GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

STARRED QUESTION NO:113
ANSWERED ON:30.11.2012
BANNED DRUGS
Nagar Shri Surendra Singh;Swamygowda Shri N Cheluvaraya Swamy

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

(a) whether the Government has taken note of the reported cases of side effects of certain drugs including painkillers in the country;

(b) if so, the details thereof along with the action taken/proposed by the Government to ban such drugs;

(c) the details of the drugs banned/unapproved during the last three years and the current year in the country;

(d) whether cases of manufacture, marketing and distribution of certain drugs which are banned/unapproved inside/outside the country have come to the notice of the Government; and

(e) 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?

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. 113 FOR 30.11.2012

(a)&(b) Yes, Madam. Based on the reports of side effects of certain drugs, following actions have been taken:

1. Manufacture, distribution and sale of "Nimesulide formulations for human use in children below 12 years of age" have been prohibited with immediate effect under the Drugs and Cosmetics Act through a Gazette Notification 82(E) dated 10.02.2011.

2. State Drug Controllers have been requested to direct manufacturers of nimesulide containing formulations for use in patients of 12 years and above to incorporate the following Box warning on label as well as package insert and other promotional literature of formulations containing Nimesulide.

"Use of Nimesulide should ordinarily be restricted to 10 days. If longer clinical use is warranted, liver function test should be assessed periodically"

3. State Drug Controllers have been requested not to grant fresh licences or renewals of the combinations products of paracetamol containing more than 325 mg per tablet or capsule. The manufacturers marketing combination products having more than 325 mg of paracetamol should limit the paracetamol contents to 325mg in a period of three years.

4. State Drug Controllers have also been advised to direct the manufacturers marketing the cholesterol lowering drugs of statin group to implement the safety changes in respect of certain cognitive effects, hyperglycemia etc. reported with statins use.
(c) The Government has prohibited / suspended manufacture and sale of the following drugs during the last three years and current year:

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.

(d)&(e) Yes, Madam. Central Drugs Standard Control Organization had conducted raids in 2011 in and around Delhi and in Mumbai to assess the withdrawal of Gatifloxacin, Tegaserod and Rosiglitazone which were prohibited in the country. Twenty three cases of new Fixed Dose Combinations (FDCs) including new strengths etc, considered as new drugs, were licenced by State Licencing Authorities (SLAs) without approval of the Drugs Controller General (India) [DCG(I)]. In all such cases, the office of DCGI has taken up the matter with respective SLAs for necessary action.

Further, State Drug Controllers have been requested in the Drugs Consultative Committee meetings to ensure that New Drugs and FDCs are not permitted 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 the infrastructure for better enforcement and develop vigilance mechanism over the drugs moving in the market.

On 1st October, 2012, the Central Government issued statutory 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 for sale or for distribution or for export of such new drugs, except in accordance with the procedure laid down under the said rules i.e without prior approval of the DCG(I).