THE CROATIAN PARLIAMENT

Pursuant to Article 88 of the Constitution of the Republic of Croatia, I hereby issue the

DECISION

PROMULGATING THE ACT ON BLOOD AND BLOOD COMPONENTS

I hereby promulgate the Act on Blood and Blood Components, passed by the Croatian Parliament at its session on 30 June 2006.

Class: 011-01/06-01/30
No.: 71-05-03/1-06-2
Zagreb, 5 July 2006

The President of the Republic of Croatia
Stjepan Mesić, m.p.

THE ACT ON BLOOD AND BLOOD COMPONENTS

I GENERAL PROVISIONS

Article 1

This Act governs the supply of the population of the Republic of Croatia with blood products, which comprises a system of social, group and individual measures and actions in the area of planning, collection, processing, testing, storage and distribution of blood products.

The provisions of this Act shall not apply to the supply of medicinal products derived from human blood or plasma.

Article 2

For the purposes of this Act, the following terms shall have the following meanings:

1. «blood» shall mean blood collected from a donor into an anticoagulant solution and processed into blood products for transfusion or for further processing,

2. «blood donor» shall mean a person who gives blood or blood components,
3. «blood recipient» shall mean a person who receives blood or blood components for therapeutic purposes,

4. «blood component» shall mean a constituent of blood collected from a blood donor (erythrocytes, leucocytes, thrombocytes, plasma),

5. «blood product» shall mean any therapeutic product for transfusion derived from human blood or blood component,

6. «plasma derived product» shall mean a therapeutic product or a medicinal product derived from human plasma,

7. «autologous transfusion» shall mean transfusion in which the donor and the recipient are the same person and in which pre-deposited blood or prepared blood components are used,

8. «blood establishment» shall mean any health establishment/part thereof that is responsible for collecting and testing of human blood or blood components, whatever their intended purpose, and their processing, storage and distribution when intended for transfusion,

9. «hospital blood bank» shall mean a hospital unit which stores and distributes blood and blood components and may perform testing of transfusion transmissible infectious markers, immunohaematological and molecular testing of patients and pregnant women, diagnostics and treatment of haemostatic disorders, transfusion control and other hospital-based, transfusion, diagnostic and therapeutic treatments,

10. «serious adverse event» shall mean any undesirable occurrence associated with the collecting, testing, processing, storage and distribution or transport of blood products that might lead to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity,

11. «serious adverse reaction» shall mean an unintended response in donor or in patient associated with the collection or transfusion of blood or blood components that is fatal, life-threatening, disabling, incapacitating, or which results in, or prolongs, hospitalisation or morbidity,

12. «blood component release» shall mean a process which enables a blood component to be released from a quarantine status by the use of systems and procedures to ensure that the finished product meets its release specification,

13. «distribution» shall mean the act of delivery of blood components to blood establishments, hospital blood banks and manufacturers of blood and plasma derived products,

14. «haemovigilance» shall mean a set of organised surveillance procedures aimed to prevent adverse or unexpected events or reactions in donors or recipients or to reduce them to a minimum,

15. «inspection» shall mean control of the application and enforcement of this Act and pertaining regulations, as well as control of the work at blood establishments according to adopted standards.
II. SOCIAL CARE TO ENSURE EFFICACIOUS, HIGH-QUALITY AND SAFE BLOOD PRODUCTS

Article 3

In exercising social care for public health in its entire territory the Republic of Croatia shall create conditions for the supply of its population with efficacious, high-quality and safe blood products.

Article 4

The Republic of Croatia shall exercise its rights, obligations, tasks and objectives in the area of the supply of its population with efficacious, high-quality and safe blood products in that it shall:

- plan the therapeutic needs of patients for medicinal products derived from human blood,
- promote the principles of self-sufficiency in the supply of its population with blood products through voluntary and unpaid blood donations,
- create conditions for raising public awareness of the necessity to collect blood and of the purpose of medicinal products derived from human blood,
- provide funds for bringing the procedures for blood collection and testing as well as for processing, storage and distribution of blood products in line with the achieved scientific and technical progress,
- initiate and ensure the development of a health information system covering the area of transfusion medicine in the Republic of Croatia,
- ensure scientific development in the area of transfusion medicine,
- create conditions for training of health workers in the area of transfusion medicine.

