# THE KHYBER PAKHTUNKHWA BLOOD TRANSFUSION SAFETY AUTHORITY ACT, 2016.

## (KHYBER PAKHTUNKHWA ACT NO. XXV OF 2016)

## CONTENTS

## CHAPTER III
## FUNCTIONS AND RESPONSIBILITIES OF THE REGIONAL BLOOD CENTRE AND BLOOD BANKS



## CHAPTER IV
## FUND, BUDGET AND ACCOUNTS



## CHAPTER V
## MISCELLANEOUS

# THE KHYBER PAKHTUNKHWA BLOOD TRANSFUSION SAFETY AUTHORITY ACT, 2016.

## (KHYBER PAKHTUNKHWA ACT NO. XXV OF 2016)

*[First published after having received the assent of the Governor of the Khyber Pakhtunkhwa in the Gazette of Khyber Pakhtunkhwa (Extraordinary),dated the 20th October,2016].*

**AN**
**ACT**

to regulate collection, testing, processing, storage, distribution, issuance and transfusion of human blood and blood components, in public and private sectors and to establish Khyber Pakhtunkhwa Blood Transfusion Safety Authority for ensuring health protection and prevention of transfusion transmissible diseases

WHEREAS it is expedient 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 including plasma, free from viruses like immunodeficiency (HIV), Hepatitis B and C or infective agents like Malarial Parasite and Treponema Palidum (Syphilies), etc., for the purpose of transfusion of safe blood in public and private sectors and to establish Khyber Pakhtunkhwa Blood Transfusion Safety Authority for and matters connected therewith or incidental thereto;

It is hereby enacted as follows:

## CHAPTER–I
## Preliminary

**1. Short title, application and commencement**.---(1) This Act may be called the Khyber Pakhtunkhwa Blood Transfusion Safety Authority Act, 2016.

(2) It shall apply to all Blood Banks and Regional Blood Centres in public and private sectors of the Province of the Khyber Pakhtunkhwa.

(3) It shall come into force at once.

**2. Definitions,---**In this Act, unless there is anything repugnant in the subject or context,-

(a) "Authority" means the Khyber Pakhtunkhwa Blood Transfusion Safety Authority established under section 4 of this Act;

(b) "Blood Bank" includes all organisations carrying out all or any of the purposes of receiving, preserving, storing, analysing, screening,

processing and issuing of blood or blood products, whether maintained by public or private sector;

(c) "blood component" means a therapeutic constituent of blood (red cells, white cells, platelets, plasma, cryoprecipitate, cryosupernatant) which can be prepared by various methods;

(d) "blood product" means any therapeutic product derived from human blood or plasma (albumin, factor concentrates, prothrombin complex concentrates, etc.);

(e) "Chairman" means the Chairman of the Authority;

(f) "Chief Executive Officer" means the Chief Executive Officer of the Authority;

(g) "Council" means the Pakistan Medical and Dental Council established under the Pakistan Medical and Dental Council Ordinance, 1962 (XXXII of 1962);

(h) "Designated Person" means a Person notified under sub-section (2) of section 16 of this Act;

(i) "donor" means a somebody who of his own free will, voluntarily and non-remunerated, donates blood or a part of his blood (plasma or cellular components) for use in the course of the medical treatment of patients or for scientific research;

(j) "Government" means the Government of the Khyber Pakhtunkhwa;

(k) "prescribed" means prescribed by the rules or regulations;

(l) "Province" means the Province of the Khyber Pakhtunkhwa;

(m) "recipient" means someone who receives transfusion of blood or blood components;

(n) "Regional Blood Centre" means any structure or body which manufactures blood and blood components and performs processes related to the promotion of blood donations, collection, testing, proceeding, storage, transport, distribution of blood and blood components, whether maintained by public or private sector at such regional level as may be determined by the Authority;

(o) "regulations" mean regulations made under this Act;

(p) "rules" mean rules made under this Act;

(q) "safe blood" means human blood or blood products which is healthy and free from human immunodeficiency HIV, Hepatitis-B and C viruses, and ineffective agents like Malarial Parasite and Treponema Palidum and other infective agents, as the Authority may specify;

(r) "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; and

(s) "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).

