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SOCIALIST REPUBLIC OF
SRI LANKA

Part II of September 21, 2007

SUPPLEMENT

(Issued on 24. 09. 2007)



NATIONAL BLOOD TRANSFUSION SERVICE

A
BILL

to provide for the regulation and monitoring of blood transfusion services;
to ensure an effective safe blood supply throughout the country in order to
give effect to the National Blood Policy; and for matters connected therewith
or incidental thereto.

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National Blood Transfusion Service

L. D. — O. 43/2001.

AN ACT TO PROVIDE FOR THE REGULATION AND MONITORING OF BLOOD TRANSFUSION SERVICES; TO ENSURE AN EFFECTIVE SAFE BLOOD SUPPLY THROUGHOUT THE COUNTRY IN ORDER TO GIVE EFFECT TO THE NATIONAL BLOOD POLICY; AND FOR MATTERS CONNECTED THEREWITH OR INCIDENTAL THERETO.

WHEREAS access to safe blood is a recognized right of every human being, therefore blood is a valuable human resource and the transfusion of blood is a valuable human resource and the transfusion of blood forms an integral part of the health system of the country :

Preamble.

AND WHEREAS the National Blood Transfusion Service will be entrusted with the responsibility of implementing the blood transfusion service throughout the country and the strengthening of the blood transfusion service shall be accorded the highest priority as blood transfusion is life saving but if not properly administered could be fatal:

AND WHEREAS a National Blood Policy has been formulated with a view to ensuring the effective and accessible service of a safe and adequate supply of blood and blood components to the public:

AND WHEREAS it has become necessary to give legal recognition to the National Blood Policy with a view to ensuring the effective and efficient implementation of the National Blood Policy:

NOW THEREFORE BE it enacted by the Parliament of the Democratic Socialist Republic of Sri Lanka as follows :—

1. This Act may be cited as the National Blood Transfusion Service Act, No. of 2007 and shall come into operation on such date as the Minister may appoint by Order published in the *Gazette*.

Short title.

2—PL 001510-375 (10/2006)



PART I

RESPONSIBILITIES AND DUTIES OF THE NATIONAL BLOOD
TRANSFUSION SERVICE

2. There shall be a National Blood Transfusion Service of the Ministry of Health, which shall be responsible—

The National
Blood
Transfusion
Service.

(a) for the collection, screening, processing, storing and supply of safe blood to —

(i) government hospitals including hospitals coming under the Ministry of Defence; and

10 (ii) Private Medical Institutions,

in which blood is intended to be used for transfusing blood or blood components to patients; and

15 (b) for the strengthening and improvement of the quality of the blood transfusion services throughout the country through a comprehensive and quality assurance approach.

3. It shall be the duty of the National Blood Transfusion Service—

Duties of the
National
Blood
Transfusion
Service.

20 (a) to exercise care in the selection of donors, in order to ensure that blood is collected only from low-risk, voluntary and non-remunerated donors;


(b) to screen all blood donated for the presence of any transmissible infections, including—

(i) Human Immuno Deficiency Virus (H.I.V.) ;

25 (ii) Hepatitis B and C;

- (iii) Syphilis;
 - (iv) Malaria; and
 - (v) any other infection as may from time to time be determined by the Director General of Health Services relating to transmissible infections, based on the guidelines issued by the World Health Organization;
- 5
- (c) to process all blood and prepare blood components;
 - (d) to store blood and blood components according to such standards as may be prescribed;
 - (e) to ensure, as far as possible the availability and accessibility of stocks of blood of all groups;
 - (f) to provide training for members of the staff of the National Blood Transfusion Service, Government hospitals and Private Medical Institutions;
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- (g) to develop a National Reference Laboratory for blood transfusion;
 - (h) to issue guidelines concerning the manner of selection of blood donors, the collection, screening, processing, storing, issuing, transportation and appropriate usage of blood and blood components —
- 15
- (i) to members of the Staff of the National Blood Transfusion Service; and
 - (ii) to members of the Staff of Government hospitals who are managing the Blood Transfusion Units of such Institutions and clinical staff attached to such institutions;
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- 25
- 2



