Administrative Action Union of Myanmar
The State Peace and Development Council

The Blood and Blood Products Law

(The State Peace and Development Council Law No. 1/2003)
The 12th Waning day of Pyatho, 1364 M.E
(29th January 2003)

The State Peace and Development Council hereby enacts the following Law:-

Chapter I
Title and Definition

1.This Law shall be called the Blood and Blood Products Law.

2.The following expressions contained in this Law shall have the meanings given hereunder:-

(a) Blood means naturally occurring fluid in the human body consisting of red blood cells, white blood cells, platelets, plasma and biochemical substances contained in the plasma.

(b) Blood product means element of blood such as red blood cells, white blood cells, platelets, plasma and biochemical substances contained in the plasma which is obtained in any manner as a result of processing.

(c) Blood transfusion instruments mean needle, syringe, tube, bottle, bag and other materials used in extracting, injecting or collecting blood and blood products.

(d) Sharp instruments mean needle, knife, and any instrument which can cause bleeding in surgical operation or on contact with any part of the human body.

(e) Committee means of the National Blood and Blood Products Committee formed under section 4.

(f) National Blood Centre means the main centre established by the Ministry of Health for enabling the discharge of functions contained in section 7.

(g) Blood Bank means the establishment for enabling the discharge of functions contained in section 8.

(h) Small-Scale Blood Bank means the establishment for enabling the discharge of functions contained in section 9.

(i) Blood transfusion service means the functions assigned to be performed by the National Blood Centre, Blood Bank and Small-Scale Blood Bank.

(j) Disposing of waste means administering by any means to eliminate blood and blood products unsuitable for use, and used blood transfusion instruments and sharp instruments.

(k) Licence means the permit issued under section 11 to establish and operate private Small-Scale Blood Bank.

Chapter II
Aims

3. The aims of this Law are as follows:-

(a) to enable saving and looking after patients' life by transfusion utilizing quality-assured blood;

(b) to prevent transfusion transmissible infection through blood and other dangers, and to enable assuring both mental and physical safety;

(c) to enable systematic supervision of extracting, collecting, storing, issuing, distributing, transfusing and disposal of waste of blood and blood products;

(d) to carry out implementation of blood donor system on voluntary basis;

(e) to contribute towards health care of patients not taking into consideration of profit in performing blood transfusion service; (f) to enable promotion, dissemination and research in respect of blood and blood products and to nurture experts thereof.

CHAPTER III
Formation or National Blood and Blood Products

Committee and Duties and Functions There of

4. The Government

(a) shall form the National Blood and Blood Products Committee comprising not more than 2.1 members with the Minister for Ministry of Health as the Chairman Director-General of the Department of Health as the Secretary, heads of the relevant ministries, government departments and organizations and representatives of the non-governmental organizations as members;

(b) may, in forming under subsection (a), determine suitable persons from among the members as the Vice Chairman and the Joint Secretary ;

(c) may re-constitute, if necessary, the National Blood and Blood Products Committee formed under sub-section (a).

5. The functions and duties of the Committee are as follows;

(a) laying down policy to perform blood transfusion service successfully in accordance with the aims of this Law;

(b) giving guidance to carry out measures as may be necessary for the prevention of blood transfusion transmissible infections; (c) issuing licence to establish Small-Scale Blood Bank, refusing to issue licence thereof , suspending the licence subject to a time limit and canceling thereof;

(d) stipulating conditions in respect of extracting, collecting, storing, importing , exporting, issuing, distributing and disposal of waste of blood and blood products;

(e) stipulating the conditions that are to be abided by in performing blood transfusion services systematic, and supervising thereof;

(f) giving guidance to carry out exhorting and organizing work for increasing the number of voluntary blood donors;

(g) giving guidance to stipulate the requirements of voluntary blood donors;

(h) giving guidance for sufficiency of required skilled persons and facilities for blood transfusion service;

(i) giving guidance to determine conditions that are to be abided by in utilizing blood and blood products, in utilizing blood transfusion instruments and sharp instruments, and in carrying out other tasks that may possibly cause transmissible infectious through blood;

(j) giving guidance on holding seminars and meetings. and conduction of training courses for the promotion and development of knowledge on blood transfusion service. and prevention of transmissible infections through blood;

