

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

UNSTARRED QUESTION NO:1113
ANSWERED ON:30.07.2010
BAN ON ALBUPAX DRUGS
Adhi Sankar Shri

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

- (a) whether the drug "Albupax used in treatment of breast cancer has been declared sub-standard by the Government;
- (b) if so, the details of the report of the Central Drugs Laboratory, Kolkata in this regard;
- (c) whether Albupax is the generic version of the international brand "Abraxane of Abraxis Bio Sciences, USA; and
- (d) if so, the measures taken by the Government to recall the product from the market or ban it?

Answer

MINISTER OF THE STATE IN THE MINISTRY OF HEALTH & FAMILY WELFARE (SHRI DINESH TRVEDI)

(a) & (b): Based on the reports of Central Drugs Laboratory, Kolkata the samples of the drug Albupax manufactured by M/s NATCO Pharma Pvt Ltd., Hyderabad were declared to be 'not of standard quality' due to presence of higher level of endotoxin than acceptable limits.

(c): The drug Albupax manufactured by M/s NATCO Pharma Pvt Ltd., Hyderabad was approved as a new drug in the country.

(d): The Central Drugs Standard Control Organisation {CDSCO} suspended the permission to manufacture the drug Albupax on 21/10/09. Following the appeal filed by the manufacturing company under the provisions of the Drugs & Cosmetics Rules, 1945, the Ministry of Health & Family Welfare vide letter dated 23/12/2009 stayed the operation of the said suspension order dated 21/10/2009 of CDSCO, pending the decision on appeal filed by the NATCO Pharma Pvt. Ltd., Hyderabad.

The CDSCO issued a letter to the manufacturing company on 25-02-2010 asking it to ensure that the fresh batches of the drug Albupax are manufactured as per requirements of the Drugs & Cosmetics Act and Rules prior to release for sale / use for patients. They were also asked to ensure that those batches of the drug Albupax, which were withdrawn including the two batches (batch. No. 202013 & 202119) which were reported to be not of standard quality by Central Drugs Laboratory, Kolkata are not available in the public for use on patients.