DRUGS & COSMETICS ACT 1940

NATIONAL BLOOD POLICY

HEMOVIGILANCE

Drugs & Cosmetics Act

- An Act to regulate the import, manufacture, distribution and sale of drugs and cosmetics.

- Human blood is covered under the *Definitions* of 'Drug' under Sec. 3(b) of Drugs & Cosmetics Act.

- Imperative that Blood Banks need to be regulated under the Drugs & Cosmetics Act and rules there under.

- License is required to Manufacture/Collect/ Sale/Distribution.

Drugs & Cosmetics Act

- The Drugs & Cosmetics Act ,1940 is a substantial part, where we find the definitions, prohibitions & punishments and are divided into various Chapters and Sections.
- The Drugs & Cosmetics Rules, 1945 is a procedural part, where the processes are defined to implement the relevant Sections of the Act and are divided into various Parts, Rules and Schedules.

Drugs & Cosmetics Rules, 1945

- In the year 1967, Central Govt. (Ministry of Health) enacted a separate provision in Schedule F Part XII B of Drugs & Cosmetics Rules.
- State Drugs Controllers were authorized to issue the licenses for blood banks.
- The standards for 'Whole Human Blood' are prescribed in Indian Pharmacopoeia.
- Various requirements such as Accommodation, Technical staff, equipments etc. for operation of blood bank were included in this Part.

Drugs & Cosmetics Rules, 1945

The Ministry of Health & Family Welfare (Govt. of India) issued a notification in the year 1989 under the Drugs and Cosmetics Rules and made the test HIV 1&2 antibodies of Whole Human Blood as mandatory requirement before transfusion.

Drugs & Cosmetics Rules, 1945

- D&C Rules were amended (Rules 68A, Part XB and Part XIIB of Schedule F) in the year 1992-93 and Drugs Controller General (India) was vested with the power of Central License Approving Authority.
- Central License Approving Authority
- Central Drugs Standard Control Organization
- www.cdsco.nic.in

Definitions……

- 'Blood' means and includes whole human blood, drawn from a donor and mixed with an anti-coagulant
- 'Blood Component' means a drug prepared, obtained, derived or separated from a unit of blood drawn from a donor.
- 'Blood Product' means a drug manufactured or obtained from pooled plasma or blood by fractionation, drawn from donors.

Part X B : Conditions For License
(Rule 122EA to Rule 122P)
Drugs and Cosmetics Rules, Part X-B

- Rule - 122 EA – Definitions
- Rule – 122F to 122N - License Application Procedure / Inspection / Reporting by Inspection Team / Grant or Rejection of License / Duration of license /Appeal provision
- License granted by Licensing Authority
- Approval by Central License Approving Authority
- License is granted & delivered to Applicant.

Part X B : Procedure and Conditions For License (Rule 122EA to Rule 122P)

Rule - 122O – Procedure of Cancellation and Suspension of Licenses.

Rule – 122P – Conditions of licenses:

Maintenance of Staff / Plant / Premises / Equipment

- Testing of whole blood / Component / Product
- Inspections
- Reporting to SLA / CLAA about changes in staff / premise

Directions issued by SLA / CLAA / Recall Directions:

- Conditions for distribution of whole blood / component / products.
- To comply provisions of the Act and Rules
- Destruction of infected blood and implementation of Bio-Medical Wastes (Management and Handling) Rules, 1996

Forms for License

	Application	License	Renewal
Blood and Components	27-C	28-C	26-G
Blood Products	27-E	28-E	26 - I

Schedule F Part XII B – Subpart I
Requirements for Blood Bank / Blood Components

A. General

B. Accommodation

C. Personnel

D. Maintenance

E. Equipments and Calibration

F. Supplies & Reagents

G. Good Manufacturing Practices

H. Criteria for Blood Donation

I. List of Equipments

J. Special Reagents

K. Testing of whole blood

L. Records

M. Labels

Schedule F Part XII B – Subpart II Blood Donation Camps

- Permission for camps to:
  - Licensed designated Regional Blood Transfusion Centre
  - Licensed Govt. Blood Bank
  - Indian Red Cross Society
  - Licensed blood bank run by registered voluntary or charitable organizations recognised by SBTC

A. Premises

B. Personnel for out-door camps

C. Equipment

Schedule F Part XII B – Subpart III Processing of Blood Components

A. Accommodation

B. Equipment

C. Personnel

D. Testing facility

E. Categories of Blood Components

F. Apheresis

- Donor Criteria
- Monitoring

Schedule F Part XII C Manufacturing of Blood Products

A. General Requirements

B. Collection and Storage of Plasma for Fractionation

C. Personnel

D. Production Control

E. Viral Inactivation Process

F. Quality Control

G. Testing

H. Storage of Finished products

I. Labeling

J. Records

K. Master Formula Record

Compliance must be specifically observed in the following aspects

Staff

- Change of staff must be informed to the DCA.
- All staff members must be vaccinated and the records be available.
- Record of the staff training, training manual and training calendar must be available.
- Medical examination of the donors must be carried out by the Medical Officer.

