

**THE PUNJAB BLOOD TRANSFUSION SAFETY ACT 2016
(XLVI of 2016)**

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TEXT

'THE PUNJAB BLOOD TRANSFUSION SAFETY ACT 2016
(XLVI of 2016)

[29th October 2016]

An
Act

to regulate collection, testing, processing, storage, distribution, issuance, transfusion of human blood, blood components, ensuring health protection and prevention of transfusion transmissible diseases.

It is necessary to regulate the collection, testing, processing and storage of human blood and blood components, as well as the rational use of safe blood and its products whenever intended for transfusion; and, to deal with ancillary matters.

Be it enacted by Provincial Assembly of the Punjab as follows:–

1. Short title, extent and commencement.– (1) This Act may be cited as the Punjab Blood Transfusion Safety Act 2016.

(2) It extends to whole of the Punjab.

(3) It shall come into force at once.

2. Definitions.– In this Act:

(a) “Act” means the Punjab Blood Transfusion Safety Act 2016;

(b) “Authority” means Punjab Blood Transfusion Authority constituted under the Act;

(c) “autologous donation” means that donor and recipient are the same;

(d) “blood” means whole blood collected from a donor;

(e) “blood center” means any structure or a body which manufactures blood and blood components; and, performs collection, testing, processing, storage, and distribution of blood and blood components to the hospital blood banks;

(f) “blood component” means a therapeutic constituent of blood including red cells, white cells, platelets, plasma, cryoprecipitate and cryosupernatant prepared by various methods;

(g) “blood establishment” means any facility carrying out one or more of the processes in the blood transfusion chain;

(h) “blood product” means any therapeutic product derived from human blood or plasma such as albumin, factor concentrates, prothrombin complex concentrates;

¹This Act was passed by the Provincial Assembly of the Punjab on 19 October 2016; assented to by the Governor of the Punjab on 28 October 2016; and, was published in the Punjab Gazette (Extraordinary), dated: 29 October 2016, pp. 2449-2459.

- (i) “deferral” means temporary or permanent suspension of the eligibility of an individual to donate blood or blood components;
- (j) “distribution” means an act of delivery of blood or blood components to other blood centres, hospital blood banks and manufacturers of blood and plasma derived products but shall not include the issuance of blood or blood components for transfusion;
- (k) “donor” means a person who, by his free will and without compensation or payment, donates blood or a part of his blood such as plasma or cellular components for use in the medical treatment or for scientific research;
- (l) “Government” means Government of the Punjab;
- (m) “haemovigilance” means a continuous process of data collection and analysis of transfusion-related adverse events and reactions, conducted to investigate their causes and outcomes, to prevent their occurrence or recurrence throughout the blood transfusion chain, and to increase the safety, efficacy and efficiency of blood transfusion, but haemovigilance shall be dependent on the traceability of blood and blood products from donors to recipients and *vice versa* (bi-directional tracking);
- (n) “hospital blood bank” means a hospital unit which receives and stores screened blood and blood components received from a blood centre, performs compatibility testing and issues blood and blood components for clinical use;
- (o) “inspection” means an official, formal and objective inspection based on the adopted standards to assess and measure the non-compliance of the Act, rules and regulations;
- (p) “Inspector” means a blood safety inspector appointed under section 9 of the Act;
- (q) “issuance” means the provision of blood or blood components by a hospital blood bank, or specialized blood transfusion service for transfusion to a recipient;
- (r) “non-compliance” means deviation from the standards prescribed by or under the Act or the Authority, as the case may be, and shall include:
 - (i) critical non-compliance that directly affects the safety of a recipient or donor; or
 - (ii) serious non-compliance that on its own does not directly affect the safety of a recipient or donor; or
 - (iii) significant non-compliance for which there is insufficient information to classify it as critical or serious non-compliance;
- (s) “offence” includes a critical and significant offence as prescribed under section 18 of the Act;
- (t) “prescribed” means prescribed by the rules or regulations made under the Act;

