

**GOVERNMENT OF INDIA  
HEALTH AND FAMILY WELFARE  
LOK SABHA**

UNSTARRED QUESTION NO:1137  
ANSWERED ON:01.03.2006  
SETTING UP OF PRIVATE BLOOD BANK  
Chaure Shri Bapu Hari;Dhotre Shri Sanjay Shamrao

**Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:**

- (a) whether approval of the Central Government is required to be taken for setting up of private blood bank in any State; and  
(b) if so, the criteria laid down or guidelines issued by the Government in this regard?

**Answer**

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH & FAMILY WELFARE (SMT. PANABAKA LAKSHMI)

(a ) & (b): Yes Sir.

Under the provisions of Drugs & Cosmetics Rules, 1945, Rule 122 F, prescribes the licensing procedure of all Blood Banks. On receipt of application, the State Licensing Authority (SLA), after taking such measures including joint inspection of the premises and if satisfied prepares the licence and forwards the same to the Central License Approving Authority (CLAA) for approval. The Government also notified under Rule 122 G vide GSR No. 733(E) dated 21st December, 2005 (copy enclosed) that "Application for grant or renewal of licence for operation of Blood Bank or processing of human blood components shall be made by the Blood Bank run by the Government, Indian Red Cross Society, Hospital, Charitable Trust or Voluntary Organisations approved by a State/Union Territory Blood Transfusion Council".

MINISTRY OF HEALTH AND FAMILY WELFARE  
(Department of Health) NOTIFICATION

New Delhi, the 21st December, 2005

G.S.R. 733(E):- Whereas a draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945 was published, as required by Sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), in the Gazette of India, Extraordinary, Part-II, Section 3, Sub-Section

(i) dated the 13th December, 2004 under the notification of the Government of India in the Ministry of health and Family Welfare (Department of Health), number G.S.R. 807 (E), dated the 13th December, 2004, inviting objections and suggestions from all persons likely to be affected thereby, before the expiry of a period of forty-five days from the date on which copies of the Official Gazette containing the said notification were made available to the public;

And, whereas copies of the said Gazette were made available to the public on 14-12-2004;

And, whereas objections and suggestions received from the public on the said draft rules have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred by Sections 12 and 33 of the said Act, the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs and Cosmetics Rules, 1945, namely:-

1. (1) These rules may be called the Drugs and Cosmetics (6th Amendment ) Rule 2005
- (2) They shall come into force on the date of their publication in the Official Gazette

2. In the Drugs and Cosmetics Rules, 1945, -

(i) in the rule 122F, in sub-rule (1), 'Explanation' shall be omitted;

(ii) rule 122G shall be numbered as sub-rule (1) thereof, and after sub-rule(1) as so renumbered, the following shall be inserted, namely :-

(2) Application for grant or renewal of a licence for operation of Blood Bank or processing of human blood components shall be made by the Blood Bank run by the Government , Indian Red Cross Society, hospital, charitable trust or voluntary organization approved by a State/Union Territory Blood Transfusion Council only.

Explanation – For the purpose of this sub-rule, "renewal" shall include renewal of any licence issued prior to the commencement of the Drugs and Cosmetics (Amendment) Rules, 2005."

(iii) In Schedule F to the said rules, in Part XII-B, under the heading 'J. SPECIAL REAGENTS', for the entry at serial number (5), the following shall be substituted, namely, -

“(5) ELISA or Rapid or RPHA test kits for Hepatitis and HIV I and II.”

[ F.No. X-11014/6/2004-DMS & PFA]  
RITA TEAOTIA, Jt. Secy.

Foot-note : The principal rules were published in the Official Gazette vide notification No. F.28-10/45-H(1) dated 21st December, 1945 and amended in the year 2005, by the following notifications published in Part II, Section 3, Sub-section (I) of the Gazette of India, namely:-

- (1) GSR 32 (E) dated 20-1-2005.
- (2) GSR 35 (E) dated 20-1-2005.
- (3) GSR 79 (E) dated 14-2-2005.
- (4) GSR 174 (E) dated 16-3-2005.
- (5) GSR 431 (E) dated 30-6-2005.