Facility Layout

- Any modifications must be notified to the Licensing Authority.
- Rest and Refreshment room must be available for the donors.
- Reception area must not be used as refreshment room for donors.
- Privacy must be available for the medical examination of the donors.

Equipments

- Alarm systems of the blood storage refrigerators must be functional.
- Recording thermograph must be available and functional for the blood storage areas.
- Instruments must be periodically calibrated.
- Emergency medicines must be checked for expiry dates.

Testing

- Sterility test of CPDA solution must be performed at the time of receipt.
- Manufacturer’s report must be available.
- Sterility test of the blood bags after the blood collection must be performed.

Grouping & Cross-matching

- Grouping and cross matching must be carried out by tube technique and not by slide technique.
- Tests for atypical antibodies must be carried out.

ELISA TEST

Test method including the Positive and Negative control must be as per the literature.

Documentation

- Laboratory manual must be prepared and available.
- Standard Operating Procedures must be prepared, reviewed and available.
- Donor's records, including the address, must be complete.
- Batch number of the blood bag must be recorded in the Donor Blood Collection Record.
- Calibration records must be available.
- Records of disposal of Sero-reactive blood and its components must be maintained appropriately.
- Records of sterilization must be maintained.

Processes

- Labels must be affixed only after complete testing.
- Two separate storages must be available for under testing and tested blood and components.
- Hospital Transfusion Committee must be formed and should be functional.

National Blood Policy

National Blood Policy & National Blood Program have been developed by the Govt of India, for the provision of Safe and Adequate blood transfusion services to the people.

National Blood Policy-Mission Statement

- Easily accessible and adequate supply of safe and quality blood collected from voluntary non-remunerated regular blood donor in well equipped premises, and is stored and transported under optimum conditions.

- Transfusion under supervision of trained personnel for all who need it irrespective of their economic or social status through Total Quality Management Approach.

OBJECTIVES OF NBP

1. To reiterate firmly the Govt. commitment to provide safe and adequate quantity of blood, blood components and blood products.

2. To make available adequate resources to develop and reorganise the blood transfusion services in the entire country.

3. To make latest technology available for operating the blood transfusion services and ensure its functioning in an updated manner.

4. To launch extensive awareness programmes for donor information, education, motivation, recruitment and retention in order to ensure adequate availability of safe blood.

OBJECTIVES OF NBP…….

5. To encourage appropriate clinical use of blood and blood products.

6. To strengthen the manpower through Human Resource Development.

7. To encourage Research & Development in the field of Transfusion Medicine and related technology.

8. To take adequate regulatory and legislative steps for monitoring and evaluation of blood transfusion services and to take steps to eliminate profiteering in blood banks.

Haemovigilance Program of India

- Collection of data related to the blood transfusion safety chain (vein to vein).

- A system for monitoring , reporting and investigation of adverse events/near misses related to blood transfusion

Hemovigilance Program of India

- Haemovigilance is a continuous process of data collection and analysis of Transfusion-related Adverse Reactions in order to investigate their causes and outcomes and prevent their occurrence or recurrence.

- All serious incidents following transfusion of blood / components / products are reported to a central point for collation , coordination of investigation & action taken in response to the incidents.

- National Institute of Biologicals, India.

Hemovigilance Program of India

Objectives:

1. To track Adverse Reactions/ Events and incidence associated with Blood Transfusion and Blood Product Administration (Hemovigilance).

2. To help identify trends, recommend best practices and interventions required to improve patient care and safety, while reducing overall cost of the healthcare system.

Hemovigilance Program of India……

- Haemovigilance is an essential part of the quality circle
- Information is fed back into the transfusion system to improve overall safety and quality of transfusion
- Both BTS and hospital transfusion activities are included
- Open, honest reporting and investigation are essential

THANK YOU