- (u) “processing” means any step in the preparation of a blood component carried out between the collection of blood and its storage;
- (v) “recipient” means a person who receives transfusion of blood or blood components;
- (w) “responsible person” means a person accountable for ensuring that every unit of blood or blood components has been collected, tested, processed, stored, distributed and issued in compliance with the provisions of the Act, rules or regulations made thereunder;
- (x) “safe blood” means the blood which is safe for both the donor and the recipient;
- (y) “screened blood” means human blood or blood products which, based on established testing methods, has been tested negative for HIV, Hepatitis B and Hepatitis C viruses or other viruses or infective agents, like malarial parasites and treponema pallidum (syphilis) or such other viruses or infective agents as the Authority may specify;
- (z) “Secretary” means the Secretary of the Authority;
- (aa) “serious adverse event” means an untoward occurrence 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 patients or which results in or prolongs hospitalization or morbidity;
- (bb) “serious adverse reaction” means an undesirable response or effect in a donor or in a patient associated with the collection or administration of blood or blood components which is fatal, life-threatening, disabling, incapacitating, or which results in or prolongs hospitalization or morbidity;
- (cc) “traceability” means the capacity of a blood transfusion system to trace blood and blood components from the donor to its final destination and *vice versa* (bi-directional tracking); and
- (dd) “unhygienic” means anything or atmosphere harmful to donor, blood, reagents or equipment.

3. Authority.– (1) The Government may, by notification, establish the Authority to be known as Punjab Blood Transfusion Authority.

(2) The Authority shall be a body corporate, having perpetual succession and a common seal with power to acquire, hold and dispose of property and shall by the said name sue and be sued.

- (3) The Authority shall consist of the following:
 - (a) three members, including at least one female member, of Provincial Assembly of the Punjab;
 - (b) Additional Secretary (Technical) to the Government, Specialized Healthcare and Medical Education Department;

- (c) Director General Health, Punjab;
- (d) Director, Institute of Blood Transfusion Services, Punjab;
- (e) Four professors, including at least one female Professor of Medicine, Surgery and Hematology or Transfusion Medicine;
- (f) Commandant, Combined Military Hospital, Lahore;
- (g) Director General of Punjab Employees Social Security Institution; and
- (h) a representative of the blood donor organizations, to be nominated by the Authority.

(4) A member, other than an *ex-officio* member, shall hold office for a period of three years from the date of assuming office but the Government may extend the term of a member for such period as it may deem necessary.

(5) The Government shall nominate the Minister for Health or Advisor to Chief Minister for Health as the Chairperson of the Authority and determine the terms and conditions of such appointment.

(6) In case of a casual vacancy in the Authority, the Government shall nominate a new member for the remaining term of the outgoing member.

4. Functions of the Authority.– (1) The Authority shall:

- (a) be responsible for the general administration, supervision, superintendence and management of the affairs of the Authority;
- (b) approve policies and schemes;
- (c) regulate all matters relating to blood transfusion throughout the Punjab;
- (d) ensure that the standards and specifications shall, at least, cover:
 - (i) the registration and licensing of blood establishments;
 - (ii) standards for processes performed by blood establishments;
 - (iii) specifications and quality control requirements of blood and blood components;
 - (iv) storage and transportation of blood and blood components;
 - (v) traceability and haemovigilance;
 - (vi) motivation of blood donors;
 - (vii) autologous donation and transfusion;
 - (viii) imparting relevant information to donors and obtaining from them appropriate information such as identification, health history and signature of the donor;
 - (ix) determining the requirements concerning the suitability of donors of blood and blood components;
 - (x) screening of donated blood including deferral criteria and possible exemption thereto; and