**3. Transfusion of safe blood**.---It shall be the responsibility of every physician, surgeon and other relevant staff to-

(a) ensure that blood and blood components being transfused are certified as safe blood by a registered or licensed Blood Bank or Regional Blood Centre;

(b) ensure rational clinical use of blood and blood components through their hospital transfusion committees, in accordance with guidelines adopted and endorsed by the Authority; and

(c) ensure that all processes performed at hospital level in relation to transfusion therapy are documented in accordance with the procedures as may be prescribed by the Authority.

## CHAPTER - II
## ESTABLISHMENT, COMPOSITION, POWERS AND FUNCTIONS OF THE KHYBER PAKHTUNKHWA BLOOD TRANSFUSION AUTHORITY

**4. Establishment of Authority**.---(1) As soon as after the commencement of this Act, Government shall by notification in the official Gazette, establish an Authority to be known as the Khyber Pakhtunkhwa Blood Transfusion Authority.

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

(3) The head office of the Authority shall be in Peshawar and shall have such other regional offices at such places in the Province as Government may deem appropriate.

**5. Constitution of the Authority**.---(1) The Authority shall consist of:

| | | |
|---|---|---|
| (a) | Secretary to Government Health Department; | Chairman |
| (b) | a Director General, Health Services; | Member |
| (c) | The Chief Executive, Health Care Commission; | Member |
| (d) | Medical Director, Khyber Teaching Hospital; | Member |
| (e) | Medical Director, Lady Reading Hospital; | Member |
| (f) | Medical Director, Hayatabad Medical Complex; | Member |
| (g) | Commandant Combined Military Hospital nominated by Government for a period of three years; | Member |
| (h) | a legal expert nominated by Government for a period of three years; | Member |
| (i) | a Senior Heamatologist nominated on rotation basis by Government for a period of three years; and | Member |
| (j) | a member civil society Blood Donors Organization Non Government Organization nominated by Government for a period of three years; | Member. |

(2) The members appointed under clauses (h) and (j) may resign their membership by tendering resignation to the Government.

(3) The members appointed under clauses (h) and (j) may be removed by Government from the membership of the Authority on grounds of an efficiency and misconduct:

Provided that before removal the member concerned shall be given an opportunity of being heard.

(4) In case of vacancy due to death, resignation or removal the Government shall fill up the vacancy by nomination of another person as member.

**6. Meetings of the Authority**.---(1) The Authority shall hold at least four meetings annually.

(2) The meetings of the Authority shall be presided over by the Chairman and in case he is absent by a member agreed upon by other members of the Authority.

(3) The decision of the meeting shall be taken by majority of the members present and in case of tie the Chairman shall have a casting vote.

(4) Quorum of the meetings shall be one third of the membership of the Authority.

(5) The Authority shall follow in respect of meetings such procedure as may be prescribed.

**7. Powers and functions of the Authority**.---The Authority shall exercise and perform the following powers and functions:

(a) adopt policy to regulate all aspects of blood transfusion in the Province and ensure that processes related to collection, testing of human blood and blood components, and to their preparation, storage, distribution, issuance and administration are undertaken only by Blood Banks or Regional Blood Centre;

(b) prescribe minimum standards and specifications for registration and licensing of the Blood Banks or Regional Blood Centre;

(c) register and issue licences to Blood Banks or Regional Blood Centre in private sector on payment of such fee and in manner as may be prescribed;

(d) renew licences issued to Blood Bank or Regional Blood Centre in private sector annually on payment of such fee as may be prescribed, subject to the condition that the instructions issued by it for safe blood transfusion were being followed by such Blood Bank or Regional Blood Centre, as the case may be;

(e) register the Blood Bank or Regional Blood Centre in public sector;

(f) cancel licenses issued to the Blood Bank or Regional Blood Centre in

private section in the prescribed manner;

(g) prescribed registration and licence fees debitable to the relevant head of account;

(h) fix service charges of the blood and blood products;

(i) ensure that the Blood Banks or Regional Blood Centre, as the case may be, are managed and run by qualified professionals having qualifications in blood transfusion, preferably Haematology and alternately clinical pathology recognized by the Council;

(j) ensure that bio-safety measures specified in the regulations framed under this Act and instructions issued by the World Health Organization (WHO) are strictly adhered to by the Blood Banks;

(k) take all necessary measures to ensure that each Blood Bank or Regional Blood Centre establishes and maintains a quality management system as defined by the Authority;

