PROVINCIAL ASSEMBLY OF SINDH
NOTIFICATION
KARACHI, THE 14TH DECEMBER, 2017

NO.PAS/Legis-B-26/2017- The Sindh Safe Blood Transfusion Bill, 2017 having been passed by the Provincial Assembly of Sindh on 06th November, 2017 and assented to by the Governor of Sindh on 30th November, 2017 is hereby published as an Act of the Legislature of Sindh.

THE SINDH SAFE BLOOD TRANSFUSION ACT, 2017

SINDH ACT NO. XXXI OF 2017

AN
ACT

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

Preamble.

WHEREAS it is expedient to regulate the collection, testing, **screening,** processing, storage, distribution, issuance, transfusion of human blood and blood components, ensuring health protection and prevention of transfusion transmissible diseases and for matters connected therewith or incidental thereto.

It is hereby enacted as follows:-

Short title, extent and commencement.

1. (1) This Act may be called the Sindh Safe Blood Transfusion Act,2017.

(2) It shall extend to the whole of the Province of Sindh.

(3) It shall come into force at once.

Definitions.

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

(a) "Authority" means the Sindh Blood Transfusion Authority established under section 3;

(b) "autologous donation" means that donor and recipient are identical;

(c) "blood" means whole blood collected from a donor;

(d) "blood bank" includes all organizations carrying out all or any of the purposes of receiving, preserving, storing, analyzing, screening, processing and issuing blood and blood products whether maintained by Government or private sector;

(e) "blood centre" means any structure or body which performs any aspect of the collection and testing of human blood or blood components, whatever their intended purpose, and their processing, storage, and distribution when intended for transfusion;

(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 process **of 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;

(i) **"blood screening" means a medical process of scanning in which the blood is tested for particular disease or other conditions transmitted through blood transfusion;**

(j) "deferral" means temporary or permanent suspension of the eligibility of an individual to donate blood or blood components;

(k) "distribution**"** means the act of delivery of blood or blood components to other blood centers, hospital blood banks and manufacturers of blood and plasma derived products but does not include the issuance of blood or blood components for transfusion;

(l) "donor" means a person who, by his free will and without compensation donates blood or a part of his blood such as plasma or cellular components for use in the medical treatment of other persons or for scientific research;

(m) "Fund" means the Fund of the Authority established under this Act;

(n) "Government" means the Government of Sindh;

(o) "haemovigilance" means a continuous process of data collection and analysis of transfusion-related adverse events and reactions in order to investigate their causes and outcomes, 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);

(p) "hospital blood bank" means a hospital unit which receives and stores screened blood and blood components received from blood centre, performs compatibility testing and issues blood and components for clinical use within the hospital;

(q) "inspection" means official, formal and objective control according to adopted standards to assess compliance of this Act and the rules and regulations made thereunder;

(r) "issuance**"** means the provision of blood or blood components by a hospital blood bank, or mixed or specialized blood transfusion service for transfusion to a recipient;

(s) "person" means natural or legal individual, partnership, association, organization, company, cooperative, trustee, agent or any group of persons;

(t) "phlebotomy" means the process of making an incision in a vein with a needle.

(u) "philebotomist" means people trained to draw blood from vein of patient for clinical or medical testing, transfusion, donation.

(v) "prescribed" means prescribed by rules or regulations;

(w) "processing**"** means any step in the preparation of a blood component carried out between the collection of blood and its storage;

(x) "recipient**"** means a person who receives transfusion of blood or blood components;

(y) "responsible person**"** in a blood establishment shall be accountable for ensuring that every unit of blood or blood components has been collected and tested, whatever its intended purpose, and processed, stored, distributed and issued, when intended for transfusion, in compliance with the provisions of this Act, the rules, and the regulations;

(z) "rules" means rules made under this Act;

(aa) "Safe blood" means human blood or blood products which, based on established testing methods, have tested negative for HIV, Hepatitis B and C viruses or other viruses or infective agents, like malarial parasites and treponema palladium (syphilis) and/or such other viruses or infective agents as the Sindh Government may, by notification in the official Gazette, specify;

(bb) "Secretary" means Secretary of the Authority;

(cc) "serious adverse event" is 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 patients or which results in, or prolongs, hospitalization or morbidity;

(dd) "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;

(ee) "traceability" means the capacity of a blood transfusion system to trace blood and blood products from the donor to its final destination and vice versa (bi-directional tracking), both for transfusions, manufacturing or disposal.

Establishment of Sindh Blood Transfusion Authority.

3. (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 Sindh 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)	Minister Health, Sindh	**Chairman**
(b)	Two members of Provincial Assembly of Sindh nominated by Speaker Sindh Assembly.	**Members**
(c)	Secretary Health, Government of Sindh	**Member**
(d)	Director, Blood Transfusion Services, Agha Khan University Hospital, Karachi.	**Member**

(e)	One Professor of Hematology or Pathology nominated by government of Sindh.	**Members**
(f)	**One representative of Regional Blood Centre (RBC) outsourced under public private partnership by Health Department.**	**Member**
(g)	Secretary of the Authority	**Member/ Secretary**

(4) The members other than ex-officio members shall, unless Government otherwise, directs hold office for a period of two years.

