

# **Division of Blood Transfusion Services**

**Ministry of Health and Family Welfare**



# Legal Aspects of Blood Banks

**1. The Drugs & Cosmetics Act 1940  
&  
The Drugs & Cosmetics Rules, 1945.**

# Drugs & Cosmetics Rules,1945

- Human blood is covered under the definition of ‘Drug’ under Sec. 3(b) of Drugs & Cosmetics Act.
- Hence, it is imperative that Blood Banks need to be regulated under the Drugs & Cosmetics Act and rules there under.

# 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.
- Various requirements such as Accommodation, Technical staff, equipments etc. for operation of blood bank were included in this Part.
- State Drugs Controllers were authorized to issue the licenses for blood banks.
- The standards for ‘Whole Human Blood’ was prescribed in Indian Pharmacopoeia.

# Drugs & Cosmetics Rules, 1945

- Due to prevalence of AIDS virus, 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.

# Drugs & Cosmetics Rules, 1945

- The requirement of a blood bank is inserted in Part X-B of the Drugs and Cosmetics Rules, 1945.
- The Rules from 122F to 122P explain the various procedures of making applications by a blood bank, fees to be paid for grant/renewal of license by the applicant and conditions of license to be followed by the applicant after grant/renewal.



# Drugs & Cosmetics Rules,1945

- In accordance with the Supreme Court order, blood bank legislation has been revised on 5.4.1999 to include Good Manufacturing Practices, Standard Operating Procedure and validation of equipments.

## **2. National blood policy**

# 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.

### **3. National plasma policy**

# National Plasma Policy

- The aim of the policy is to facilitate national access to Plasma Derived Medical Products (PDMPs) for therapeutic use.

# **National Plasma Policy Objectives**

# National Plasma Policy

1. To reiterate that Government will facilitate availability and utilization of safe and adequate quantity of plasma derived products for clinical/ therapeutic use.
2. To make available adequate resources to develop and organize the plasma/plasma derived medical products mobilization throughout the country.
3. To take adequate Regulatory and Legislative steps for monitoring of activities related to plasma derived products.



# National Plasma Policy

5. To strengthen Quality Systems in Blood Transfusion Services for plasma collection, transportation, processing, production and distribution of plasma derived medical products.
4. To encourage Research & Development in the field of blood components, plasma fractionation and plasma derived products.

## **4. NACO Guidelines for Blood Storage Centers**

# NACO Guidelines for Blood Storage Centers.

- It contains detailed guidelines, formulated by an expert group for setting up a blood storage facility at identified First Referral Unit ( FRUs) with up to 50 beds.
- For setting up similar units at hospitals with more beds, the same guidelines would apply but the requirement of equipment and consumables may increase.

# NACO guidelines for Blood Storage Centers

- First referral Units, Community Health Centers, Primary Health Centers or any other hospitals are required to obtain approval from the State/Union Territory licensing authority.
- This document contains guidelines for the application that needs to be made to The State Licensing Authority.

# NACO Guidelines for Blood Storage Center

- Requirements for approval
- Suggested quantities to be available
- Storage and Transportation
- Disposal, Documentation, Training.
- Rules and Procedures
- Equipments specification

# NACO guidelines for Blood Storage Centers

Standard operating procedures For :

- Blood Grouping ( ABO )
- Rh Grouping
- Compatibility Testing
- Labeling & Issue of Blood.

# NACO guidelines for Blood Storage Centers

## Clinician's Guidelines Regarding :

- Obstetric condition for whole blood
- Responsibility of clinicians
- Administering Blood
- Transfusion Reactions
- Appropriate use of Blood Components
- Blood Substitutes
- Plasma Substitutes.

# **5. Hemovigilance**

## **Haemovigilance Program of India**

National Institute of Biologicals & Indian Pharmacopoeia  
Commission Collaboration





# 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.

# Hemovigilance Program of India

## Objectives:

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

## **6. Biomedical Waste (Management & Handling) rules, 1998.**

# Biomedical Waste (Management & Handling) rules

- Ministry of Environment and Forests , Govt. of India has notified Bio-Medical Waste ( management and handling) Rules, 2011 under the Environment ( Protection) Act, 1986.



# Biomedical Waste (Management & Handling) rules

1. The rules apply to all persons who generate biomedical waste.
2. Every institution shall either set up requisite bio –medical waste treatment facilities like autoclave/ microwave/hydroclave, shredder in the premises or ensure it at an approved common waste treatment facility.
3. Every institution shall apply for grant of authorization to the prescribed authority.
4. Bio-medical waste shall be segregated in the color coded containers.

# **Biomedical Waste (Management & Handling) rules**

5. There are eight categories of Bio-medical waste which shall be disposed of in accordance with Schedule I of the rule.
6. District Level Monitoring Committees under the chairmanship of District Medical Officer shall monitor the compliance.
7. Compliance to the guidelines issued by the Central Pollution Control Board, Ministry of Environment and Forests, Ministry of Health and Family Welfare, Government of India has now become mandatory for management of Bio-medical waste.

## **7. The International Society of Blood Transfusion (ISBT) Ethical code for Blood Donation & Transfusion**

## 7. ISBT – Code of Ethics (contd...)

- Donation of Blood & Hematopoietic cells, should be voluntary & the donor should NEVER be compelled.
- The donor should provide INFORMED CONSENT.
- A profit motive should not be the basis for an establishment & running of a blood service.
- Anonymity between donor and recipient must be ensured.



## ISBT – Code of Ethics (contd...)

- The donor should understand the risks to others of donating infected blood and his or her ethical responsibility to the recipient.
- Blood donation must not involve discrimination of any kind.
- Blood must be collected under the overall responsibility of a suitably qualified, registered medical practitioner.
- Blood is a public resource and access should not be restricted.
- Wastage should be avoided.

# ISBT – Code of Ethics Hospitals : Patients

- Patients should be informed of the known risks and benefits of blood transfusion and/or alternative therapies and have the right to accept or refuse the procedure.
- Transfusion therapy must be given under the overall responsibility of a registered medical practitioner.

## **8. International standard ISO 3826 for blood bags**

## 8. ISO 3826-3:2006

The manufacturers of the plastic containers are expected to disclose to the national control authority, if requested by them, full details of the:

- plastic materials
- their methods of manufacture
- chemical names
- additives