blood product,
b) full name of the preparation producer, and
c) Other data for treatment process and the undesirable marginal effects.

30.5 When the undesirable marginal effects are seen, the notification should also include the date of birth of the person and sex.

Article 31
Report for blood collection and its use

31.1 The NCBTK annual report will contain the blood donors' number, the amount of the collected blood and blood products, the imported and exported amount of blood and its components as well the number of the blood products used during the previous year. It also should report about the number of the registered and refused donors.

31.2 Data about the blood donors in report will be anonymous.

31.3 The NCBTK will prepare quarterly report about the number of blood donors as agent transmitters of the infectious diseases which can be transmitted by blood transfusion and identified by test. The NCBTK will have this specific list for each testing type.

31.4 Report for blood donors identified as agent transmitters of infectious diseases will contain as follows:

a) age
b) sex,
c) data on whether the donor is for the first time or as a multiple donor,

31.5 The Center will forward lists to National Institute for Public Health of Kosovo each three months.

31.6 Data will be gathered and delivered on the anonymous and confidential basis.

Article 32
Infected blood

32.1 Blood and its components shall not be used as long as the foreseen biological analysis and is not performed and diseases tests that can be transmitted by blood transfusion. Authorized transfusion institutions will test all collected samples. Documentations for tests results will be kept in a manner determined by Ministry of Health by a sub-legal act

32.2 When the blood infection verified, the authorized transfusion institution will immediately inform the Kosovo NCPH about the test results. The infected blood dose will be removed from usage and exterminated biologically. The sample of the infected blood will be kept in a place, particularly foreseen for that until its extermination.

Article 33
Infected blood donors

33.1 When HIV/AIDS verified or suspected in or hepatitis virus or other disease agent that can be transmitted by blood transfusion, the doctor in charge of the authorized transfusion institution will immediately notify the donor about the verified infection and direct and consult for further actions

33.2 Shall be verified the data how often up to that moment the blood donor has donated blood and the kept samples of his/her blood should be retested and identify his/her blood recipients from the previous donated blood.

33.3 These blood recipients will immediately be informed, advise how to act and be tested about the identified infection. Recipients will give written approval for testing.

Article 34
Infected patients

34.1 When the medical institution verifies or suspects that a person being treated with blood or blood products for therapeutic purposes has been infected, the medical institution where the person was tested will immediately begin the research of infection origin.

34.2 Blood and blood components prepared from blood which has infected the person being treated, will be informed as well as the donor of this blood which through infected blood transfusion has caused an infection or exists a suspicion of doing that.

34.3 When verified or suspected that a person being treated with blood or blood products for therapeutic purposes has been infected, then will be notified the Kosovo Agency for Medical Products National Institute for Public Health of Kosovo and the authorized official person to register and attend the undesirable marginal effects of the medical products.

34.4 The Producer of the medical products shall be notified, too. Producer shall undertake the respective measures for attendance of the blood donor and recommend additional tests. Infected product will be treated in the same way as the infected blood.

34.5 The further measures will be taken in compliance with dispositions of article 34 of this Law.

Chapter IV

Article 35
Coordination Council for blood supply

Coordination council for blood and blood products supply-hereinafter as: Coordination council is made up in accordance with Administrative Direction for Professional Advice No. 27/2004, issued by Ministry of Health.

Article 36
Supervision

36.1 Supervision of the application of this Law and sub-legal acts is regulated by the Ministry of Health.

36.2 The Professional supervision in the authorized Institutions is regulated by the Health Inspectorate.

Chapter V

Article 37
Financing of the Transfusion Service

37.1 Financing of Transfusion Service will be done in order to have the secure blood and blood components, safety for donors, safety for recipients, an adequate development of Transfusion Service, control of all work phases dealing with blood receiving, processing and its donation.

37.2 Financing of Transfusion Service will be done in compliance with Law for Health.

Chapter VI
DISCIPLINARY AND PUNISHABLE DISPOSITIONS

Article 38

38.1 In cases of non application and violations of dispositions of this Law measures will be taken according to Articles 118, 119 and 120 of Health Law.

38.2 This Law dispositions violation when constituting a criminal act will be punished under Chapter XXI of Kosovo Penal Code.

Chapter VII
TRANSITIONAL DISPOSITIONS

Article 39

To implement the article 18 of this law, the Ministry of Health in term of 2 months from the day this law steps into force, will issue the legal sub normative act.

Article 40

In order to implement this law, Ministry of Health is obliged, that within the term of 6 months from the day it gets into force, to issue legal sub normative acts as defined by this law.

Article 41

This Law becomes effective after being approved Kosovo Assembly and its promulgation by Special Representative of Secretary General.

Law No. 02/L-101
13 April 2007

President of Kosovo Assembly,

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Kolë Berisha