(l) ensure that any serious adverse reaction related to the collection, testing, processing, storage and distribution, issuance or administration of blood and blood components, observed in donors or patients, which may have a influence on the quality and safety of blood and blood components or on donor or patient and staff safety, are notified to the Authority;

(m) take all necessary measures to ensure that blood and blood components collected, tested, processed, stored, released, distributed or issued can be traced from donor to recipient and vice versa;

(n) take all necessary measures to ensure that the system used for the labeling of blood and blood components complies with the identification system;

(o) manage and report data for planning, implementation and evaluation of services;

(p) take all necessary measures to ensure that access is provided to documents (operational procedures, guidelines, training, reference manuals and reporting forms) for officials entrusted with inspections and control measures;

(q) hold regular meetings with the authorities designated by Government, delegations of experts and other relevant parties to exchange

information on the experience acquired with regard to the transfusion of safe blood, blood product and procedures related thereto;

(r) set up minimum requirements for record keeping for blood banks and keep records of the data received from the blood banks establishments with regard to registration and licensing, inspections, responsible person and notification of serious adverse reactions;

(s) organize inspections and appropriate control measures in blood banks on regular basis;

(t) prescribe procedure for appointment, terms and conditions of service, disciplinary and other service matter for the employees of the Authority;

(u) approval of financial plans and annual budget; and

(v) perform any other function assigned to it by Government from time to time.

**8. Committees**.---The Authority shall establish the following committees and may establish other committees for assistance to the Executive Officer in relation to the performance of functions of the Authority and determine the membership, remuneration of members and terms of reference of each committee:

(a) Technical Committee;

(b) Licensing Committee;

(c) Hospital Blood Transfusion Committees;

(d) District Blood Transfusion Committee; and

(e) Grievances Redressal Committee.

**9. Chief Executive Officer**.---(1) The Authority shall appoint a person as a Chief Executive Officer on such terms and conditions and such qualification as may be prescribed.

(2) The Chief Executive Officer shall, subject to the supervision and control of the Authority, manage the affairs of the Authority and may exercise such powers as are delegated to him by the Authority.

(3) In particular, the Chief Executive Officer may,-

(a) manage the administration, operations and functions of the Authority;

(b) act as the principal accounting officer responsible and accountable for the management of the Authority funds and assets in an efficient and effective manner; and

(c) to provide leadership or directions to all staff of the Authority.

(4) The Chief Executive Officer shall be Secretary to the Authority with no right of vote and shall prepare and circulate agenda and minutes of the Authority meetings.

(5) The Chief Executive Officer shall not be an employee of any health care service provider both public and private sectors nor have interest or share in any Blood Bank.

**10. Inspectors**.---(1) The Authority may appoint the Inspectors on such terms and conditions and with such qualifications as may be prescribed for the purposes of this Act within such local limits as it may assign to them respectively:

Provided that no person who has any financial interest in any Blood Bank or blood center as the case maybe, shall be so appointed.

(2) The Inspector shall-

(a) inspect the Blood Bank or Regional Blood Centre, as the case may be, at the time of issuance and renewal of license or on receipt of a complaint by aggrieved person or any person;

(b) seal the premises of the Blood Bank or Regional Blood Centre, as the case may be, which is not registered under this Act or repeatedly violates the provisions of this Act or rules and regulations made thereunder;

(c) confiscation of the equipment used and any other materials which is dangerous or detrimental to any person therein or otherwise unsuitable for the purpose for which it is used or carried out;

(d) seizure and prevention of the release of blood or blood components which are considered unsafe; and

(e) take samples of blood, blood components, blood product or any other chemical or substance used for the preservation of blood for ascertaining the safety thereof.

**11. Employees of the Authority**.---To carry out the purposes of this Act, the Authority may, from time to time appoint employees on such terms and conditions as may be prescribed.

**12. Public servant**.---The employees of the Authority shall be deemed to be public servants within the meaning of section 21 of the Pakistan Penal Code (Act XLV of 1860).

**13. Delegation**.---The Authority may, by general or special order, delegate its power or function to the Chairperson or a member or any other employee of the Authority under this Act, subject to such conditions or restrictions as it may determine.

**14. Protection from liability**.---No suit or other legal proceedings shall lie against the Authority and various Committees constituted under this Act, Chief Executive Officer and employees of the Authority for anything done in good faith in the execution or purported execution of this Act and rules or regulations made thereunder.

