Pursuant to Article 95, item 3 of the Constitution of Montenegro, I hereby pass the

ENACTMENT PROMULGATING THE LAW ON BLOOD PROVISION

I hereby promulgate the Law on Blood Provision adopted by the Parliament of Montenegro at its second meeting of the second regular session in 2007, on 27 November 2007.

No: 01-1388/2
Podgorica, 11 December 2007

President of Montenegro
Filip Vujanović, m.p.

LAW ON BLOOD PROVISION

I GENERAL PROVISIONS

Article 1

This Law shall set the requirements and the standards of quality, safety and surveillance for the collection, testing, processing, storage, distribution, issuance, and use of human blood and blood components.

Article 2

Collection, testing, processing, storage, distribution, issuance, control of quality and use of blood and blood components shall be done in accordance with the principles of good manufacturing practice, European Union Directives and WHO recommendations, as well as other regulations governing this area.

The activity referred to in paragraph 1 of this Article shall be performed in accordance with the principle of self-sufficiency by providing the necessary number of voluntary unpaid blood donors.

Article 3

For the purpose of this Law, the following terms shall have the following meaning:
- **blood** shall mean whole blood collected from a donor and processed either for transfusion or for further manufacturing;
- **blood transfusion** shall mean the process of transferring blood or blood components from a donor to a recipient;
- **autologous transfusion** shall mean transfusion in which the donor and the recipient are the same person;

- **whole blood unit** shall mean a prescribed blood quantity given by a donor per one donation;
- **blood component** shall mean a constituent of blood (erythrocytes, leukocytes, thrombocytes, plasma, cryioprecipitate) that is prepared by application of physical methods (centrifuging, filtering, freezing);
- **blood derivative** shall mean a protein product obtained from plasma by applying one of chemical or physico-chemical methods;
- **blood donation** shall mean a humane gesture performed in accordance with the principles of voluntarism, non-remuneration, and anonymity;
- **blood donation initiative** shall mean the set of activities aimed to motivate, inform, organize, educate and invite blood donors, for the purpose of meeting the national needs for blood;
- **blood donor** shall mean a healthy person who voluntarily donates blood or blood components;
- **first-time blood donor** shall mean a person who has never before donated blood or blood components;
- **regular blood donor** shall mean a person who regularly donates blood or blood components during the last two years in health institutions at the territory of Montenegro, while complying with the minimum time interval between the donations;
- **repeat blood donor** shall mean a person who donates blood or blood components again in the same health institution at the territory of Montenegro, after the two-year period;
- **deferral** shall mean temporary or permanent suspension of the eligibility of an individual to donate blood or blood components;
- **good manufacturing practice** shall mean a system for ensuring the quality aimed to have the products consistently produced and controlled in accordance with the quality requirements and with the goal to correspond to the envisaged purpose;
- **good laboratory practice** shall mean a system for ensuring the quality aimed to have the laboratory activities consistently implemented and controlled in accordance with the quality requirements;
- **good clinical practice in transfusiology** shall mean an optimum use of blood and blood components in clinical practice;
- **apheresis** shall mean a procedure for obtaining one or several target blood components through an apparatus for automatic processing of whole blood, whereby unused blood quantities are returned to the circulation of the donor, during or at the end of the procedure;
- **cytapheresis** shall mean an apheresis procedure intended for collection of cell-based components of blood, such as erythrocytes, leukocytes and thrombocytes;
- **plasmapheresis** shall mean an apheresis procedure intended for collection of plasma for therapeutic purposes;
- **distribution** shall mean the act of delivery of blood and blood components to health institutions that use blood in medical treatment;
- **issuing of blood and blood components** shall mean the act of delivery of blood and blood components prepared for transfusion to a recipient;
- **self-sufficiency** shall mean the provision of sufficient quantities of safe blood for the needs of citizens from own sources;
- **haemovigilance** shall mean an organized system of surveillance relating to serious adverse events or reactions in blood donors or recipients, and shall include the epidemiological follow-up of blood donors;

- **standard operating procedure (SOP)** shall mean a detailed document containing all activities in accordance with the principles of good transfusiological practice;
- **serious adverse event** shall mean any unexpected event associated with the collection, testing, processing, storage and distribution of blood and blood components that might lead to death or life-threatening, disabling or incapacitating conditions for the recipient that results in, or prolongs, hospitalization;
- **serious adverse reaction** shall mean an expected reaction in donor or recipient associated with the donation of blood or transfusion of blood or blood components that is fatal, life-threatening, disabling or results in, or prolongs, hospitalization.

