

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

UNSTARRED QUESTION NO:793

ANSWERED ON:01.03.2013

BANNED UNAPPROVED DRUGS FIXED DOSE COMBINATIONS

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

- (a) the details of the drugs banned/unapproved during the last three years and the current year in the country;
- (b) whether cases of manufacturing and sale of unapproved Fixed Dose Combinations (FDCs) and certain other drugs which are banned/unapproved inside/ outside the country have been reported in certain parts of the country;
- (c) if so, the details thereof indicating the number of such cases reported and the action taken against the offenders during the said period, State/UT-wise; and
- (d) the measures taken/proposed by the Government for strict monitoring of manufacturing and sale of FDCs and other drugs in the country?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABIAZAD)

(a): The Central Government has prohibited / suspended the manufacture, sale and distribution of the following drugs during the last three years and current year in the country through Gazette Notification:

1. Rimonabant.
2. Rosiglitazone.
3. Nimesulide formulations in children below 12 years of age.
4. Cisapride and its formulations for human use.
5. Phenylpropanolamine and its formulations for human use.
6. Human Placental Extract and its formulations for human use except its
 - (i) Topical application for wound healing, and
 - (ii) Injection for pelvic inflammatory disease.
7. Sibutramine and its formulations for human use.
8. R-Sibutramine and its formulations for human use.
9. Gatifloxacin formulation for systemic use in human by any route including oral and injectable
10. Tegaserod and its formulations
11. Letrozole for induction of ovulation in anovulatory infertility.
12. Serodiagnostic test kits for diagnosis of tuberculosis

(b) & (c): A drug banned / restricted in one country may continue to be marketed in other countries as the respective government examines the usage, doses, indications permitted etc. and overall risk-benefits ratio and takes decisions on the continued marketing of any drug in that country.

The State Drug Control Departments conduct raids to check the banned drugs in the market.

The Central Drugs Standard Control Organization had also conducted raids in 2011 in and around Delhi and in Mumbai to check the withdrawal of Gatifloxacin, Tegaserod and Rosiglitazone after these drugs were prohibited. It was found that in 29 shops banned

drugs were sold after the issue of notification in the Gazette of India and in the remaining shops banned drugs were found stocked, but were not sold after the date of the said notification. Action was initiated in those cases as per the provision of the Drugs and Cosmetics Act, 1940.

Twenty three cases of new Fixed Dose Combinations (FDCs) considered as new drugs were also found to be licenced by State Licensing Authorities (SLAs) without approval of the Drugs Controller General (India). SLAs in all these cases were asked to take action under the Drugs and Cosmetics Act, 1940.

(d): The Central Government has issued directions under Sections 33 P of Drugs and Cosmetic Act, 1940 to all State / UT Governments to instruct their respective drug licensing authorities to abide by the provisions prescribed under the Drugs and Cosmetics Rules for grant of manufacturing licenses for the drugs falling under the definition of the term "new drug" and not to grant licenses for manufacture , sale or distribution or export of such new drugs, except in accordance with the procedure laid down under the said rules i.e., with prior approval of the Drugs Controller General (India) {DCG(I)} only. Further, in case of FDCs manufactured under valid license granted by State Licensing Authority but whose safety and efficacy had not been examined by the office of DCG(I), the State / UT Governments have been advised to ask the concerned manufacturers to prove the safety and efficacy of such FDCs before the office of DCG (I) within a period of 18 months, failing which such FDCs will be considered for being prohibited for manufacture and marketing in the country.

The State Drug Controllers have also been requested in the meetings of the Drugs Consultative Committee to ensure that manufacturing licences of new drugs and FDCs are not granted without approval from the office of DCG(I) and the drugs prohibited by the Central Government are withdrawn from the market with immediate effect. States have also been advised to strengthen their infrastructure for better enforcement and develop vigilance mechanism over the drugs moving in the market.