(5) The non-official members may be writing under his hand addressed to Government resigns his office earlier or be removed by Government.

(6) Any person appointed on a casual vacancy in the office of non-official member shall hold office for the unexpired portion of the term of such vacancy.

4. (1) The Authority shall - **Powers and functions of the Authority.**

(i) adopt or develop uniform policy covering all aspects of safe blood transfusion throughout Sindh;

(ii) register and issue licenses to blood establishments, blood center, hospital blood bank in the prescribed manner;

(iii) ensure the standards for processes performed by blood establishments, related to collection, testing of human blood and blood components, whatever their purpose, and to their preparation, storage, distribution, issuance and administration when intended for transfusion, are undertaken only by institutions that have been licensed and by professionals certified for that purpose;

(iv) prescribe the standards and specifications in the form of rules and regulations to give effect to the provisions of this Act;

(v) take all necessary measures to ensure that each blood centre establishes and maintains a quality system;

(vi) ensure that any serious adverse events related to the collection, testing, processing, storage and distribution, issuance and/or administration of blood and blood components, which may have an influence on the quality and safety of blood and blood components or on the donors' 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;

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

(viii) take all necessary measures to ensure the system used for the

labeling of blood and blood components complies with the identification system prescribed by regulations;

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

(x) 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;

(xi) 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 implementation of this Act;

(xii) set up minimum requirements for record keeping for blood establishments, categorize the blood establishments indicating which process the blood establishments are entitled to perform, 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;

(xiii) exercise such other power and perform such other function as may be necessary for achieving the objectives of this Act.

(2) The Authority may –

(i) suspend or revoke the license of a person if any condition of the license of any provision of this Act, rules or regulations has been infringed;

(ii) prescribe minimum standards and specification for registration and licensing;

(iii) collaborate with other institutions, professional bodies and experts;

(iv) organize inspections and appropriate control measures in blood establishments, blood banks and blood centers, to ensure that the requirements of this Act, rules or regulations and standards are complied with.

Appointment of Secretary.

5. (1) Government shall appoint the Secretary of the Authority of BPS-20 having qualification of post graduation of Pathology and Blood Banking, on such terms 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.

Functions and Responsibilities of Hospital Blood Banks and registered blood banks.

6. (1) A hospital blood bank and registered blood banks shall perform the functions such as reception, storage, compatibility testing and issuance of blood and blood components at the hospital premises, in compliance with its license.

(2) Every hospital blood bank and registered blood bank shall have qualified personnel directly involved in compatibility testing, storage, transport and issuance of human blood and blood components, which shall be qualified to perform those tasks.

(3) Every hospital blood bank and blood bank shall officially designate a responsible person.

(4) Every hospital blood bank shall have a dedicated location, staff and set of reagents and equipment for the performance of each type of processes and minimum requirements with regard to process flow, personnel, equipment, reagents and documentation shall be compliant with the standards adopted and endorsed by the Authority.

(5) Every physician and other medical practitioners registered with the Pakistan Medical and Dental Council, while transfusing blood to a patient, shall ensure that the blood being transfused is duly certified as safe blood by a registered blood establishment after carrying out due tests necessary to issue a requisite certificate, and administration of blood and blood components may only be done under the responsibility of the physician in charge with patient's care, based on a written prescription, after a thorough medical examination and patient's informed consent.

(6) Hospitals with their hospital blood banks are responsible for the rational and appropriate clinical use of the blood components supplied, and the clinical use of transfusion therapy shall be done in accordance with rules, regulation and guidelines adopted by the Authority,

(7) The Hospital shall, for the purpose of transfusion of safe blood, introduce Hospital Transfusion Committees.

(8) All processes performed at hospital level in relation to transfusion therapy shall be documented in accordance with rules and regulations.

(9) The registered blood bank shall be limited and allowed on need assessment basis as per area and shall be permitted to open their branch in any hospital or place as per need and subject to approval of Authority.

Documentation, Record Keeping and Traceability.

7. The blood establishment shall –

(a) maintain documentation on operational 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, donations and whole blood donations not used; number of every blood component produced and distributed, as well as screening results of 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.

Notification of Serious Adverse Events and Reactions.

8. (1) A blood establishment shall immediately inform the Authority, in the prescribed format, of any serious adverse event or serious adverse action.

Data protection and Confidentiality.

9. (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 this Act to which third parties have access, have been rendered anonymous so that the donor is no longer identifiable.

(3) For that 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;

(c) no unauthorized disclosure of such information occurs, whilst guaranteeing the traceability of donations;

Safe Blood Transfusion Committee.

10. Government may, for the purpose of creating awareness for the availability of safe blood and motivation for voluntary blood donations, set up Safe Blood Transfusion Committees consisting of philanthropists, social workers and such other persons as it may deem appropriate.

