Amendments to Indian Drugs and Cosmetics Act and Rules Pertaining to Blood Banks in Armed Forces

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MJAFI 2005; 61 : 264-266

Key Words : Amendments; Drugs and Cosmetics rules, Blood bank

Introduction

Under the cover of transfusion medicine hides the reality of blood safety and efficacy in clinical practice. The recent publication of the journalist Douglas Starr on blood is an epic in history of medicine and commerce which clearly describes the urgent need for regulatory frame works to protect public from unnecessary damage due to lack of standards and quality management in blood supply.

Blood transfusion services are a vital part of the National Health Services. The exponential advancement in the field of transfusion medicine has brought into focus blood transfusion safety and regulatory requirement. A comprehensive legislation to ensure quality control on collection, testing, storage, distribution and infusion of blood and blood components was formulated by the Drug Controller General of India (DCGI) [1]. The Director General of Health Services (Ministry of Health and Family Welfare) carries out amendments from time to time relating to blood transfusion services in the Drugs and Cosmetics Act, 1940 and Rules thereunder to meet the latest requirements for blood safety.

The problems of transfusion associated acquired immuno deficiency syndrome resulted in a notification in 1989 under the Drugs and Cosmetics Act which made the test for HIV mandatory. The Drugs and Cosmetic Rules were again amended (Rules 68A, Part X B and Part XII B of Schedule F) in the year 1992-93 and the DCGI was vested with the power of Central Licence Approving Authority (CLAA) to approve the licence of notified drugs viz blood and blood products, IV fluids, vaccines and sera [1].

Human blood is covered under the definition of “Drugs” under Section 2(b) of Drugs and Cosmetics Act. Hence it is imperative that the blood banks need to be regulated under the Drugs and Cosmetics Acts and

Rules thereunder and the licence is granted for operating a blood bank by the State and Central Licencing Approving Authorities after inspection (1).

Amendments: Drugs and Cosmetics Rules

The Drugs and Cosmetics Rules 1945 was published as required by sections 12 and 13 of Drugs and Cosmetics Act, 1940 (23 of 1940). Drugs and Cosmetics (1st Amendment) Rules, 1992 was published on 22 Jan 1993 vide GSR 28(E) [2]. Seeing the dismal state of blood banks a writ petition titled “Common Cause Vs Union of India” was filed in the Supreme Court of India in the year 1992. In a landmark judgement Supreme Court passed the following ruling :

- All blood banks to be licensed within 2 years.
- Eliminate professional donors within 2 years.
- Steps for starting special post-graduate courses (MD) in Transfusion Medicine be initiated.

The 1st Amendment dated 22 January 1993 [2] related to collection, storage, processing and distribution of whole blood, blood components by blood banks and licensing of all blood banks being made mandatory – Sec 18(c)

Accomodation for Blood Bank

Total area of 150 sq m shall be provided for blood banks (100 sqm) with additional 50 sq m for preparation of blood components. It shall consist of the following rooms:

- Registraton and medical examination room
- Blood collection room (Airconditioned – AC)
- Room for blood component preparation (AC to maintain temperature between 20-25 degree)
- Room for lab for blood group serology (AC)
- Room for lab for testing diseases like Hepatitis, HIV, Syphilis and Malaria (AC).

Table 1 shows the staffing pattern as per FDA.

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Table 1**Blood bank staff as per food and drug administration**

Staff	Blood units collection per year	
	0-1000	1000-5000
MO	2	4
Registered nurse	1	1
Blood bank technician	4	5
Lab assistant	1	4
Lab attendents	2	5
Servant sweeper	1	1
Medical social worker	1	1
Store clerk	1	2
Record Asst	1	1
Driver	-	1
Total	14	25

A few extracts of Drugs and Cosmetics (2nd Amendment) Rules, 1999 published on 05 April 1999 vide GSR 245(E)[3] are as follows:

- a) Accomodation – refreshments cum rest room (AC)
- b) Staff – Only diploma and degree in Medical Laboratory Technology (DMLT) are acceptable and certificate holders are not to be treated as technicians.
- c) Equipment-
 - i) Incinerator and Dielectric tube sealer were made compulsory
 - ii) Only PVC bags are to be used for blood collection
 - iii) Equipment to be calibrated at specified intervals
- d) Label- Prominent display of the blood donor status whether voluntary/replacement
- e) Camps can be arranged by-
 - i) Licensed regional blood transfusion centers
 - ii) Licensed government blood banks.
 - iii) Indian Red Cross Society.

The 1st Amendment of Drugs and Cosmetics Rules, 1945 published on 04 January 2001 vide GSR 6(e)[4] were that whole human blood collected and transfused by centers run by Armed Forces Medical Services in border areas, small mid-zonal hospitals including peripheral hospitals, field ambulances, mobile medical units and other field medical units including blood supply units shall be subject to all the provisions of chapter IV of the Act and Rules made thereunder which are as follows:

- a) These centers shall collect, process and transfuse blood in emergent situations which require life saving surgeries.
- b) These centers shall be under the direct supervision of a qualified medical officer, as specified in

condition (i) of rule 122-G.

- c) Each blood unit shall be tested for HIV I and II antibodies, Hepatitis B surface antigen, Hepatitis C antibodies, malarial parasites and other tests specified under the monograph 'Whole Human Blood' in current edition of Indian Pharmacopeia.
- d) These centers shall have adequate infrastructure for storage and transportation of blood.
- e) The blood collected and tested by such centers shall be transfused by the center itself and may be made available for use by other peripheral Armed Forces Hospitals or centers during operational circumstances.

As per the 2nd Amendment of Drugs and Cosmetics Rules, 1945 published on 29 January 2001 vide GSR 40(e)[5] Hepatitis C virus antibody testing was made mandatory wef 01 June 2001.