II ORGANIZATION AND COMPETENCY OF THE BLOOD TRANSFUSION INSTITUTE

Article 4

The Blood Transfusion Institute of Montenegro (hereinafter referred to as: the Institute) shall perform the activity referred to in Article 2 of this Law.

The Institute shall also perform its activity through organizational parts in health institutions the activity of which is associated with the use of blood for medical treatment, in accordance with the acts of the Institute.

Article 5

In performing the activity referred to in Article 2 of this Law, the Institute shall:

- provide a necessary number of voluntary blood donors in cooperation with the Red Cross of Montenegro;
- initiate and encourage voluntary blood donation initiative, and take care about voluntary blood donors in cooperation with the Red Cross of Montenegro;
- collect, test, process, store, distribute, and issue blood and blood components;
- provide for quality plasma for therapy and satisfaction of needs of citizens for blood derivatives obtained by fractionation;
- carry out apheresis procedures;
- collect hematopoietic stem cells, and participate in the transplantation programme;
- provide for unrelated bone marrow donors, and keep the registry of such donors;
- collect autologous blood;
- carry out prenatal immuno-haematological testing of blood of pregnant women;
- carry out testing in the area of HLA tissue standardization and transplantation immunology;
- perform laboratory diagnostics, as follows: immuno-haematological and immuno-genetic, confirmatory testing, biochemical, micro-biological and testing of haemostatic disorders;
- implement the policy regarding blood quality control;
- rationally use blood and blood components, and issue blood;
- immuno-haematological laboratory testing of patients;
- keep records in the area of issuance of blood and blood components;

- carry out education, researches, development and training of employees;
- carry our surveillance and monitor the effects of blood transfusion;
- participate in the work of the Blood Transfusion Committee;
- perform other activities in accordance with law and foundation act.

Article 6

The provisions of the Law on Health Care shall apply to the establishment and operations, as well as other issues of importance for the operations of the Institute, unless otherwise prescribed by this Law.

III BLOOD QUALITY AND SAFETY

1 Blood Collection

Article 7

Blood collection shall mean the selection of a blood donor, determination of the quantity of drawn blood and methods of blood drawing.

Blood collection shall be done in the Institute and in the field by mobile teams.

Blood collection shall be done under a professional medical surveillance.

In collecting, treating, processing blood and blood components, the Institute shall be obliged to comply with the achievements in transfusiology and rules of good manufacturing practice, as well as to meet the requirements regarding premises, personnel and equipment.

A state administration body competent for health affairs (hereinafter referred to as: the Ministry) shall prescribe the manner and procedure for collecting blood and blood components, as well as more detailed requirements regarding premises, personnel and equipment.

Article 8

Blood collection shall be done in accordance with the already planned or suddenly increased needs for blood, in accordance with the principle of self-sufficiency for the needs for blood and blood components.

Needs for blood shall be determined by the annual needs plan, and sudden needs shall be provided by extraordinary actions for blood donation and other measures.

The Institute shall adopt the annual needs plan, in cooperation with the Red Cross of Montenegro.

The Institute shall be obliged to provide for five-day reserves of blood and blood components, as well as one-month reserves of consumable material for blood processing.

Article 9

The Ministry, Red Cross of Montenegro, Institute and other health institutions, media, educational institutions and other organizations, shall be obliged to inform the citizens about the importance of blood donation, as well as to support promotional actions organized for the purpose of blood collection.

Promotion of voluntary blood donation initiative in printed and electronic media shall be free of charge.

Article 10

Blood donors may be all healthy persons from 18 to 65 years of age for whom it is determined by medical, laboratory and epidemiological checkups that they can donate blood, without causing a danger to their health, and without endangering the health of recipients.

Notwithstanding paragraph 1 of this Article, a donor may be a minor or a person who is deprived of his business capacity, with a written consent of a parent or guardian.

Article 11

Autologous transfusion and apheresis procedures for blood collection and necessary analyses shall be done in accordance with the principles of good clinical practice in transfusiology.

In case of surgeries that envisage more severe blood loss, a medical doctor who is treating a patient shall be obliged to inform the patient with the possibility of autologous transfusion.

Article 12

Blood can be drawn only after the obtained written consent of the blood donor who has been informed by a medical doctor about the manner and possible adverse consequences of blood drawing, necessary analyses, use of his personal data or data about his blood type and test findings.

The blood donor shall confirm the written consent referred to in paragraph 1 of this Article, as well as the accuracy of given data, by completing and signing a questionnaire.

The Ministry shall prescribe the contents of the questionnaire referred to in paragraph 2 of this Article.

Article 13

A medical doctor shall carry out a health check-up of a donor, assess health condition and obtain data on the donor referred to in Article 12 of this Law, as well as provide the information to the donor.

