

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

STARRED QUESTION NO:275

ANSWERED ON:19.08.2011

SALE OF BANNED DRUGS

Das Gupta Shri Gurudas;Gandhi Shri Feroze Varun

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

- (a) whether certain prohibited drugs including Gatifloxacin and Tegaserod have been found to be prevalent in the market across the country;
- (b) if so, the details of such drugs detected in the raids conducted by the Drugs Controller General (India) during the last three years and the current year so far, State/UT-wise;
- (c) the action taken/proposed by the Government against the culprits and also to check the manufacture and sale of these drugs in the country;
- (d) whether the Government has recently approved certain Fixed Dose Combinations/drugs whose manufacturing and marketing licenses had been suspended earlier; and
- (e) if so, the details thereof alongwith the reasons therefor?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD)

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

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 275 FOR 19TH AUGUST, 2011

(a) & (b): Some drugs like Gatifloxacin formulation for systemic use in human by any route including oral and injectable and Tegaserod and its formulations were banned by the Central Government by the Gazette Notification GSR 218(E) dated 16th March, 2011. Another drug namely Rosiglitazone was banned earlier by the Gazette Notification GSR 910(E) dated 12.11.2010.

To assess the withdrawal of these banned drugs from the market, raids were conducted by the Central Drugs Standard Control Organization (CDSCO) in and around Delhi and in Mumbai. Availability of following drugs was detected at 81 sale outlets out of 143 inspected during the raids conducted on the 15th and 16th June, 2011, in Delhi and Bhiwadi (Rajasthan):

Gatifloxacin Injection 1822 Bottles
Gatifloxacin Tablets 6014 Tablets
Tegaserod Tablets 1182 Tablets
Rosiglitazone Tablets 858 Tablets

In Mumbai, raids were conducted on 16th June, 2011 and a total of 25 Gatifloxacin tablets were found stocked in 3 premises.

Such raids in respect of banned drugs were conducted for the first time by the office of Drugs Controller General (India).

(c): The following actions have been taken by the office of Drugs Controller General (India) to check the manufacture and sale of these banned drugs in the country and also about the drugs seized in the said raids:

(1) The Drugs Controller General (India) had written to all State Drugs Controllers on 28.03.2011 to ensure that the manufacturing licences granted in their States for manufacture of the said drugs formulations are cancelled with immediate effect and the formulations recalled from the market on top priority. They were also asked to direct the chemists and druggists to stop the sale of these formulations with immediate effect and return the unused stocks to the manufacturers.

(2) The stocks of such drugs detected with the chemists in and around Delhi were seized as per provisions of the Drugs and Cosmetics Act, 1940, and produced before the Court for safe custody pending further investigations.

(3) The cases detected in Mumbai were referred to Food and Drugs administration, Maharashtra, for taking appropriate action.

(d) & (e): No such Fixed Dose Combinations / drugs have been recently approved whose manufacturing and marketing licenses had

been suspended earlier.