- 2
- (iii) to the members of Private Medical Institutions, who are managing the blood Transfusion Units of such Institution and clinical staff attached to such institution.
- 5 (i) to take steps to ensure —
- (i) that blood and blood components supplied or transfused to patients are tested and screened according to prescribed standards;
- 10 (ii) the training of Medical Officers both in the Government hospitals and Private Medical Institutions in blood transfusion procedures ;
- (j) to ensure the compliance with the provisions of this Act and any regulations made thereunder, and all directions given by the Minister and the Committee appointed under section 18 in terms of the Act;
- 15 (k) to dispose of all materials contaminated with blood in a safe manner;
- (l) to accept whole blood and red cell concentrate units supplied to licensees for the purpose of transfusing of blood to patients, if such blood or units are returned ten days prior to the date of expiry of such product and it is in good condition;
- 20 (m) to take appropriate follow up actions in accordance with prescribed National Standards in the event of a positive transmissible infection in the donated blood being discovered;
- 25 (n) to conduct research and to collect and record data, concerning the development and maintenance of the National Blood Transfusion Service;
- 

- (o) to provide facilities for training persons required to carry out the work of the National Blood Transfusion Service.

PART II

7/5

ISSUE OF LICENSES AND THE DUTIES OF THE LICENSEES

- 4. (1) From and after the coming into operation of this Act, any Private Medical Institution registered under the Private Medical Institutions (Registration) Act, No. 21 of 2006, which intends to establish a Blood Bank within its institution, shall submit an application in the prescribed form accompanied by the prescribed fee, to the Director General of Health Services (hereinafter referred to as the "Director General") for a license — Issue of Licenses.
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- 15
 - (a) to collect or process blood or blood components intended to be used for the transfusion to patients; and
 - (b) to store or supply blood or blood components for the purpose of transfusion to patients.
- 20 (2) The application shall be accompanied by such additional information as may be prescribed.
- 25 (3) Upon receipt of an application under subsection (1), the Director-General, may having regard to the necessity of maintaining a safe public health system—
 - (a) issue a license, subject to such terms and conditions as are required in that regard; or
 - (b) refuse to issue a license.
- (4) A license issued in terms of this section shall be valid for a period of one year and shall not be transferable, and accordingly any such transfer shall be null and void.



5. Every Private Medical Institution which has been issued a license (hereinafter referred to as the "licensee") shall at all times exhibit such license in a conspicuous place in such institution. License to be exhibited.
- 5 6. The National Blood Transfusion Service shall keep and maintain a register of every license, issued under this Act, along with all relevant details of the licensee. Register to be maintained by the National Blood Transfusion Service.
7. The licensee shall at all times —
- (a) safeguard and uphold the National Blood Policy;
- 10 (b) maintain records and furnish such records to the National Blood Transfusion Service, when requested to do so. Duties of licensee relating to records.
8. (1) Where a licensee ceases to operate a Blood Bank to which the license relates, it shall forthwith notify the National Blood Transfusion Service that it has ceased to operate the Blood Bank. Duty of a licensee to inform the National Blood Transfusion Service when it has ceased to operate a blood bank.
- (2) On receipt of a notice under subsection (1), the National Blood Transfusion Service shall remove the name of such licensee, from the register maintained by it under section 6 and shall recommend to the Director-General to cancel the license issued to such Private Medical Institution.
- 20 (3) Where the National Blood Transfusion Service has reason to believe that the licensee does not operate a Blood Bank, the National Blood Transfusion Service may send a notice by registered post, to such licensee, requiring it to furnish proof, within three weeks from the date of such notice, that it has not ceased to operate a Blood Bank. Where a licensee fails to submit proof required by the notice within such period specified in the notice, the National Blood
- 30 Transfusion Service shall remove the name of the licensee

from the register maintained by it under section 6, and shall recommend to the Director-General to cancel the license issued to such Private Medical Institution.

5 (4) The National Blood Transfusion Service shall in writing inform the Private Medical Institution whose name is removed from the register, of the fact of such removal and cancellation of the license.

9. Every licensee shall, within thirty days of any change in the particulars contained in its application, notify the Director-General in writing, of such change. Any change in particulars in the application for a license to be notified to the Director-General.

10. A license issued under this Act, may be renewed by the Director-General for a period of one year, on an application made in that behalf in the prescribed form, within a period of three calendar months, prior to the expiry of the license in force. Renewal of license.

