GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

STARRED QUESTION NO:236
ANSWERED ON:11.03.2011
BANNED MEDICINES
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Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Drugs Controller General (India) [DCG(I)] has recently banned certain medicines on the recommendations of the Drug Technical Advisory Board (DTAB) in the country;

(b) if so, the details thereof alongwith the reasons therefor;

(c) the names of the medicines which have been banned by the DCG(I) on the recommendations of the DTAB during each of the last three years indicating the reasons for the same;

(d) whether certain medicines banned abroad are still being sold in the country; and

(e) if so, the reasons therefor alongwith the steps taken or proposed by the Government to address the issue?

Answer

MINISTER OF THE STATE IN THE MINISTRY 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. 236 FOR 11TH MARCH,2011

(a)&(b): The Central Government has prohibited six drugs on the recommendations of the Expert Committee constituted by DTAB in view of the safety issues involved in the use of these drugs by a Gazette Notification dated 10.02.2011 with immediate effect. The names of these drugs along with the brief reasons for their ban are furnished below:

1. Nimesulide formulations in children below 12 years of age - Nimesulide containing products are not permitted in many countries in children under 12 years of age. The drug has been considered to be hepatotoxic and children are considered more susceptible to hepatotoxicity.

2. Cisapride and its formulations for human use - Use of this drug is reported to be associated with increased risk of serious cardiac arrhythmia.

3. Phenylpropanolamine and its formulations for human use - Use of this drug is associated with risk of hypertensive episodes like cardiac congestive failures and hemorrhagic strokes.

4. Human Placental Extract and its formulations for human use - There is no clear evidence of efficacy of this drug in most of the conditions and there are safety concerns like transmission of blood born infections, immunoreactions and unwanted exposure to hormones associated with its use.

5. Sibutramine and its formulations for human use - Use of this drug is associated with increased risk of cardiovascular events such as heart attack and stroke.

6. R-Sibutramine and its formulations for human use - Use of this drug is associated with increased risk of cardiovascular events such as heart attack and stroke.

(c) Apart from the aforementioned six drugs banned recently, the following drugs have been banned during the last three years:

1. Rosiglitazone, on 12th November, 2010 - Use of this drug is associated with increased risk of cardiovascular events such as congestive heart failure and myocardial infarction.

2. Rimonabant, on 11th December, 2009 - Use of this drug is associated with increased risk of psychiatric side effects.

3. Diclofenac and its formulations for animal use, on 4th July, 2008 - Extensive use of this drug in animals was leading to harmful effects on vultures. The vulture population was depleting as it was observed that vultures fed on carcass of animals treated with diclofenac were dying.

(d)&(e): 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 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 safer substitutes and overall safety profile of the drug. These conditions are different for different countries. It is for this reason that a drug banned / restricted in one country may continue to be marketed in other countries. There is a well laid mechanism in India to review the status of the drug formulations as and when any serious adverse event is reported in the International journals, WHO Newsletters or when a drug formulation is reported to have been banned/ withdrawn in some countries. The use of the drug, so reported, is assessed in consultation with the expert committees set up for the purpose, based on available technical information, benefit-risk ratio, local needs and availability of safer alternatives etc. The Central Government prohibit manufacture and sale of drugs in the country under Section 26A of the Drugs and Cosmetics Act, 1940.