

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

UNSTARRED QUESTION NO:4816  
ANSWERED ON:18.12.2009  
WITHDRAWAL OF MEDICINES  
Bali Ram Dr.

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

- (a) the details of the medicines which have been withdrawn from the market in the country during the last three years and the current year as per the order of Drug Controller General of India (DCGI);
- (b) the reasons for the withdrawal of these medicines from the market;
- (c) whether DCGI has recently ordered to withdraw any breast cancer drugs and oral insulin from the market; and
- (d) if so, the details thereof and the reasons therefor?

**Answer**

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

(a) & (b): Since year 2006, Government of India has banned diclofenac and its formulations for animal use under section 26-A of Drugs and Cosmetic Act. Apart from this based on the recommendations of the expert committee, office of Drugs Controller General (India) {DCG (I)} has asked State Licencing Authorities (SLA) and manufacturer/importer to withdraw / discontinue the marketing authorisation of lumiracoxib and rimonabant for safety reasons.

(c) & (d):

(1) With regards to breast cancer drugs, DCG(I) vide letter No.QA/GNL/BCN/INV-ABR dated 16th July,09 directed in public interest to M/s. Natco Pharma Ltd., Hyderabad, A.P to recall the Paclitaxal injection (Albupax) Batch No. 202013 and 202119 manufactured by them, as the Director, Central Drugs Laboratory, Kolkata vide letter no. 32-10/2009-SS/1049 dated 13-07-2009 informed that said batches of paclitaxal injection (Albupax) were found to be not of standard quality for the reason that " Samples does not confirm to manufacturers specification with respect to Endotoxin test", subsequently new drug permission granted to Natco Pharma in respect of breast cancer drugs was suspended vide letter No.QA/GNL/BCN/INV-ABR, dated 20/10/09.

(2) With regards to oral insulin, it may be informed that the office of DCG (I) has not ordered any withdrawal of the same i.e. Oral Insulin from the market recently. However, it is pertinent to mention that permission to import and market human insulin aerosol suspension granted to M/s Shreya Life Science was withheld by the Office of DCG(I) vide order no. 4/GB-48/BIN/07-DC dated 26/03/09.