11. The Director-General may on the recommendation of the National Blood Transfusion Service, cancel a license or refuse to renew a license issued under this Act, if he is satisfied, after affording the licensee of an opportunity of being heard, that the licensee— Cancellation of license.

- (i) has contravened any provision of this Act or of any regulation made thereunder or any term or condition to which such license is subject to; or
- 25 (ii) has operated the Blood Bank in such a manner as is detrimental to the safety of any person or persons who have availed themselves of the services provided by it, through such Bank; or
- (iii) has failed to uphold the National Blood Policy.



12. (1) Any Private Medical Institution which is aggrieved by the refusal of the Director-General to issue a license to such Private Medical Institution or by the cancellation of a license or refusal to renew a license may, within thirty days after the receipt of the decision of the Director-General refusing to issue a license, or canceling or refusing to renew a license, as the case may be, appeal, in writing against such decision to the Secretary of the Ministry of the Minister in charge of the subject of Health.

Appeals
against
refusal to
issue license,
cancellation
&c.,

10 (2) Any Private Medical Institution aggrieved by the decision of the Secretary to the Ministry of the Minister in charge of the subject of Health, on an appeal made to him under subsection (1), may appeal in writing, against such decision to the Minister, whose decision shall be final. Both such appeals shall be disposed of within a period of one month.

(3) The procedure for the hearing of appeals shall be as prescribed.

13. The Minister may from time to time issue in writing general or special directions to the National Blood Transfusion Service, Government Hospital or any Private Medical Institution for the purpose of giving effect to the provisions of this Act and it shall be the duty of the National Blood Transfusion Service, Government Hospital or such Private Medical Institution to give effect to such directions.

Directions.

14. The National Blood Transfusion Service or any person authorized in writing by the National Blood Transfusion Service may enter at any time, any premises in which a licensee is operating a Blood Bank or any premises in respect of which such licensee is providing any services which it is authorized to provide by a license issued under this Act, for the purpose of ascertaining whether the provisions of this Act or the terms and conditions of such license are being complied with.

Powers of
entry.

15. Every Director of a Private Medical Institution which carries on the business of a Blood Bank without being licensed under this Act, shall be guilty of an offence under this Act, and shall on conviction after summary trial before a Magistrate be liable to a fine not exceeding two hundred thousand rupees or to imprisonment for a term not exceeding seven years or to both such fine and imprisonment. Operating a Blood Bank without a license an offence.

16. Every person, who— Offences.

10 (a) contravenes any provision of this Act or any regulation made thereunder ;

(b) makes any statement, in an application or declaration made by him or in any record maintained by him, knowing such statement to be false in any material particulars ; or

15 (c) resists or obstructs the National Blood Transfusion Service or any person authorized in writing by such service, in the exercise, by such service or person, of the powers conferred by this Act,

20 shall be guilty of an offence under this Act and shall on conviction after summary trial before a Magistrate be liable to a fine not exceeding one hundred thousand rupees or to imprisonment of either description for a term not exceeding five years or to both such fine and imprisonment.

17. (1) A licensee shall— Duties of Licensees.

25 (a) exercise care in the selection of donors, in order to ensure that blood is collected only from low-risk, voluntary and non-remunerated donors ;

(b) establish blood storing facilities in accordance with such specifications as may be prescribed ; by NBT's

(c) obtain blood and blood components from Blood Banks of National Blood Transfusion Service and ensure as far as possible the availability and accessibility of stocks of blood of all groups ;

5 (d) take steps to ensure that blood and blood components supplied or transfused to patients are tested and screened ;

note to
be from
NBTS
responsible
to NBTS

(e) take all steps to ensure that only Medical Officers trained by the National Blood Transfusion Service, are engaged in blood transfusion and to provide training to Medical Officers attached to Private Medical Institutions in keeping with the National Blood Policy and guidelines issued by the National Blood Transfusion Service ;

(f) comply with all the provisions of this Act and the Regulations made thereunder ;

(g) comply with any directions issued by the Monitoring Committee and the Minister ;

20 (h) dispose of materials contaminated with blood in a safe manner ;

(i) take appropriate follow up actions in accordance with the prescribed National Standards in the event of a positive transmissible infection in the donated blood being discovered ;

25 (j) not charge any amount in excess of the amount paid by such licensee to the National Blood Transfusion Service for each unit of blood or blood component :

30 Provided however any service charge or charges for additional tests if carried out can be recovered separately by the licensee according to the guidelines as may be set out by the Monitoring Committee ;



- (k) carry out the functions in accordance with the prescribed National Standards and the direction of the Monitoring Committee of the National Blood Transfusion Service.

