GOVERNMENT OF INDIA

MINISTRY OFHEALTH AND FAMILY WELFARE

RAJYA SABHA

QUESTION NO02.03.2010

ANSWERED ON

DANGEROUS COMPONENTS IN ANTI CANCER DRUG .

64 Dr. Ram Prakash

Will the Minister of COALHEALTH AND FAMILY WELFAREINFORMATION AND BROADCASTINGHEALTH AND FAMILY WELFARE be pleased to state :-

(a) whether dangerous components have been found in the anti-cancer medicine, Albupax;

(b) whether the Central Drugs Standard Control Organisation (CDSCO) had made a recommendation in October, 2009 to cancel the permission to manufacture this drug as well as to withdraw the stock of this drug available in the market on the basis of laboratory report and assessment report of the production unit of the company; and

(c) if so, the reasons for granting permission to manufacture this drug?

ANSWER

THE MINISTER OF HEALTH AND FAMILY WELFARE

(SHRI GHULAM NABI AZAD)

(a)to (c) A statement is laid on the Table of the House.

STATEMENT REFERRED TO IN REPLY TO RAJYA SABHA STARRED QUESTION NO. 64 FOR 2nd MARCH 2010.

(a) & (b) The Central Drug Laboratory, Kolkata, in its test report has declared the drug Albupax (paclitaxal Albumin bound particle inject-able 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) 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.

(c) 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 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.