GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:1840
ANSWERED ON:23.03.2012
BANNED UNAPPROVED DRUGS
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Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Government proposes to suspend manufacture, sale and distribution of a number of medicines including Ketoprofen for its adverse affects on vulture population across the country;

(b) if so, the details thereof and if not, the reasons therefor;

(c) the details of medicines banned/unapproved during the last three years in the country;

(d) whether sale of certain medicines banned/unapproved inside/outside the country including diclofenac has been reported in the country; and

(e) if so, the details thereof and the steps taken/proposed by the Government against the manufacture, sale and distribution of banned/unapproved drugs in the country?

Answer

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

(a) & (b) The decision to ban or withdraw a drug by the regulatory authorities is normally based on the risk assessment process, which is influenced by a number of factors existing at a given point of time such as disease pattern in a country, indications and dosages of the drug permitted, varying reactions of certain ethnic groups in a given population, availability of safter substitutes and overall safety profile of the drug. There is no proposal under consideration to ban ketoprofen for animal use as Central Drugs Standard Control Organisation (CDSCO) has not received any such report establishing that use of ketoprofen in animals is having adverse effect on vulture population.

(c) The Government has issued notifications for prohibited / suspended manufacture and sale of the following drugs during the last three years:

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) The manufacture and sale of unapproved drugs or drugs prohibited in the country is an offence and is punishable under the

Drugs and Cosmetics Act, 1940. The drugs prohibited outside the country are examined by the Expert Committees set up for the purpose to examine their marketing or otherwise in the country. If the drug is considered harmful for use in the country, its manufacture and sale is prohibited under the said Act. The drug diclofenac was prohibited for manufacture and sale for animal use in the country. However, the drug is permitted to be manufactured and sold for human use.

The State Licencing Authorities, which implement the provisions of the Drugs and Cosmetics Act, 1940 and Drugs and Cosmetics Rules, 1945 for regulating the sale of drugs, ensure through a system of inspections and surveillance that the prohibited or unapproved drugs are not marketed in the country. The violations, if any, are dealt with in accordance with the provisions of the Drugs and Cosmetics Act, 1940.