III. ACCESSIBILITY OF BLOOD PRODUCTS

Article 5

In order to ensure the accessibility of blood products to all health institutions through a transfusion service network, a required number of blood establishments shall be set up on national and local levels.

Article 6
The transfusion service network shall be defined within the general health service network in accordance with the Healthcare Act.

Article 7

Planning, collection and testing of blood, and processing, storage and distribution of blood products may be performed by a health institution or a part thereof licensed for one of these activities by the minister responsible for health (hereinafter: the Minister) in accordance with the provisions of this Act (blood establishment).

Article 8

The licence referred to in Article 7 of this Act shall be granted, at the request of a health institution, by the Minister in the form of a decision establishing the fact that the health institution meets the requirements laid down for providing the service concerned.

No complaint may be lodged against the decision referred to in paragraph 1 of this Article, but administrative proceedings may be instituted instead.

A blood establishment where blood products are manufactured shall employ a responsible person – a medical doctor specialist in transfusion medicine with a minimum of five years of professional experience in that specialisation who will be responsible for collection, testing, processing, storage and distribution of blood products in accordance with this Act.

More detailed conditions concerning the required premises, personnel and equipment for carrying out the activities referred to in paragraph 1 of this Article shall be laid down by the Minister in an ordinance, subject to a previously obtained opinion of the competent Chamber.

Article 9

The Minister shall issue an ex officio a decision on the withdrawal of the licence referred to in Article 7 of this Act, if a licensed blood establishment is found:

- to have ceased to comply with the requirements of Article 8 of this Act,
- not to comply with the provisions of this Act and pertaining regulations.

IV. TRANSFUSION SERVICE LICENCE

Article 10
Collection and testing of blood and processing of blood products in the Republic of Croatia may be performed only by a blood establishment in possession of a licence for the provision of such transfusion services.

The licence referred to in paragraph 1 of this Article shall be issued or denied by the Minister by a decision against which no complaints may be lodged, but administrative proceedings may be instituted.

Article 11

An application for the licence referred to in Article 10 of this Act shall be submitted to the Minister and shall contain:

- name and seat of the health institution,
- personal data of the responsible person in the institution,
- personal data of the person responsible for transfusion service in the institution,
- specification of procedures and operations for which the licence is requested,
- documentation describing the operations and quality system, including the responsible persons,
- description of premises and equipment for procedures/operations for which the licence is sought,
- results of external quality control.

Article 12

The licence referred to in Article 10 of this Act shall be issued for a period of five years to cover all or some procedures applied in the collection and testing of blood and processing of blood products.

Article 13

A blood establishment shall apply for the renewal of its licence for the collection and testing of blood and processing of blood products not later than 90 days prior to the expiry of the licence.

The provisions of Articles 10 and 11 of this Act shall appropriately apply to the renewal of the licence for services referred to in paragraph 1 of this Article.

Article 14
A blood establishment shall apply without delay for the Minister's approval of any changes in the procedures for the collection and testing of blood and processing of blood products which may affect their efficacy, quality and safety.

The approval referred to in paragraph 1 of this Article shall be given by the Minister at the request of the blood establishment concerned.

No complaint may be lodged against the decision referred to in paragraph 2 of this Article, but administrative proceedings may be instituted instead.

**V. BLOOD TESTING**

**Article 15**

Blood establishments licensed to test blood products shall test every single donation of blood or blood component.

Testing methods and requirements shall be laid down by the Minister through an ordinance and at least for:

- ABO and Rh D Groups,
- the following transfusion transmissible infections in the donors:
  - HIV1/2, hepatitis B, hepatitis C and syphilis.

**VI. QUALITY ASSURANCE FOR BLOOD AND BLOOD COMPONENTS**

**Article 16**

Blood establishments shall have in place a quality assurance system as part of their transfusion services.

More detailed standards for the quality assurance system referred to in paragraph 1 of this Article, aligned with the requirements of internationally recognised standards applicable to transfusion medicine and taking into account scientific and technical progress, shall be laid down by the Minister.

In order to ensure the quality of blood products, all personnel involved in the collection and, testing of blood, and processing, storage and distribution of blood products shall be appropriately qualified and provided with regularly updated training consistent with a special law.