A medical doctor must not allow that blood is drawn from a donor for whom it is determined, in accordance with the prescribed medical standards, that there are reasons for his deferral.

2. Blood testing, storage and distribution

Article 14

Every blood unit or blood component intended for medical treatment shall be subject to immuno-haematological testing, and must be tested for infectious disease markers (HbsAg, HIV, HCV, and TPH), and additional tests shall be performed if required by specific epidemiological situation and in accordance with specific needs.

Article 15

If it is determined or there is a reasonable doubt that a blood donor is infected by some of the causes of disease that are transmitted by blood, the medical doctor referred to in Article 13 of this Law shall be obliged to inform immediately a donor about the found infection, contagious disease or that he is a carrier of infectious disease cause, as well as to inform him about the found health disorder and advise him about the further behaviour regarding the medical treatment and avoiding risky behaviour.

In the case referred to in paragraph 1 of this Article, a medical doctor shall be obliged to verify how many times the donor donated blood so far, test again the kept samples of his blood, and determine who received his blood donated in the past.

The medical doctor referred to in paragraph 1 of this Article shall be obliged to inform immediately the recipient of that blood and advise him to have the tests for the found infectious disease done.

Testing of the recipient referred to in paragraph 3 of this Article cannot be done without his written consent.

Article 16

Infected blood unit shall be withdrawn from use and biologically destroyed.

Infected blood sample shall be stored in a place determined for such a purpose.

The Institute shall be obliged to submit a notification about the found infectious disease to the competent institutions, in accordance with the regulation governing the manner of notifying about infectious diseases.

3. Blood Traceability

Article 17

Collection, testing, processing, storage, distribution and issuance of blood and blood components must be traced and recorded from a donor to a recipient, as well as from a recipient to a donor.

The Institute shall provide for the system of measures for identification of each collected blood unit and blood component.

Each blood unit and blood component must have an identification number that enables traceability of blood and blood components.

Data needed for full blood traceability shall be kept for at least 30 years.

Article 18

In collecting blood, the Institute shall take and record the data on each donor and each blood unit in electronic and written form.

Article 19

The Institute shall keep the registry of each donated blood unit and blood component, regardless whether it is issued for clinical use, fractioning, research, or is rejected due to unsuitability for further use.

The Institute shall keep the registry of each used blood unit and blood component.

The registry shall include data on issued blood unit and data on the recipient.

The Ministry shall prescribe the contents of the registry referred to in paragraphs 1 and 2 of this Article.

Article 20

Blood that has not been used shall be stored and disposed of in accordance with a separate regulation governing medical waste management.

Unused blood for autologous transfusion must not be used for other persons.

Article 21

The Institute shall import blood and blood components in extraordinary situations or in case of rare blood types, with a prior approval of the Ministry.

The Institute, with the consent of the Ministry, may export plasma as a raw material for obtaining blood derivatives for the needs of the citizens of Montenegro.

The Government of Montenegro shall approve humanitarian aid in blood and blood components that Montenegro provides to other states.

4. Use of Blood

Article 22

The Blood Transfusion Committee shall be established for the purpose of monitoring rational use of blood, adverse effects and other issues associated with the use of blood in medical treatment, in health institutions that use blood in the course of their activity.

The Blood Transfusion Committee shall consist of medical doctors, transfusiology specialists and specialists in other areas of health care that use blood and blood components in their work.

Article 23

A medical doctor who in a medical treatment uses blood and blood components shall be responsible for a justifiable use and correctness of the procedure when using blood in accordance with good clinical practice.

A medical doctor referred to in paragraph 1 of this Article shall keep the prescribed documentation, perform a final verification of data on identity of patient and taken blood component, monitor the patient during the transfusion, treat adverse reactions to transfusion, determine positive effects, as well as adverse (expected or unexpected) reactions to transfusion.

The documentation referred to in paragraph 2 of this Article shall be kept for at least 15 years.

The Ministry shall prescribe the contents of the documentation referred to in paragraph 2 of this Article.

Article 24

Before he receives blood, the patient must give a written consent, that he has been informed about the need and procedure regarding transfusion, its possible adverse consequences, and that he accepts that transfusion is given.

In case of use of blood in medical treatment of a minor or person deprived of business capacity, a medical doctor shall be obliged to inform about the circumstances referred to in paragraph 1 of this Article his parent or guardian and obtain their written consent.

In case it is impossible to obtain the consent referred to in paragraphs 1 and 2 of this Article, a medical doctor shall act in accordance with the principles of medical profession.