## CHAPTER III
## FUNCTIONS AND RESPONSIBILITIES OF THE REGIONAL BLOOD CENTRE AND BLOOD BANKS

**15. Functions and responsibilities of Regional Blood Centre**.---Every Regional Blood Center 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) take all possible measures to encourage voluntary and non-remunerated blood donations and not accept blood from paid donors;

(c) make certain that procedures and criteria prescribed by the Authority for donor selection and collection of blood are met;

(d) follow the criteria of permanent and temporary blood donor deferral prescribed by the Authority and to communicate the reasons therefore through a qualified health professional;

(e) be supported by such staff as may be determined by Government in case maintained, by public sector or as may be determined by the Authority in case maintained by private sector.

(f) 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 as may be determined by the Authority;

(g) have a set of equipment for the performance of each type of processes relating to blood transfusion;

(h) submit an annual report to the Authority in the format prescribed by the Authority; and

(i) not receive or supply blood unless it is registered with the Authority and is in possession of a valid licence issued to it by the Authority.

**16. Functions and responsibilities of Blood Banks**.---(1) Every Blood Bank shall-

(a) receive and store blood and blood components and perform compatibility tests before issuance of blood and blood components;

(b) have qualified personnel having experience in compatibility testing, storage, transport and issuance of human blood and blood components;

(c) have a dedicated location, staff and set of reagents and equipment for the performance of each type of processes relating to blood transfusion;

(d) ensure that blood and blood components issued by them are transfused in a licensed medical institution by a doctor registered with the Pakistan Medical and Dental Council;

(e) maintain a separate department, equipment and staff for the purpose of receiving blood donations and for selection, handling, care and safety of the donors;

(f) cause the donated blood and blood products to be screened to ensure that the blood is a safe blood and record a certificate to this effect on each blood bag meant for transfusion;

(g) possess equipment required for hemoglobin estimation, blood grouping, cross matching, antibodies detection and screening of infectious agents including human immunodefinency, Hepatitis B and C viruses, Malaria, Syphilis and any other communicable disease as may be determined by the Authority;

(h) equip itself with proper reservation and storage of blood, blood products and ensure un-interrupted power supply for refrigeration;

(i) observe standard operation procedure approved by the Authority and more particularly specified in the regulations; and

(j) submit periodical reports to the Authority in respect of blood donations received by it with break-up of blood groups, detection of antibodies and screening of infectious agents; and

(k) not receive or supply blood unless it is registered with the Authority and is in possession of a valid licence issued to it by the Authority.

(2) All Blood Banks or Regional Blood Centres as the case may be, shall notify to the Authority the name of the Designated Person.

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

(4) Where the Designated Person is permanently or temporarily replaced, the Blood Bank or Regional Blood Centre, as the case may be, shall provide immediately the name of the new Designated Person and his date of assuming charge as such to the Authority.

(5) The Designated Person shall ensure distribution of blood and blood components to hospitals, based on hospital Blood bank requests, in accordance with provisions set up by a written contract.

**17. Documentation, record keeping and traceability**.---(1) All Blood Banks or Blood Centres as the case may be, shall maintain documentation on procedures, guidelines, training, reference manuals and reporting forms.

(2) Blood Banks or Regional Blood Centres as the case may be, shall 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 and number of every blood component produced and distributed, as well as screening results of donated blood.

(3) The records shall be kept for a minimum of 15 years.

(4) Blood Banks or Regional Blood Centres, as the case may be, shall 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.

(5) The data needed for full traceability in accordance with this section shall be kept for at least 30 years.

**18. Notification of Serious Adverse Reactions**.---(1) Serious adverse reactions shall be notified in accordance with the procedure and notification prescribed by the Authority.

(2) Blood Banks shall have a procedure in place to accurately, efficiently and verifiably withdraw from distribution or issuance of any blood or blood components associated with the notification referred to above.

**19. Data Protection and Confidentiality**.---(1) All Blood Banks or Regional Blood Centres performing blood collection shall take all necessary measures to ensure that all data, including genetic information, collated within the scope of this Act, to which third parties have access, have been rendered anonymous so that the donor is no longer identifiable.

(2) For the purpose mentioned in sub-section (1), every Blood Bank or Regional Blood Centre 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 donations.

**20. Heamovigilance**.---The Authority shall continuously perform heamovigilance in order to insure safe transfusion of blood, prevent serious adverse reactions and to maintain documentation regarding blood procedures.