- (xi) procedures for notifying serious adverse reactions and events, notification format and guidelines on optimal clinical use of blood;
- (e) ensure that any serious adverse events related to the collection, testing, processing, storage and distribution, issuance or administration of blood and blood components, which may have an influence on the quality and safety of blood and blood components or on donor and staff safety, as well as any serious adverse reactions observed in donors that may be attributed to the donation or in patients that may be attributed to the transfusion are notified to the Authority;
- (f) take all necessary measures to ensure that blood and blood components collected, tested, processed, stored, released, distributed or issued are traced from donor to recipient and *vice versa*;
- (g) take all necessary measures to ensure that the system used for the labeling of blood and blood components complies with the identification system;
- (h) manage and report data for planning, implementation and evaluation of services;
- (i) take all necessary measures to ensure that access is provided to documents (operational procedures, guidelines, training, reference manuals and reporting forms) to the officials entrusted with inspections and control measures;
- (j) hold regular meetings with the bodies designated by the Government, delegations of experts and other relevant parties to exchange information on the experience acquired with regard to the implementation of the Act;
- (k) register blood establishments, categorize them indicating which processes the blood establishments are entitled to perform, issue licenses, and, subject to the fulfillment of prescribed conditions, renew licenses;
- (l) regulate matters relating to the meetings of the Authority; and
- (m) perform such other functions as may be prescribed.
- (2) The Authority may:
 - (a) suspend or revoke the license of a person if any condition of the license or any provisions of the Act, rules or regulations has been infringed;
 - (b) prescribe minimum standards and specifications for registration and licensing;
 - (c) collaborate with other institutions, professional bodies and experts;
 - (d) take all necessary measures to ensure that each blood establishment establishes and maintains a quality management system as prescribed by the Authority;
 - (e) set up minimum requirements for record keeping of blood establishments and keep records of the data received from the blood

establishments with regard to registration and licensing, inspections, responsible person and notification of serious adverse reactions and events; and

- (f) organize inspections and appropriate control measures in blood establishments, to make certain that the requirements of the Act, and any rules, regulations, and standards hereunder, are complied with.

5. Secretary.— (1) The Government shall appoint the Secretary of the Authority on such term and conditions as it may determine or as may be prescribed.

(2) The Secretary shall be the Chief Executive Officer of the Authority and shall exercise such powers as may be prescribed or as are delegated to him by the Authority.

(3) A person shall not be appointed as Secretary if he is a director, officer or employee of any healthcare service provider or has an interest or share in any blood establishment.

6. Technical Committee.— (1) The Authority shall, for a specified period, constitute the Technical Committee, consisting of the following:

- (a) Additional Secretary (Technical) to the Government, Specialized Healthcare and Medical Education Department;
- (b) Director, Institute of Blood Transfusion Services, Punjab;
- (c) Two Professors of Haematology;
- (d) a representative of the blood donor organizations, to be nominated by the Authority; and
- (e) a legal expert.

(2) The Authority shall nominate the convener of the Technical Committee from amongst its members.

(3) The Technical Committee shall provide advice on any matter referred to it by the Authority including matters related to blood transfusion standards and quality assurance.

7. Licensing Board.— (1) There shall be a Licensing Board consisting of the following:

- (a) Secretary;
 - (b) one haematologist; and
 - (c) one other technical expert nominated by the Authority for a specified period.
- (2) The Secretary shall be the convener of the Licensing Board.
- (3) The Licensing Board shall:
- (a) review all inspection reports and decide on the issuance of licenses to blood establishments, blood centers, hospital blood banks, and specialized blood transfusion services; and
 - (b) categorize non-compliances observed as critical or significant.

(4) The Licensing Board, in case of non-compliance or violation of the Act, rules or regulations, may, in the manner prescribed by the Authority:

- (a) refer a case to the Inspector concerned or the local police for prosecution in the blood safety court;
- (b) direct sealing of the premises of the blood establishment;
- (c) impose fine up to one hundred thousand rupees;
- (d) order to take into custody the blood, blood components, equipment and any other materials being used in violation of the Act, rules or regulations;
- (e) enter or seal the blood establishment in the case of any gross violation of the Act, rules or regulations;
- (f) mark, seal or otherwise secure any equipment or material in the case of any violation of the Act, rules or regulations;
- (g) place a blood establishment on probation;
- (h) suspend or cancel the license of the blood establishment; and
- (i) debar the re-licensing of the blood establishment for the specified period.

