Office of the Controller, Drugs and Food Control Organisation, J&K, Jammu

The Principal Secretary,
Health & Medical Education Depptt.,
J&K Government,
Civil Secretariat, Jammu.

No.: DFO/ 0-204/1 500-30
Dated:- 23-02-10

Subject:- Guidelines for Blood storage Centres run by first Referral units/Hospitals having Blood Banks for the process of Whole Human Blood.

Sir,

This takes reference to the discussions in the review meeting convened by Hon’ble Minister for Health, Horticulture & Floriculture on 12th of February 2010 wherein it was decided to have blood storage centres so as to make abundant availability of Whole Human Blood or its components. The blood storage centres have been exempted from obtaining licence under the provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945. However, certain guidelines have to be followed by the authorities of Referral Units/Hospitals and the storage centres. The exemption to obtain licence under Schedule ‘K’ to Drugs & Cosmetics Act, 1940 have been made applicable to blood banks and referral units which are consuming captive consumption/ transfusing the blood or blood components less than 2000 units per annum. The details are as under:-

1. **The conditions applicable to blood bank for obtaining exemption from the purview of taking licenses from State Drug Controller:-**

   1. The Hospital/FRU should have blood banking licence for processing of Whole Human Blood and/or its components issued by the authorities and captive consumption of Whole Human Blood I.P. or components shall be less than 2000 units per annum.

   2. The Whole Human Blood and/or its components shall be procured only from Government Blood banks and/or Indian Red Cross Society Blood Bank duly licensed by the State Drugs Controller/Licensing Authority.

   3. The establishment shall maintain records and registers including details of procurements of Whole Human blood I.P. and/or blood components, as required under Schedule ‘F’ part XII B of the Drugs and Cosmetics Rules, 1945 & the hospital/establishment shall store samples of donors blood as well as patients sera for a period of seven days after transfusion.

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The blood bank shall test the following mandatory tests before supplying to Blood storage centres:-

(a) Blood grouping  
(b) antibody testing  
(c) Hemoglobin contents  
(d) HIV-I and HIV-II antibodies  
(e) Hepatitis B Surface antigen  
(f) Hepatitis C antibody  
(g) Malarial parasite  
(h) Syphilis or VDRL;

All the tests shall be mentioned on the label of the bottle/blood unit with date of testing as well.

5. A letter of consent for supply of Whole human blood and/or blood components to the blood storage centres along with application.

II. Requirements of Blood Storage Centres (BSCs):

1. List of equipments provided in the BSCs which include Blood Bank refrigerator of appropriate capacity fitted with alarm device and temperature indicator with regular temperature monitoring that shall be provided to store blood units between 2°C to 8°C as per specifications under Schedule ‘F’ part XII B of the Drugs and Cosmetics Rules, 1945.

2. The applicant shall furnish:

   a. Name of the Medical Officer responsible for conducting operation of blood storage center with attested copies of MBBS or MD qualification.
   b. Name of the Blood Bank Technician with certified copies of qualifications and experience of blood bank technician having no DMT qualification should also be produced.
   c. The source of procurement of Whole Human Blood and/or its components namely the name and address of the licensed blood banks.
   d. Plan of the premises (Approved) not less than two rooms of minimum area of 10 sq. metres each.

3. Inspection by the Regulators:- The blood bank to supply blood to BSCs to be inspected by the Inspectorate staff who shall recommend for approval to State/Union Territory Licensing Authority through inspection. The team shall verify the mode of transport or
containers used for supply of blood units/components for ensuring proper storage conditions as are required under Schedule 'F' part XII B of the Drugs and Cosmetics Rules, 1945.

4. Role of Licensing Authority:- The State/Union Territory Licensing Authority shall forward the approved BSCs to Central Licensing Authority at New Delhi and Zonal Officers At Ghaziabad with validity of approval for a period of two years. The blood bank shall apply for onward renewal before three months prior to expiry of the approval.

Yours’ faithfully,

(Satish Gupta)
Controller
Drug & Food Control Organization,
J&K, Jammu

Copy to the:-

1. Principal, Govt. Medical College, Jammu/Kashmir for favour of information.
2. Director, Health Services, Jammu/Kashmir.
4. Chief Medical Officers____________________(all).
5. Dy. Controller, Drugs and Food, Jammu/Kashmir for further instructions to ADCs & DL (Mfg.).