**Article 17**
Blood establishments shall keep records of provided transfusion services in a format to be prescribed by the Minister through an ordinance.

Information contained in the said records shall be forwarded by blood establishments to the Croatian Institute for Transfusion Medicine in a manner and at intervals laid down in the ordinance referred to in paragraph 1 of this Article.

Information contained in the records referred to in paragraph 1 of this Article shall be kept by the Croatian Institute for Transfusion Medicine for a minimum of 15 years.

Article 18

The Croatian Institute for Transfusion Medicine shall submit to the competent authority (hereinafter: the Ministry) information contained in the records of blood establishments to be kept in compliance with the ordinance passed by the Minister.

The methods and intervals of submitting information contained in the records of blood establishments shall be laid down in the ordinance referred to in paragraph 1 of this Article.

The Ministry shall establish and maintain a unified system of keeping information referred to in paragraph 2 of this Article.

VII. MONITORING ADVERSE EVENTS

Article 19

The system of traceability and labelling of each processed blood product from the donor to the recipient and vice versa throughout the country is a set of procedures and measures developed to enable unmistakable identification of each single donor, each dose taken, each blood component processed and each patient.

The system of traceability and labelling of blood products shall be adjusted to international systems of traceability and labelling to ensure the traceability of blood products on international level.

Blood establishments shall apply a traceability and labelling system in carrying out their activities referred to in Article 7 of this Act.

The blood and blood component traceability and labelling system shall be laid down by the Minister through an ordinance, subject to a previously obtained opinion of the competent Chamber.

Article 20

The Croatian Institute for Transfusion Medicine shall establish a unified national system of monitoring adverse and unanticipated events and reactions related to:
- the collection and testing of blood, and processing, storage and distribution of blood products which may affect their efficacy, quality and safety,

- the administration of blood products in case of any suspicion concerning their efficacy, quality and safety.

The system of documentation, classification and assessment of the seriousness of adverse and unanticipated events and reactions shall allow for international exchange of information.

Blood establishments shall immediately notify in writing the Croatian Institute for Transfusion Medicine and the Ministry on any serious adverse event or a serious adverse reaction that may occur.

Blood establishments shall have in place an efficient and safe procedure to withdraw from distribution the blood products which have caused or which may induce a serious adverse event or a serious adverse reaction.

**Article 21**

Health institutions which administer blood products for transfusion treatment shall have in place a procedure of reporting serious adverse events or serious adverse reactions occurring within the institution.

Health institutions shall immediately notify in writing the Croatian Institute for Transfusion Medicine and the Ministry on any serious adverse event or a serious adverse reaction referred to in paragraph 1 of this Article.

**Article 22**

Records of serious adverse events and serious adverse reactions referred to in Articles 20 and 21 of this Act shall be kept by the Croatian Institute for Transfusion Medicine.

**Article 23**

An ordinance concerning the monitoring of serious adverse events and serious adverse reactions referred to in Articles 20 and 21 of this Act shall be passed by the Minister upon a previous opinion of the competent Chamber.

**VIII. IMPORT AND EXPORT OF BLOOD AND BLOOD COMPONENTS**

**Article 24**
Blood and blood components may not be exported from the Republic of Croatia.

Under exceptional circumstances, however, in the event of natural disasters and other extraordinary situations, or where justified by medical emergencies, the Minister may approve an export of blood and blood products.

In cases referred to in paragraph 1 of this Article blood tests shall be performed in accordance with Article 15 of this Act.

**Article 25**

Blood and blood components may not be imported into the Republic of Croatia.

Under exceptional circumstances, however, in the event of natural disasters and other extraordinary situations, or where justified by medical emergencies, the Minister may approve an import of blood and blood products.

Imported blood and blood products shall meet the requirements laid down in this Act. Tests shall be performed in accordance with Article 15 of this Act.

**IX. QUALITY AND SAFETY OF BLOOD AND BLOOD COMPONENTS**

**Article 26**

Promotion and organisation of blood donations in the Republic of Croatia shall be governed by the principles of voluntariness, gratuitousness, anonymity and solidarity.

It is prohibited to give pecuniary compensation to a donor for donated blood or blood component.

A donor is prohibited from receiving pecuniary compensation for donated blood or blood component.