Article 25

If the use of blood and blood components results in adverse consequences, a medical doctor shall be obliged to inform immediately, and in accordance with good clinical practice, the Blood Transfusion Committee, health institution where the patient receives the medical treatment, and the Institute.

Article 26

If a health institution determines or has a reasonable doubt that a patient who has been under medical treatment got infected by received blood or blood component, the health institution, in which the patient has been under medical treatment, shall be obliged to determine a unit of infected blood and donor who, by donating infected blood, caused infection or there is a reasonable doubt that he caused the infection.

The health institution referred to in paragraph 1 of this Article shall be obliged to inform about the infection competent health institutions, in accordance with separate regulation governing notification about infectious diseases.

IV DATA PROTECTION

Article 27

In all procedures regarding drawing of blood, protection of privacy of blood donors shall be ensured.

Determining identity of a blood donor and results of laboratory testing shall be done in accordance with the principle of medical ethics.

Article 28

Data on blood donors shall be collected and used only for purposes determined by this Law, as well as for the purposes determined by the law governing records in the area of health.

The Institute shall keep the records on blood donors.

Article 29

The Institute shall keep, in a safe place, all data, personal data including genetic data, as well as other data obtained in the course of its activity.

All data referred to in paragraph 1 of this Article shall be confidential.

Article 30

The access to the data referred to in Article 29 of this Law shall be allowed only to an authorized person.

The data that can be accessed by the authorized person shall be kept in such a manner that a voluntary donor cannot be identified without authorization.

Article 31

Any unauthorized disclosure of data, deletion or change in a donor's medical card and information system, data on deferral of a person as a voluntary donor, as well as any communication or transfer of information, shall be prohibited.

The provision referred to in paragraph 1 of this Article shall not apply to data processing for statistical purposes, as well as data processing for epidemiological and scientific researches.

V SUPERVISION

Article 32

The application of this Law and regulations adopted on the basis of this Law, as well as provision of quality and safety in collection of blood and blood components shall be done:

- by verifying the quality of professional work in accordance with law, and
- inspection supervision.

Article 33

Health inspectors shall perform the inspection supervision activities within the competency of the Ministry, in accordance with law.

VI PUNITIVE PROVISIONS

Article 34

A pecuniary fine in the amount from 30 fold to 200 fold of the minimum cost of labour in Montenegro shall be imposed on a health institution, if it:

1) draws blood from a donor without a prior written consent (Article 12);
2) draws blood from a donor for whom the reasons for deferral are determined (Article 13);
3) fails to perform tests of blood or blood components for infectious disease markers transmitted by blood (Article 14);
4) fails to inform a donor about a found infection, contagious disease or that he is a carrier of infectious disease, and advise on further behaviour (Article 15);
5) fails to keep the records or keep the documentation contrary to Articles 17, 17 and 19 of this Law;
6) stores unused blood and blood components contrary to a separate regulation (Article 20, paragraph 1);
7) uses unused blood for autologous transfusion for other persons (Article 20, paragraph 2);
8) imports blood and blood components without the approval of the Ministry (Article 21, paragraph 1);
9) exports plasma as a raw material for obtaining blood derivatives without the consent of the Ministry (Article 21, paragraph 2);
10) gives transfusion without a written consent of a patient or uses blood in a medical treatment of a minor or person deprived of business capacity without a written consent of a parent or guardian (Article 24);
11) fails to inform the Transfusion Committee and the Institute about adverse consequences of giving transfusion (Article 25);
12) fails to determine infected blood unit and donor who, by donating blood, caused infection, and fails to inform about found infection health institutions in accordance with the regulation governing the manner of notifying about infectious diseases (Article 26);
13) fails to keep data in accordance with law (Articles 27, 28, 29, 30 and 31).

A pecuniary fine in the amount from 10 fold to 20 fold of the minimum cost of labour in Montenegro shall be imposed for the offence referred to in paragraph 1 of this Article in a responsible person.

VII TRANSITIONAL AND FINAL PROVISIONS

Article 35

The Institute shall be established within 12 months from the effective day of this Law.

Article 36

Enabling regulations for implementation of this Law shall be adopted within 12 months from the effective day of this Law.

Until the adoption of the regulations referred to in paragraph 2 of this Article, the regulations that were effective until the effective day of this Law, unless they are contrary to this Law, shall apply.

Article 37

The Blood Transfusion Committees referred to in Article 22 of this Law shall be established within six months from the effective day of this Law.

Article 38

This Law shall come into effect on the eighth day upon its publication in the Official Gazette of Montenegro.

SU-SK No: 01-443/8
Podgorica, 27 November 2007

Parliament of Montenegro
Speaker of the Parliament
Ranko Krivokapić, m.p.