8. Appellate Committee.— (1) The Government shall, for a specified period, constitute an Appellate Committee consisting of four members, including a Haematologist or blood transfusion expert and a legal expert.

(2) The Government shall nominate one of the members as convener of the committee.

(3) A person aggrieved by any decision or order of the Authority or the Licensing Board may prefer an appeal to the Committee within fifteen days from the communication of such decision or order.

(4) The Committee may, after due investigation and affording opportunity of hearing to all concerned, pass an appropriate order within thirty days.

9. Inspectors.— (1) The Government shall appoint blood safety Inspectors in each district.

(2) An Inspector shall carry out inspection of blood establishments and perform other functions assigned to him by the Authority.

(3) An Inspector shall implement the decisions of the Licensing Board, with the assistance of the local police, if required.

(4) An Inspector shall inspect and report an unregistered establishment to the Authority.

10. Functions of blood centers.— (1) A blood centre shall implement the requirements of the Act, the rules and regulations made thereunder.

(2) A blood centre shall:

- (a) perform processes related to the promotion of blood donations, collection, testing, processing, storage, transport, distribution of human blood and blood components according to the license issued;
- (b) not accept blood from paid donors and shall ensure to get blood and blood components for transfusion through voluntary and non-remunerated blood donations;
- (c) follow the procedures and criteria prescribed by the Authority for donor selection of blood;
- (d) follow the criteria of permanent and temporary blood donor deferral prescribed by the Authority;
- (e) communicate the reasons for deferral to the donor through a qualified health professional registered with the Pakistan Medical and Dental Council, and shall provide counseling, if so required;
- (f) while performing testing of donated blood, ensure that each donation of blood and blood components is tested for ABO and Rh blood groups and screened for HBV, HCV, HIV, Malaria, Syphilis and any other communicable disease or such other disease as may be prescribed;
- (g) not receive or supply blood unless it is registered and licensed under the Act;
- (h) have qualified personnel having relevant qualification from a recognized institution for the collection, testing, processing, storage, transport and distribution of human blood and blood components;
- (i) have a dedicated department, staff and set of equipment for the performance of each type of processes under the license;
- (j) comply with minimum requirements for the performance regarding location, process flow, personnel, equipment, reagents and documentation adopted and endorsed by the Authority;
- (k) submit an annual report to the Authority in such form as may be prescribed or determined by the Authority;
- (l) notify to the Authority the name of the responsible person and job description of other staff working in the blood centre; and
- (m) distribute blood and blood components to a hospital, based on hospital blood bank request, and in accordance with provisions of a written contract.

(3) The responsible person in a blood centre shall be a qualified individual, preferably having post-graduate qualification in blood transfusion, haematology or clinical pathology recognized by the Pakistan Medical and Dental Council.

(4) Where the responsible person in a blood centre is permanently or temporarily replaced, the blood centre shall immediately communicate the name and other details of the new responsible person to the Authority.

11. Functions of hospital blood banks.– (1) Every hospital blood bank shall observe and implement the requirements of the Act, rules and regulations.

(2) A hospital blood bank shall:

- (a) receive, store and perform compatibility tests before issuance of blood and blood components;
 - (b) have qualified personnel directly involved in compatibility testing, storage, transport and issuance of human blood and blood components;
 - (c) designate a responsible person in the hospital blood bank;
 - (d) have a dedicated location, staff and set of reagents and equipment for the performance of each type of licensed processes; and
 - (e) ensure that blood and blood components issued by them are transfused in a licensed medical institution by a clinician registered with Pakistan Medical and Dental Council.
- (3) The physician shall ensure that blood and blood components being transfused are certified as safe blood by a licensed blood establishment.
- (4) The hospital administration shall ensure rational clinical use of blood and blood components through the hospital transfusion committee in accordance with guidelines adopted and endorsed by the Authority.
- (5) All processes performed at hospital level in relation to transfusion therapy shall be documented in accordance with the prescribed procedures.