**Article 27**

Blood and blood components may be donated only by persons of age for whom a medical doctor referred to in Article 29, paragraph 2 of this Act has found that no medical reasons exist which may pose a health risk to the donor or the patient.

As an exception to paragraph 1 of this Article, autologous transfusion donors of blood or blood components need not necessarily be persons of age.

**Article 28**
Prospective donors of blood or blood components shall be informed about possible reactions during blood collection, the extent of blood testing and personal data protection.

Information referred to in paragraph 1 of this Article shall be provided by the medical doctor referred to in Article 29, paragraph 2 of this Act who shall also request information required to assess the eligibility of donors of blood or blood components.

Article 29

Before any donation of blood or blood components the medical doctor shall examine the prospective donor.

The medical doctor examining prospective donors shall be appointed by the responsible person of a blood establishment referred to in Article 8, paragraph 3 of this Act.

The scope of examination referred to in paragraph 1 of this Article and the criteria for the selection of donors shall be laid down by the Minister through an ordinance.

Article 30

Before any donation of blood or blood components the potential donor shall give his or her consent to voluntary donation of blood or blood components.

The consent referred to in paragraph 1 of this Article shall be given in writing as an expression of the donor's free will, based on proper information concerning the purpose of donation and usual risks involved in it.

The informed consent form referred to in paragraph 1 of this Article shall be prescribed by the Minister through an ordinance.

Article 31

The Croatian Institute for Transfusion Medicine shall keep a register of blood donors.

The register referred to in paragraph 1 of this Article shall in particular include data on individuals suspended from the eligibility to donate blood or blood components on a temporary or permanent basis.

Article 32

The register of blood donors shall be a part of the national information system covering the transfusion services.

The register shall be accessible to all health institutions engaged in blood collection.

Funds required for keeping the register shall be provided from the State Budget.
Article 33

Donation of blood and blood components in the territory of the Republic of Croatia shall be promoted by the Croatian Institute for Transfusion Medicine and the Croatian Red Cross.

Promotional activities shall be continuous and in line with the need for sufficient quantities of blood and blood components country-wide and all year round.

Article 34

A national annual blood donation action plan shall be drawn up by the Croatian Institute for Transfusion Medicine and the Croatian Red Cross on the basis of anticipated needs for blood products of all health institutions.

Article 35

Requirements in respect of premises and equipment to be met by organisers of blood donation actions shall be laid down by the Minister.

X. DATA PROTECTION

Article 36

Health-related information about blood donors, including data referred to in Articles 15 and 28 of this Act, shall be kept confidential and protected from unauthorised access.

Article 37

Personal data on donors shall constitute a professional secret.

Personal data referred to in paragraph 1 of this Article shall be kept and communicated in accordance with special regulations governing professional secret and personal data protection.

XI. INSPECTION AND CONTROL MEASURES

Article 38

Inspectional supervision to ensure that this Act and pertaining regulations are complied with, as well as inspection and control measures in blood establishments shall be carried out by the Ministry's health inspection service.
Inspection and control measures referred to in paragraph 1 of this Article shall be carried out by health inspectors and other public employees in accordance with a separate law.

**Article 39**

Health inspectors shall carry out regular inspectional supervision referred to in Article 38 of this Act at least once in two years.

In case of a serious adverse event health inspectors shall carry out an emergency inspection.

**Article 40**

In carrying out inspectional supervision referred to in Article 39 of this Act health inspectors shall have the right and duty to:

1. order a blood establishment to work in compliance with the requirements of this Act and other regulations,

2. order to eliminate detected irregularities and defects within the prescribed period of time,

3. impose a ban on any activities which contravene this Act and other relevant regulations,

4. suspend the operation of a blood establishment which fails to meet requirements in respect of personnel, equipment and premises,

5. impose a ban on the operation of an establishment engaged in the planning, collection and testing of blood, and processing, storage, distribution or issuing of and blood products without the Minister's approval,

6. impose a ban on the operation of an establishment engaged in the collection and testing of blood, or processing of blood products without a licence covering that particular activity,

7. order to withdraw from distribution blood products which fail to meet the requirements of this Act and other relevant regulations,

8. declare a blood product hazardous waste and order its disposal if it does not comply with relevant standards,

9. order other measures to be taken within their powers by virtue of this Act and other relevant regulations.

