

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

UNSTARRED QUESTION NO:2706

ANSWERED ON:06.12.2000

A BLOODY MESS .

NARESH KUMAR PUGLIA;NEDURUMALLI JANARDHANA REDDY;PAWAN KUMAR BANSAL;PRABHUNATH SINGH;RASHID ALVI;VARKALA RADHAKRISHNAN

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

- (a) whether attention of the Government has been drawn to the news-item captioned `A Bloody Mess` appearing in the `Hindustan Times` dated November 12, 2000;
- (b) if so, the details thereof;
- (c) the number of patients who suffered serious side effects after being treated with tainted Albupan;
- (d) whether National Institute of Communicable Diseases(NICD) and AIIMS have failed to perform their duty by ensuring that blood products imported are free from all types of bacteria or contamination before permitting sales thereof in the market;
- (e) whether any Indian company is manufacturing blood products;
- (f) if so, the details of their products; (g) the details of blood products imported in India alongwith the import policy of blood products/medicines; (h) whether Government are aware that blood products (Albupan) given to patients with severe liver disorder/severe protein deficiency is imported and the same are found tainted in most of the cases; (i) if so, the details thereof; and (j) the action taken/proposed to be taken to safe blood transfusions and a healthy blood collection/donation policy?

**Answer**

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI A. RAJA)

(a), (b) & (c) Yes, Sir. This news-item is based on a story in a German magazine `Stern` regarding the impact of contaminated blood from M/s Albovina, GmbH, Austria during 1994-96. Blood products are imported from various countries. One such blood product, human albumin injection 20% (Albupan) was imported from M/s Albovina, GmbH, Austria by M/s Panacea Biotech, New Delhi during 1994-96 under Form-10 licence. No complaints have been received after administration of Albupan.

(d) No, Sir. National Institute of Communicable Diseases (NICD) and AIIMS are performing the necessary tests to ensure that the blood products are free from HIV, HBV & HCV infections.

(e) & (f) Yes, Sir. Three Indian companies, (1) M/s National Plasma Fractionation Centre (NPFCC), Mumbai; (2) M/s Bharat Serum and Vaccines, Mumbai and (3) M/s Serum Institute of India, Pune are involved in manufacturing of blood products in the country. While NPFCC, Mumbai manufactures blood products using indigenous plasma, M/s Bharat Serums and Vaccines, Mumbai and M/s Serum Institute of India, Pune use imported bulk immunoglobulins. The products that are manufactured are - Albumin, Gammaglobulin and Coagulation Factors.

(g) The blood products that are imported into the country are Albumin, various Immunoglobulins and Anti-Haemophilic Factors. For the import of such drugs, a licence in Form-10 under Drugs & Cosmetics Rules is granted to the respective importer after scrutinising the source plasma profile, manufacturing processes including viral inactivation and quality assurance documents. Each imported consignment has to be accompanied by the valid batch release certificate issued by the National Control Authority of the country of origin. Further, each imported batch from every consignment is tested for freedom from HIV 1 & 2, HbsAg and HCV prior to release for use.

(h) No, Sir.

(i) Does not arise.

(j) The revised Drugs & Cosmetics Rules of April, 2000 deals with steps to ensure safe blood donation, collection and transfusion. The National Blood Policy that is awaiting Government approval is expected to function as the framework to ensure safe blood transfusion services in the country.