GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:4602
ANSWERED ON:23.04.2010
SUSPENSION OF DRUGS
Bali Ram Dr. ;Bhagat Shri Sudarshan

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

(a) whether the Government has revoked the suspension on Albupax which was initially found to be not the standard quality;

(b) if so, the details thereof alongwith the reasons therefor;

(c) whether the Government had also banned 294 Fixed Dose Combinations as irrational combinations;

(d) if so, whether out of the said banned combinations, ban on 140 Fixed Dose Combinations has been revoked;

(e) if so, the details thereof alongwith the reasons therefor; and

(f) the corrective measures taken by the Government in the matter?

Answer

THE MINISTER OF STATE FOR HEALTH & FAMILY WELFARE(SHRI DINESH TRIVEDI)

(a) & (b) The Central Drug Laboratory, Kolkata, in its test report has declared the drug Albupax (paclitaxal Albumin bound particle injectable suspension) "to be not of standard quality" due to the presence of higher level of Endotoxin than acceptable limits. On the basis of the test reports, the Central Drugs Standard Control Organisation (CDSCO) by its letter dated 21.10.2009 suspended the permission to manufacture the said drug by following the laid down procedure and also asked the manufacturer to recall the product from the market. The first permission to manufacture a new drug is given by the CDSCO on the basis of the certificate of analysis, test report, safety and efficacy data of the drug provided by the manufacturer as per the requirement of Drugs & Cosmetics Act and Rules. During manufacturing, the firm is also required to comply with the conditions of permission and manufacturing Licence issued by the State Drug Controller relating to requirements of Good Manufacturing Practices (GMP), Products specifications etc. The manufacturer of the drug Albupax had provided certificate of analysis wherein all the parameters including Endotoxin were within acceptable limits. Accordingly, the permission to manufacture the drug was granted.

The Government has stayed the operation the suspension order dated 21.10.2009 of the CDSCO with effect from 23.12.2009 pending a decision on the appeal filed by the manufacturer.

(c) to (f): The Office of Drugs Controller General (India) (DCG) (I) had in the year 2007 prepared a list of 294 Fixed Dose Combinations (FDCs) reported to be available in the market which were not approved by DCG (I). The list was communicated to the State Drug Controllers to take necessary action with respect to these FDCs with the direction for suspension of licence of the FDCs under reference. However, some of the manufacturers association filed writ petition in the Hon'ble High Court of Madras and obtained order of stay on all further proceedings on the said direction.