**XII. PENAL PROVISIONS**

**Article 41**
A fine of HRK 70,000 to 100,000 shall be imposed on a legal entity which:

1. plans, collects and tests blood, or processes, stores or distributes blood products without the Minister's approval (Article 7),

2. collects or tests blood, or processes blood products without a licence issued by the Minister (Article 10),

3. exports blood or blood components from the Republic of Croatia in contravention of Article 24 of this Act,

4. imports blood or blood components into the Republic of Croatia in contravention of Article 25 of this Act.

A fine of HRK 7,000 to 15,000 for an offence referred to in paragraph 1 of this Article shall also be imposed on the responsible person in the legal entity concerned.

A fine of HRK 5,000 to 15,000 for an offence referred to in paragraph 1 of this Article shall also be imposed on the natural person involved.

An attempted offence referred to in paragraph 1 of this Article shall be punishable.

**Article 42**

A fine of HRK 70,000 to 100,000 shall be imposed on a blood establishment which fails to:

1. notify the Croatian Institute for Transfusion Medicine and the Ministry on any serious adverse event or serious adverse reaction (Article 20, paragraph 3),

2. protect confidential health information about the donor from unauthorised access (Article 36).

A fine of HRK 7,000 to 10,000 for an offence referred to in paragraph 1 of this Article shall also be imposed on the responsible person in the establishment concerned.

**Article 43**

A fine of HRK 30,000 to 50,000 shall be imposed on a blood establishment which:

1. in case of any changes in the procedures for the collection or testing of blood, or processing of blood products which may have an adverse effect on their efficacy, quality and safety, fails to apply for the Minister's approval (Article 14, paragraph 1),

2. in providing transfusion services fails to keep the required records (Article 17, paragraph 1)
3. fails to submit to the Croatian Institute for Transfusion Medicine information contained in its records in a timely manner (Article 17, paragraph 2),

4. provides pecuniary compensation for donated blood (Article 26, paragraph 2),

5. collects blood from an underage or adult person in contravention of Article 27 of this Act,

6. fails to inform a prospective donor of blood or blood components about possible reactions during blood collection, the extent of blood testing and the protection of personal data (Article 28),

7. fails to carry out the required medical examination of a potential donor of blood or blood components (Article 29),

8. collects blood or blood components without the required informed consent of the donor (Article 30)

A fine of HRK 3,000 to 7,000 for an offence referred to in paragraph 1 of this Article shall also be imposed on the responsible person in the establishment concerned.

A fine of HRK 3,000 to 7,000 for an offence referred to in paragraph 1, items 5, 6, 7 and 8 of this Article shall also be imposed on the medical doctor in the blood establishment.

An attempted offence referred to in paragraph 1, points 4, 5 and 8 of this Article shall be punishable.

**Article 44**

A fine of HRK 30,000 to 50,000 shall be imposed on the Croatian Institute for Transfusion Medicine for failure to submit to the Ministry information contained in the records kept by blood establishments in a timely manner (Article 18, paragraph 1).

A fine of HRK 3,000 to 7,000 for an offence referred to in paragraph 1 of this Article shall also be imposed on the responsible person in the Croatian Institute for Transfusion Medicine.

**Article 45**

A fine of HRK 1,000 to 5,000 shall be imposed on a natural person who receives pecuniary compensation for donated blood or blood components (Article 26, paragraph 3).

**XIII. TRANSITIONAL AND FINAL PROVISIONS**

**Article 46**
The ordinances that under this Act the Minister is authorised to issue shall be issued within six months following the entry into force of this Act.

**Article 47**

Health institutions which were granted a licence for the provision of transfusion services by virtue of regulations in force before the date of entry of this Act into force shall bring their work and operation in line with the provisions of this Act and the pertaining ordinances within six months of the day on which the ordinances referred to in Articles 8 and 16 of this Act take effect.

**Article 48**

On the date of entry into force of the ordinances referred to in Article 46 of this Act, the Ordinance on blood and blood components (Official Gazette 14/99) shall cease to have effect.

**Article 49**

This Act shall enter into force on the eighth day after the day of its publication in the Official Gazette.

Class: 500-01/05-01/04
Zagreb, 30 June 2006

THE CROATIAN PARLIAMENT
The President
of the Croatian Parliament
Vladimir Šeks, m. p.