As per the 3rd Amendment of Drugs and Cosmetics Rules, 1945 published on 28 March 2001 vide GSR 218(e)[6] Blood Donation Camps shall be substituted by the Indian Red Cross Society or a licensed blood bank run by voluntary or charitable organization.

Drugs and Cosmetics Rules, 1945 were published on 20 December 2001 vide GSR 909(e)[7]. It exempted Blood Storage centers run by First Referral Unit, Community Health Centre, Public Health Centre or any hospital from obtaining license.

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Whole human blood is included in the Indian Pharmacopoeia under Schedule 'C' of the Drugs and Cosmetics Rules. The requirement of blood banks is given under schedule 'F' of the said rule. It is indicated in BP, USP and FDA of USA. Since whole human blood is required in a diseased state and to cure diseases like anaemia and extreme blood loss, blood is considered to be a drug. Since blood and blood products are drugs, license is required for blood transfusion under Section 18 (c) of the said act. Any person who collects blood meant for transfusion without license is liable for penalty under Section 27(b)(ii) of the said act.

The offences committed under Drugs and Cosmetics Act/Rules are indicated at Annexure – I. The offences committed and penalties in manufacture and sale of adulterated drug under Section 27(B) are listed in Annexure-II.

Discussion

Human blood is the elixir of life. It is essential for human life and there are no substitutes. Blood transfusion services form a vital part in the national health delivery system. Blood is categorized as a 'drug' under Section

Annexure - I**Offences and penalties as laid down under the drugs and cosmetics act and rules thereunder concerning blood banks**

Offence	Penalty
Blood bank without valid licence	Imprisonment not less than 1 year but may extend more than 3 yrs. Fine not less than Rs.5000/-
Manufacture or sale of contaminated blood with HIV/HBV/non-sterile.	Imprisonment not less than 5 years but may extend to a term of life. Fine not less than Rs.10,000/-
Manufacture or sale of blood which is not labeled	Imprisonment not less than 1 year but may extend to 2 years. Fine: Rs.1000/-
Manufacture or sale of blood not in accordance with conditions of licence	Imprisonment not less than 1 year but may extend to 2 years. Fine as per Section 27(d).

2 (b) of the Drugs and Cosmetics Act, 1940. This act and the rules thereof provide the legal framework for regulating the functioning of blood banks. Since initial formulation, the ambit of the Drugs and Cosmetics Act, 1940 has expanded and the rules have accordingly been frequently amended to incorporate ongoing and current concerns [8].

1st Amendment of the Drugs and Cosmetics Rules, 1945 published on 04 January 2001 vide GSR 6(e) (4), is a landmark amendment concerning the exemption of licensing to blood transfusion centers run by Armed Forces Medical Services in border areas, small midzonal hospitals including peripheral hospitals, field ambulances, mobile medical units and other field medical units including blood supply units in border, sensitive and field areas. However, the conditions mentioned in the Amendments Rules have to be fulfilled.

The Armed Forces Transfusion Services (AFTS) with 52 hospital blood banks is a well-organized network providing components to Armed Forces personnel and their dependants. The AFTS also provide support for civilian emergencies, natural disasters and to populations in remote and inaccessible areas. These amendments will ensure optimal quality control on collection, testing, storage, distribution and infusion of safe blood and blood components. It is an endeavour to continually improve and upgrade the availability and safety of blood products for optimal patient care.

Annexure - II**Offences and penalties under drugs and cosmetics act and rule regarding blood banks**

Offence	Penalty
(i) Manufacture for sale of adulterated/spurious drug.	Imprisonment not less than 5 years but may extend to life imprisonment. Fine: not less than Rs.10,000/-
(ii) Adulterated drug not covered above	Imprisonment not less than 1 year but may extend to 3 years. Fine: Rs.5000/-
(iii) Manufacture of drug without valid licence	Imprisonment not less than 1 year but may extend to 3 years. Fine: Rs.5000/-
(iv) Spurious drug not covered above.	Imprisonment not less than 3 years but may extend to 5 years. Fine: not less than Rs.5000/-
(v) Drug manufactured in contravention of any other provision of act/rules.	Imprisonment not less than 1 years but may extend 2 years with fine.
(vi) Non-disclosure of information/not keeping the documents.	Imprisonment for 1 to 2 years or fine or both.
(vii) Subsequent offences for (i) & (ii)	Imprisonment not less than 6 years but may extend to 10 years. Fine: not less than Rs.10,000/-
(viii) Subsequent offences for (iii)	Imprisonment not less than 6 years but may extend to 10 years. Fine: not less than Rs.10,000/-
(ix) Subsequent offences for (iv)	Imprisonment not less than 2 years but may extend to 4 years. Fine: not less than Rs.5000/- or both.

References

1. Drugs and Cosmetics Act, 1940 and Rules, 1945; 7th Ed 2002.
2. The Gazette of India: Extraordinary, Ministry of Health and Family Welfare, notification GSR 28(E), 22 Jan 1993.
3. The Gazette of India: Extraordinary, Ministry of Health and Family Welfare, notification GSR 245 (E), 05 Apr 1999.
4. The Gazette of India: Extraordinary, Ministry of Health and Family Welfare, notification GSR 6(e), 04 January 2001.
5. The Gazette of India: Extraordinary, Ministry of Health and Family Welfare, notification GSR 40(e), 29 January 2001.
6. The Gazette of India: Extraordinary, Ministry of Health and Family Welfare, notification GSR 218(e), 28 Mar 2001.
7. The Gazette of India: Extraordinary, Ministry of Health and Family Welfare, notification GSR 909(e), 20 Dec 2001.
8. Transfusion Medicine Technical Manual. Directorate General of Health Services, Ministry of Health and Family Welfare 2nd Ed 2003.