**Explanation**.---Haemovigilance means a continuous process of data collection and analysis of transfusion-related adverse events and reactions, conducted in order 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;

## CHAPTER IV
## FUND, BUDGET AND ACCOUNTS

**21. Fund**.---(1) There shall be a fund to be known as Khyber Pakhtunkhwa Blood Transfusion Authority Fund.

(2) The Fund shall consist of-

(a) such sums as Government may grant by way of seed money;

(b) grant-in-aid in lieu of services rendered to Health/Blood Bank;

(c) donations from domestic and international donor agencies and other institutions;

(d) grant of money and sums borrowed or raised by the Authority for the purpose of meeting any of its obligations or discharging any of its duties;

(e) fee or other charges imposed under this Act; and

(f) all other sums, which may in any manner become payable to or vested in the Authority in respect of any matter incidental to the exercise of its functions and powers.

(3) The Fund shall be utilized for the purpose of Authority and shall be regulated under the overall supervision of the Authority in such a manner as may be prescribed by the Authority.

**22. Annual budget**.---(1)The Authority shall prepare and approve annual budget for a financial year in the prescribed manner.

(2) No expenditure shall be made for which provision has not been made in any approved budget except if made from any previously approved contingency fund, unless further approval is sought and obtained from the Authority.

**23. Annual report and accounts**.---(1) The Chief Executive Officer shall within ninety days from the end of each financial year, prepare a report on the activities and performance of the Authority, and submit a copy of the report to Government, after approval from the Authority.

(2) The Authority shall keep proper accounts and shall as soon as practicable, after the end of each financial year, prepare a statement of accounts of the Authority through Chief Executive Officer for the financial year which shall include a balance sheet and an account of income and expenditure.

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

(4) The Authority shall, within one hundred and twenty days of the end of each financial year, together with the annual report of the Authority, send a copy of the statement of accounts of the Authority certified by the auditor and a copy of auditor's report to Government.

(5) The Authority may invest money not required for immediate expenditure in Government Saving Scheme or in fixed deposit with banks approved by Government.

## CHAPTER V
## MISCELLANEOUS

**24. Penalty for contravention**.---Whoever contravenes any of the provisions of this Act shall be punished with imprisonment for a period not less than six months and which may extend to three years, or with fine which shall not be less than fifty thousand rupees and may extend to ten hundred thousand rupees, or with both.

**25. Cognizance of contravention**.---No court shall take cognizance of any contravention under this Act, except on a complaint in writing made by the Authority or on the report of Inspector provided that this will not debar the person aggrieved by any such contravention to seek remedy of his grievance through a court of law.

**26. Removal of difficulties**.---If any difficulty arises in giving effect to any provision of this Act, Government may make such order not inconsistent with the provisions of this Act as may appear to it to be necessary for the purpose of removing such difficulty.

**27. Overriding effect**.---Notwithstanding anything to the contrary contained in any other law, the provisions of this Act shall have an overriding effect and the provisions of any such law to the extent of inconsistency to this Act shall cease to have effect.

**28. Appeal**.---The Blood Bank or Regional Blood Center as the case may be, whose registration has been cancelled shall have the right to appeal to High Court within thirty (30) days of such cancellation.

**29. Power to make rules**.---Government may, by notification in the official Gazette, make rules for giving effect to the provisions of this Act.

**30. Power to make regulations**.---The Authority may make regulations, not inconsistent with the provisions of this Act and the rules, for carrying out the purposes of this Act.

**31. Repeal and saving**.---(1) The Khyber Pakhtunkhwa Transfusion of Safe Blood Act, 1999 (Khyber Pakhtunkhwa Act No. IX of 1999) is hereby repealed.

(2) On commencement of this Act,-

(a) all employees of the Khyber Pakhtunkhwa Safe Blood Transfusion Authority under the repealed Act; and

(b) all assets and liabilities, including furniture, fixtures, machinery and vehicles etc;

shall stand transferred to the Khyber Pakhtunkhwa Blood Transfusion Authority established under this Act.

(3) Notwithstanding the aforesaid repeal, anything done, action taken, rules made, and notification or order issued under the aforesaid Act, shall, so far as it is not inconsistent with the provisions of this Act, be deemed to have been done; taken, made or issued, appointed, constituted, given, commenced or taken, under this Act, and shall have effect accordingly.