12. Documentation, record keeping and traceability.– A blood establishment shall:

- (a) maintain documentation on procedures, guidelines, training, reference manuals and reporting forms;
- (b) maintain records of the information obtained from donors, including their identification, health history, temporary and permanent deferral and signature; total number of donors and donations; whole blood donations not used; number of every blood component produced and distributed, as well as screening results of the donated blood;
- (c) keep the record safe for a minimum of fifteen years; and
- (d) implement a system for the identification of every single blood donation, every single blood unit and components thereof, allowing full traceability to the donor as well as to the transfusion and its recipient.

13. Information to the Authority.– A blood establishment shall immediately inform the Authority, in the prescribed manner, of any serious adverse event or serious adverse reaction.

14. Data protection, etc.– (1) Every blood establishment shall have a procedure in place to accurately, efficiently and verifiably prevent distribution or issuance of any unhealthy blood or blood components.

(2) The blood establishment performing blood collection shall take all necessary measures to ensure that all data, including genetic information, collected under the Act to which third parties have access have been rendered anonymous so that the donor is no longer identifiable.

(3) For the purpose, every blood establishment performing blood collection shall ensure that:

- (a) data security measures are in place and safeguards are provided against unauthorized data additions, deletions or modifications to donor files or deferral records and transfer of information;
- (b) procedures are in place to resolve data discrepancies; and
- (c) no unauthorized disclosure of such information occurs, whilst guaranteeing the traceability of donation.

15. District blood transfusion committees.– (1) The Government may constitute District Blood Transfusion Committees, consisting of philanthropists, social workers and such other persons as the Government may deem appropriate.

(2) A Committee shall perform such functions as are assigned to it by the Authority or as may be prescribed.

16. Registration and licensing.– (1) A blood establishment shall not receive or supply blood unless it is registered with the Authority and holds a valid license issued by the Authority in such manner and on payment of such fee as may be prescribed.

(2) The Authority may issue a provisional license to a blood establishment in a case where the non-compliance is not critical, subject to the condition that the blood establishment shall rectify the non-compliance documented by the Authority within the specified time.

17. Obligation.– A person shall:

- (a) not operate a blood establishment unless it is registered with Authority and holds a valid license under the Act;
- (b) fully observe the provisions of the Act or rules or regulations; and
- (c) ensure that the standards prescribed or specified by the Authority are fully implemented.

18. Offence.– The offence under the Act shall be of two kinds:

- (a) “critical offence” which means an offence involving a serious adverse event or serious adverse reaction;
- (b) “significant offence” means an offence falling under any of the following categories:
 - (i) unhygienic premises;
 - (ii) inadequate number of staff or engagement of non-qualified staff and untrained staff;
 - (iii) the use of any equipment, including the storage equipment which is not functioning according to prescribed protocols or standing operating procedures;
 - (iv) non-observance of standard operating procedures;
 - (v) any equipment present in blood unit not functioning according to prescribed temperature;

- (vi) improper display of standard operating procedures in working areas of the blood unit;
- (vii) use of substandard or expired consumable, reagent, chemical, disposal, kit, solution or water in use of blood unit or manufactured by a non-registered manufacturer;
- (viii) improper maintenance of records regarding an inventory relating to blood, blood products, consumables, disposables, chemicals in use or stock, issued or used, expired, discarded, supplied, re-deposited;
- (ix) lack of alternate source for electric supply causing interrupted functioning of cold chain or processing in blood unit;
- (x) improper labeling of blood, blood products, blood samples with careless, incomplete, non-legible, erasable, tampered, overwritten written or a label without bar-coding;
- (xi) improper transportation of blood and blood products or reagent; and
- (xii) lack of separate areas for donor reception, history taking and examination, donor bleeding, cross-matching and screening of blood in a Blood Bank.

19. Penalty.— (1) Subject to subsection (2) whoever, either by himself or through another person, commits an offence under section 18 or willfully contravenes any of the provisions of the Act, rules, regulations or standards prescribed thereunder shall be punishable with imprisonment of either description for a term which may extend to seven years and with fine which may extend to one million rupees.