5

PART III

ADMINISTRATION

18. The Minister shall appoint a Committee, which shall be called the Blood Transfusion Service Monitoring Committee (in this Act referred to as the "Committee") consisting of—

Constitution of the Blood Transfusion Service Monitoring Committee.

10

(i) the following *ex-officio* members-

(a) the Director-General who shall be the Chairman of the Committee ;

15

(b) the Director of the National Blood Transfusion Service ;

(c) the Director of the National Sexually Transmitted Diseases and AIDS Control Programme ;

20

(d) the Director of Private Medical Institutions ; and

(e) the Deputy Director-General of Laboratory Services ; and

(f) the Deputy Director of Public Health Services ; and

25

(ii) the following members (hereinafter referred to as the "appointed members")—

30

(a) a Professor from the Medical Faculty of the University of Colombo nominated by the University Grants Commission, established under the Universities Act, No. 16 of 1978;

(b) a Hematologist nominated by the College of Hematologists ;



- (c) a Physician nominated by the College of Physicians ;
- (d) a Surgeon nominated by the College of Surgeons ;
- 5 (e) an Obstetrician nominated by the College of Obstetricians and Gynecologists ;
- (f) two representatives nominated by the registered Private Medical Institutions from among themselves ; and
- 10 (g) two consultants and ten Senior Medical Officers from the National Blood Transfusion Service.

19. A person shall be disqualified from being appointed or continuing as a member of the Committee— Disqualification from being a member.

- 15 (a) if he is or becomes a Member of Parliament or any Provincial Council or any local authority ; or
- (b) if he is not, or ceases to be, a citizen of Sri Lanka ; or
- (c) if he is under any law in force in Sri Lanka or in any other country found or declared to be of unsound mind ; or
- 20 (d) if he is serving or has served a sentence of imprisonment imposed by any court in Sri Lanka or any other country ; or
- 25 (e) if he has any financial or other interest as is likely, to affect prejudicially the discharge by him of his functions as member of the Committee.

20. (1) Every appointed member shall unless he vacates office earlier by death, resignation or removal, hold office for a term of three years from the date of his appointment and shall unless he has been removed from office, be eligible for re-appointment. Term of office of the appointed members.



(2) An appointed member shall, cease to be a member of the Committee on his ceasing to hold the office which he represents.

(3) Any member of the Committee may be removed for 5 reasons assigned.

(4) Where any member ceases to hold office under subsections (1) or (2), the Minister shall having regard to the provisions of section 18, appoint a suitable person for the unexpired period of the term of office of such person.

15 21. The objectives of the Committee shall be — Objectives of the Committee.

- (a) to develop, supervise and monitor the prescribed standards required to be maintained by the National Blood Transfusion Service ;
- 10 (b) to evaluate the standards maintained by the licensees ;
- (c) to ensure that at least the minimum qualifications for recruitment and minimum standards of training of persons are adhered to.

20 22. (1) The Committee shall regulate the transaction of business at meeting of the Committee. Transaction of business of Committee and quorum.

(2) The quorum for a meeting of the Committee shall be eight members.

23. In the implementation of the objectives on set out in section 21 the Committee shall have the power to — Powers of the Committee.