Inspection.

11. The Authority may inspect any blood establishment to rule out any illegal blood baking and seal it if any irregularity is found therein and is not working in accordance with the provision of this Act.

Registration and licence.

12. (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 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.

Fund of the Authority.

13. (1) There shall be a **non lapsable** fund of the Authority known as the Sindh Blood Transfusion Authority Fund which shall vest in the Authority.

(2) The fund shall consist of –

(a) grants made by Government, Federal Government or councils;

(b) income received from registration fees and license fee;

(c) sale proceeds of movable or immovable properties;

(d) all other sums receivable and loans obtained by the Authority.

(3) The amounts credited in the Fund shall be deposited with the schedule bank approved by Government.

(4) The Authority may invest its funds in any security of the Federal Government or any Provincial Government or any other security approved by Government.

Maintenance of Accounts.

14.(1) The accounts of the Authority shall be maintained in such form and in such manner as may be prescribed.

(2) The accounts maintained under sub section (1) shall be audited by the Auditor General of Pakistan.

(3) A statement of accounts duly audited by the auditors under sub-section (2), shall be furnished to Government, as soon as may be, after the end of every financial year.

Penalty for Contravention.

15. (1) A person who contravenes the provisions of this Act shall be punishable with a fine which may extend to five hundred thousand rupees but not less than fifty thousand rupees or imprisonment for a term which may extend to three years, or with both.

(2) A person who willfully or recklessly contravenes the provisions of this Act and thereby causes physical injury to another person shall be guilty of an offence punishable with imprisonment for a term which may extend to five years or with a fine which may extend to ten hundred thousand rupees.

(3) A person committing an act of unauthorized interference carried out for the purpose of this Act and thereby causing damage to any facility, equipment, material or person, such person shall be guilty of an offence punishable with imprisonment for a term which may extend to three years or with a fine which may extend to two hundred thousand rupees or with both.

(4) A person who conceals or connives to conceal or falsely presents or connives to falsely present any records, material, procedure, or situation, without lawful excuse, or obstructs an evaluator from accessing record, material, or other relevant evidence in case of an investigation of contravention of the provisions of this Act, rules and regulations, shall be guilty of an offence punishable with imprisonment for a term not exceeding six months or with a fine which may extend to one hundred thousand rupees or with both.

(5) A person, having been convicted previously of an offence under this Act, rules and regulations shall be punishable with imprisonment which may extend to five years, or with a fine which may extend to tend hundred thousand rupees, or with both.

(6) Where the person is guilty of an offence under this Act, rules or regulations is a company, group practice, hospital, department, corporation, firm, or institution, every director, partner, and employee of any of these shall, unless he proves that the offence was committed without his due knowledge or consent, be guilty of the like offence.

(7) The Authority shall be entitled to publish the name of any person

convicted of an offence under this Act, rules or regulations in such a manner as the Authority may direct.

(8) In case a person has been convicted of an offence under this Act, rules or regulations, the Authority shall be entitled to confiscate the equipment used and any other related materials in respect of which the contravention was committed and to dispose of it as it deems adequate.

(9) Notwithstanding the provisions this section, if the Authority is satisfied that any blood establishment has contravened the provisions of this Act, it may-

(i) issue an adverse findings report and put the blood establishment on probation;
(ii) order cessation of operation of the blood establishment;
(iii) seize and prevent the release of blood or blood products which violate prescribed rules and regulations or are considered unsafe;
(iv) cancel the license of the blood establishment;
(v) temporarily or permanently debar the re-licensing of the blood establishment.

Institution of proceedings.

16. No prosecution shall be instituted for any offence under this Act except at the instance of the Secretary or any officer authorized by Government in this behalf by general or special order in writing.

Cognizance of offences.

17. No Court other than the Court of Judicial Magistrate of First Class shall take cognizance of any offence under this Act.

Removal of difficulties.

18. If any difficulty arises in giving effect to any provisions of this Act, the Government, may be notification in the Official Gazette, make such provisions as may appear to it to be necessary for the purpose of removing the difficulty.

Rules.

19. Government may, by notification in the official gazette, make rules for carrying out the purposes of this Act.

Regulations.

20. The Authority may, with previous sanction of Government, make regulations not inconsistent with the provisions of this Act or rules made thereunder.

Delegation of powers.

21. The Authority may, by general or special order, and subject to such conditions as it may impose, delegate any of its powers, functions and duties, to the Chairperson or Secretary or any other officer of the Authority.

Repeal and savings.

22. (1) The Sindh Safe Blood Act of 1997 is hereby repealed.

(2) Notwithstanding the repeal under sub-section (1), the rules and regulations framed and notifications and orders issued under the repealed Act, shall continue to remain in force until altered, repealed or amended by the competent authority.

BY ORDER OF THE SPEAKER
PROVINCIAL ASSEMBLY OF SINDH

G.M.UMAR FAROOQ
SECRETARY
PROVINCIAL ASSEMBLY OF SINDH