(2) Whoever, either by himself or through another person, willfully contravenes the provisions of clause (b) of subsection (2) of section 11 shall be liable to fine which may extend to fifty thousand rupees but which shall not be less than ten thousand rupees.

(3) An offence under the Act shall be non-bailable.

20. Cognizance.— A court shall not take cognizance of an offence under the Act except on a complaint in writing by an officer authorized by the Authority.

21. Offences by companies.— (1) Where an offence under this Act has been committed by a Company, every person, who at the time of the commission of the offence, was in charge of the Company, shall be liable to punishment for the offence and the Company shall also be liable to the punishment of fine specified for the offence.

(2) Notwithstanding anything contained in sub-section (1), where it is proved that the offence is attributable to any neglect on the part of any director, manager, secretary or other officer of the Company, such director, manager, secretary or other officer shall also be liable to punishment for the offence.

Explanation.— In this section, “Company” means a body corporate and includes a firm or any other association of persons.

22. Publication of offender's name.— The Authority shall publish the name of any person convicted of an offence under the Act in such manner as may be prescribed.

23. Secretariat and employees.— (1) The head-office of the Authority shall be at Lahore and it may have such other offices in the Punjab as the Authority, with the approval of the Government, may determine.

(2) The Authority may employ, in the prescribed manner, such officers and staff as may be necessary for the performance of functions under the Act.

24. Fund of the Authority.— (1) The Government shall establish a Fund of the Authority to be known as the Punjab Blood Transfusion Authority Fund which shall vest in the Authority.

(2) The Authority shall maintain the Fund in the prescribed manner.

(3) The Fund shall consist of:

(a) grants received from the Government through budgetary allocations;

(b) income received from registration fees and license fee and all other sums received by the Authority;

(c) money received from the Federal Government or any international organization by way of grant, loan, advance or others;

(d) money received from the disposal of movable and immovable property of the Authority; and

(e) any other money received by the Authority.

25. Accounts and Audit.— (1) The Authority shall maintain complete and accurate books of accounts of its actual expenses and receipts in the manner prescribed.

(2) The Board shall approve the annual budget of the Authority in the prescribed manner.

(3) The accounts of the Authority shall be audited annually by the Auditor General of Pakistan.

26. Delegation.— The Authority may delegate any of its functions to the Secretary or any other officer of the Authority except the following functions:

(a) making of regulations;

(b) approval of budget of the Authority in addition to the budget allocated by the Government; and

(c) making of policies.

27. Miscellaneous.— (1) The Act shall apply to the collection and testing of blood and blood components, and to their processing, storage, distribution, issuance and use but it shall not apply to blood stem cells.

(2) The Authority may allow import into or export from the Punjab of blood and blood components provided that the requirements of quality and safety under the Act shall be observed.

(3) The following principles shall also be followed with regard to the blood transfusion process:

- (a) blood donation shall be a voluntary, anonymous and non-remunerated act;
- (b) transfusion is a not-for-profit health sector activity;
- (c) implementation of a common set of standards across blood establishments shall ensure an equivalent level of quality and safety of blood and blood components in the Punjab, regardless of the source; and
- (d) self-sufficiency in blood and blood components and its rational and optimal use in compliance with modern good clinical practices shall be the priority of the Government.

(4) A person shall not perform blood transfusion therapy unless it is prescribed and performed under a physician's responsibility and surveillance and may only be performed in licensed medical institution.

28. Immunity.— No suit or other legal proceedings shall be instituted against the members, officer or officials of the Authority for any actions taken in good faith under the Act.

29. Power to make rules.— The Government may, by notification in the official Gazette, make rules to carry out the purposes of the Act.

30. Power to make regulations.— Subject to the Act and the rules, the Authority may, by notification in the official Gazette, frame regulations to give effect to the provisions of the Act.

31. Repeal.— The Punjab Transfusion of Safe Blood Ordinance, 1999 (XXXVI of 1999) is hereby repealed.