- 25 (a) authorize any member of the Committee or any person authorized in writing in that behalf by the Committee, to enter at any reasonable time, any premises where a blood bank is established and blood transfusion procedures are carried on, to
30 inspect the records required to be maintained at such



- 5 bank, in order to ascertain, whether the premises are being maintained with due regard to the health and safety of patients and whether provisions of any regulations applicable in the case of blood transfusion service are being complied with and to make recommendations to the Chairman of the Committee for appropriate action ;
- 10 (b) review from time to time the conditions that are prescribed for the issue of licenses and to revise and amend them in order to maintain the required standards ;
- 15 (c) prevent blood or blood components being sold to any person for use in relation to patients, other than recovering the cost of a blood unit paid to the National Blood Transfusion Service and any other service charges ; *as prescribed in Section 17*
- 20 (d) formulate a quality assurance programme for patient care and monitoring the implementation of the same ;
- 25 (e) advice and make recommendations to the Minister on all matters pertaining to blood safety and the implementation of the National Blood Policy ; and
- (f) identify the action to be taken by the Director-General in the event of any non-compliance, by a medical officer or other officer.

as recommended by the Committee mentioned in Section 17 of this Act

PART IV

GENERAL

(1) The Minister may make regulations in respect of Regulations.
 30 all matters required by this Act to be prescribed or in respect of which regulations are required or authorized to be made under this Act.



(2) Without prejudice to the generality of subsection (1), the Minister may make regulations for, or in respect of, any or all of the following matters :—

- 5 (a) the form of the application and the particulars to be contained therein, the form of the license to be issued and the terms and conditions if any, to which such license should be subject to ;
- 10 (b) the records, books, registers, receipts, statements, forms or any other documents which shall be kept or maintained in the National Blood Transfusion Service and blood banks of the Private Medical Institutions ;
- 15 (c) the National Standards required to be followed in the composition, quality and appropriate use of blood or blood components ;
- 20 (d) defining staffing patterns (including minimum qualifications) initial training and in service training and courses that should be followed by persons attached to the National Blood Transfusion Service and the Blood Banks ;
- 25 (e) adoption of universally accepted precautions for the prevention and control of infections ;
- (f) the procedure or practice to be followed in entertaining and disposing of any complaint by any aggrieved person, against any Private Medical Institution, or any person attached thereto ;
- (g) the method of collection, preservation, storing and testing of blood or blood components ;
- (h) the Forms to be used for the purposes of this Act ;



- (i) the procedure to be followed in the analysis or examination of blood, the taking of samples and fees to be paid for the analysis or examination of blood or blood components ;
- 5 (j) the rate to be charged for each unit of blood or blood components supplied to any Private Medical Institution.

(3) Every regulation made by the Minister shall be published in the Gazette and shall come into operation on
10 the date of publication or on such later date as may be specified therein.

(4) Every regulation made by the Minister, shall as soon as convenient after its publication in the Gazette be brought before Parliament for approval. Every regulation which is
15 not so approved shall be deemed to be rescinded as from the date of disapproval but without prejudice to anything previously done thereunder.

(5) The Notification of the date on which any regulation is deemed to be so rescinded shall be published in the Gazette.

20 25. (1) Any Nursing Home which is registered under the Private Medical Institutions (Registration) Act, No. 21 of 2006 and which operates a blood bank may notwithstanding the provisions of this Act, continue to operate a blood bank for a period of nine months from the date of coming into
25 operation of this Act. Transitional provision.

(2) Upon the expiry of a period of six months out of the total period of nine months referred to in subsection (1), a Private Medical Institution shall apply for a license, in terms of the provisions of this Act, to continue to operate any Blood
30 Bank.

26. In the event of any inconsistency between the Sinhala and Tamil text of this Act, the Sinhala text shall prevail.

Sinhala text to prevail in case of inconsistency.

27. In this Act unless the context otherwise requires— Interpretation.

5 “Private Medical Institution” means any premises used or intended to be used for the reception of, and the providing of nursing and treatment for persons suffering from any sickness, injury or infirmity, which is registered as a nursing home under the Private Medical Institutions (Registration) Act, No. 21 of 2006, and shall include a hospital, a nursing home, a maternity home, dental surgery, dispensary and surgery, cooperative hospital with the cover of a Medical Officer registered within the Sri Lanka Medical Council ;

“blood ” means whole human blood ;

20 “Blood Bank” means a place or organization or unit or institution which provides facilities for the collection, storage and distribution of blood or blood components when place or organisation may or may not possess facilities for the collection and processing of blood ;

25 “blood component” means blood constituents prepared by the process of mechanical separation of whole blood or plasma for the purpose of transfusion to patients ;

30 “donor” means a person who donates blood and satisfies the criteria as is required by the Director-General without accepting in return any consideration whether by way of cash or kind, from any source.