

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

UNSTARRED QUESTION NO:2709

ANSWERED ON:11.03.2011

BANNED DRUGS

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

- (a) whether certain Ranbaxy manufactured generic drugs banned by the US Food and Drug Administration (FDA) are still in circulation in the country;
- (b) if so, the details thereof alongwith the reasons therefor;
- (c) the steps taken/proposed by the Government to ban these drugs in the country;
- (d) whether FDA has also limited the dose of paracetamol drug to 325 mg when given in combination with steroidal anti-inflammatory drug while in India, several potentially harmful combination have been approved containing 500mg or more paracetamol; and
- (e) if so, the reasons therefor alongwith the corrective measures taken/proposed by the Government in this regard?

**Answer**

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

- (a) to (c): Central Drugs Standard Control Organization (CDSCO) has not received any communication from US Food and Drug Administration (FDA) in respect of any ban on generic drugs manufactured by M/s Ranbaxy Laboratories Limited.
- (d) & (e): The USFDA has recently issued an advisory to the manufacturers in USA for limiting Paracetamol to 325 mg in prescription combination products. USFDA has however, further advised that the patients who take these combinations for pain medications may continue to take them as directed by their Healthcare providers. Government of India has not taken any view on the rationality of USFDA decision and its relevance in Indian conditions.