(k) giving guidance to conduct research in respect of transmissible infections through blood and blood products;

(l) issuing permit to the government departments and organizations and Red Cross Society desirous of establishing Blood Bank or Small-Scale Blood Bank;

(m) communicating and cooperating with the government departments and organizations, international organizations, and local and international non-governmental organizations for, effective and successful implementation 'of blood transfusion service;

(n) forming of required State Divisional District and Township Blood Bank Committees to supervise the Blood Bank and Small-Scale...Blood Banks .and stipulating functions and duties thereof;

(o) submitting recommendation to the Ministry of Health to proceed with the conferring of honour by the State to voluntary blood donors who conform to the stipulations including the number of times of blood donation.

(p) forming required Sub-Committees and stipulating functions and duties thereof to carry Ot1t the functions and duties of the , Committee effectively.

6. The Committee may delegate its functions and duties to any organization or department.

CHAPTER IV
Functions of the National Blood Centre

7. The functions or the National Blood Centre are as follows :

(a) carrying out the functions of extracting t calming, storing, distributing and disposing of waste of blood and blood products that conform to the standard and are free from micro-organism causing acquired immune deficiency syndrome {AIDS), viral hepatitis, venereal disease, malaria and other transmissible infections through blood :

(b) prescribing norms and standards on matters of skill and technology in respect of blood .transfusion service ;

(c) carrying out exhorting and organizing work to increase the number of blood donors and to obtain safe blood ;

(d) safeguarding the reputation and interests of the voluntary blood donors;

(e) making necessary arrangements for re-vitalization of voluntary blood donor during the process of blood donation ;

(f) awarding blood donor badges and certificates of honour to the voluntary blood donors ;

(g) submitting to, the Committee for enabling conferring of honour by the State to the voluntary blood donors who conform to the stipulations including the number of trines of blood donation ;

(h) disseminating and promoting knowledge in respect of blood and blood products ;

(i) conducting training courses, holding meetings, conducting research and nurturing experts in respect of blood and blood products ;

(i) manufacturing and di5tributing required reagent to enable grouping and screening of blood and blood products ;

(k) performing functions and duties assigned by the Committee from time to time.

CHAPTER V
Functions of the Blood Bank and Small-Scale Blood Bank

8. The functions of the Blood Bank are as follows :

(a) Carrying out the functions of the extracting collecting, storing, issuing, distributing and disposal of waste of blood and blood products in conformity with the conditions as stipulated ;

(b) Carrying out exhorting and organizing work to increase the number of blood donors and to obtain safe blood;

(c) Carrying out the functions of collecting & storing, issuing, distributing and disposal of waste of blood that conform to the standard, and are free from micro-organism causing AIDS, viral hepatitis venereal disease, malaria and other transmissible infections through blood ;

(d) , Safeguarding the reputation and interests of the voluntary blood donors

(e) Making necessary arrangements for re-vitalization of voluntary blood donor during the process of blood donation ;

(I) Awarding blood donor badges and certificates of honour to voluntary blood donor ;

(g) Submitting to the Committee for enabling conferring of the relevant award of honour to the voluntary blood donors who conform to the. stipulations including the number of times of blood, donation;

9. The Small-Scale Blood Bank shall comply with the conditions stipulated in carrying out the works of storing, issuing and disposal of waste of blood and blood products received .from National "Blood Centre arid Blood Banks, or of blood products imported legally for treatment of the patient.

Chapter VI
Application and Issuance of Licence

10. A person desirous of establishing a private Small-Scale Blood Bank shall apply to the organization or department assigned duty by the Coma licence, in conformity with the stipulations.

11. The organization or department assigned duty by the Committee under section 10 may, after scrutiny of the application, issue or refuse to issue the licence.

12. The organization or department assigned duty by the Committee may, after scrutiny of the application for renewal of licence in conformity with the stipulations renew the licence.

13. The Ministry of Health shall determine the tenure of licence, licence fees and licence renewal fees.

Chapter VII
Administrative Action

14. If the licence holder violates any of the conditions contained in the licence or fails to abide by any notification, order and directive issued under this Law, the organization or department assigned duty by the Committee may pass any of the following administrative orders:-

(a) warning;

(b) suspending the licence subject to a time limit;

(c) cancellation of licence.

Chapter VIII
Appeal

15. A person dissatisfied with the order or decision passed on him in respect of refusal to issue licence, or suspending the licence subject to a time]i1nit, or cancellation of licence by the organization or department assigned duty by the Committee. may file an appeal to the Committee within 60 days from the date on which such order or decision had been passed.

16. The Committee may, in respect of the appeal under section 15, confirm. revise or cancel the order or decision passed by the organization or department assigned duty by the Committee.

17. The decision passed by the Committee under section 16 shall be final and conclusive.

Chapter IX
Offences and Penalties

18. Whoever, without permission , extracts. collects, stores, issues or distributes blood or blood products shall. on conviction, be punished with imprisonment for a term which may extend to seven years. and may also be liable to a fine.

19. Whoever without licence, establishes a private Sma1I-Scale Blood Bank shall, on conviction , be punished with imprisonment for a term which may extend to five years, and may also be liable to a fine.

20. Whoever. without consent of the person extracts blood from the said person shall on conviction, be punished with imprisonment for a term which may extend to five years, and may also be liable to a fine.

21. Whoever. without consent of the person or in the case of a person incapable of giving consent of the person who is capable of giving consent on his behalf transfuses blood or blood product shall, on conviction, be punished with imprisonment for a term which may extend to five years, and may also be liable to a fine.

22. Whoever commits any of the following acts shall on conviction, be punished with imprisonment for a term which may extend to three years, or with fine or with both:-

(a) transfusing into any person blood or blood products not obtained from the National BIood Centre, Blood Bank or SmalI-Scale Blood Bank, or of blood or blood products not imported legally.

(b) transfusing into any person blood or blood products without grouping and matching the blood and blood products of patient and of donor.

(c) transfusing of blood or blood products past the expiry date into any person:

(d) extracting from or transfusuig into any person blood or blood products by using blood transfusion instrument past the expiry date or which is not free from micro-organism or which has been utilized once;

(e) using sharp instrument not in conformity with the stipulations.

23. Whoever sells or buys blood with money or other consideration for business purpose shall, on conviction, be punished with imprisonment for a tern which may extend to three years, or with fine, or with both.

24. Whoever violates any prohibition or fails to abide by any duty contained in the notification, order and directive issued under this Law in order to prevent the transmissible infection through blood shall, on conviction be punished with imprisonment for a term which may extend to six months, or with fine, Or with both.

25. Whoever abets in the commission of any offence contained in this Law shall be liable to the penalty provided for such offence under this Law.

Chapter X
Miscellaneous

26. Prior sanction of the Ministry of Health shall be obtained in prosecuting under this Law .

27. No suit or prosecution shall lie against any medical practitioner or any person who performed under the instruction of the medical practitioner, or any person who is skilled, experienced and competent in transfusing blood and blood products for transfusing blood or blood products in good faith, to save the life of the patient in an emergency case.

28. The Central National Blood Bank and the Blood Banks established by the Ministry of Health prior to the enactment of this Law shall be deemed to be the National Blood Centre and Blood Bank and Small-Scale Blood Bank respectively according to the nature of blood transfusion service, and shall carry on the blood transfusion service as stipulated.

29. The government department or organization and Red Cross Society desirous of establishing the Blood Bank or Small-Scale Blood Bank shall seek the permission of the Committee.

30. On a dispute arising as to whether or not a substance is blood or blood products, the decision shall be made by the Committee. The decision of the Committee shall be final and conclusive.

31. The Ministry of Health-

(a) shall bear the expenditure of the Committee;

(b) shall make arrangements for enabling the discharge of the office work of the Committee;

(c) may grant suitable remuneration to non-goven1Jnental members of the Committee.

32. The notifications orders and directives issued by the Ministry of Health and Department of Health in respect of blood donation, extracting, collecting, storing, issuing, distributing, transfusing and disposal of waste of blood and blood products or utilization of sharp instruments prior to the enactment of this Law may continue to be applicable in so far as they are not inconsistent with this Law.

33. In implementing of the provisions of this Law:-

(a) the Ministry of Health may. with the approval of the Government, issue such rules and procedures as may be necessary ;

(b) the Committee, the Ministry of Health and the Department of Health may issue such notifications, orders and directives as may be necessary.

(Sd.) Than Shwe
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