GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

STARRED QUESTION NO:271
ANSWERED ON:25.07.2014
SUSPENSION OF DRUGS
Mohan Shri P. C.

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

(a) Whether the Government has suspended the manufacture, sale and distribution of certain drugs in the recent past;

(b) If so, the details of the drugs suspended and the reasons for their suspension during the last three years and the current year in the country;

(c) Whether the Government had undertaken any scientific study to ascertain the health risk with the use of these drugs on Indian population prior to their suspension in the country if so, the details thereof and if not, the reasons therefor;

(d) Whether the Government has recently revoked the suspension of the manufacture and sale of certain drugs in the country, if so, the details thereof and the reasons therefor; and

(e) The mechanism put in place by the Government to keep continuous vigilance on the drugs causing health risks?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. HARSH VARDHAN)

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

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 271 FOR 25TH JULY, 2014

(a) Yes.

(b) The manufacture, sale and distribution of the following drugs was suspended by the Government during last three years and in the current year:

2011

(1) Use of letrozole for induction of ovulation in anovulatory infertility

2012: Nil

2013

(1) Dextropropoxyphene and formulations containing Dextropropoxyphene for human use,

(2) Fixed dose combination of Flupenthixol + Melitracen for human use

(3) Analgin and all formulations containing analgin for human use

(4) Pioglitazone and all formulations containing Pioglitazone for human use

2014: Nil

(c) As and when safety issue of any marketed drug is reported in the literature / other countries, the continued use of that drug is examined in consultation with expert committee /Drug Technical Advisory Board (DTAB). DTAB is a statutory technical advisory body under the Drugs and Cosmetics Act, 1940. Based on the recommendations of the expert committee / DTAB, further action on continued use of the drug is taken.

(d): Based on a subsequent review by the DTAB, the suspension of the following drugs was revoked and the drugs were allowed to be marketed in the country with certain conditions:

(1) Pioglitazone and its formulations were permitted to be manufactured and sold, subject to the condition that the manufacturers shall mention the following on package insert and promotional literature of the drug:

(i) The drug should not be used as first line of therapy for diabetes.

(ii) The manufacturer should clearly mention following box warning in bold red letters.

`Advice for healthcare professionals:-

Patients with active bladder cancer or with a history of bladder cancer sand those with uninvestigated haematuria, should not receive pioglitazone.

Prescribers should review the safety and efficacy of pioglitazone in individuals after 3-6 months of treatment to ensure that only patients who are deriving benefit continue to be treated. Pioglitazone should be stopped in patients who do not respond adequately to treatment (e.g, reduction in glycosylated haemoglobin, HbAlc).

Before starting pioglitazone, the following known risk factors for development of bladder cancer should be assessed in individuals: age; current or past history of smoking; exposure to some occupational or chemotherapy agents such as cyclophosphamide; or previous irradiation of the pelvic region.

Use in elderly patients should be considered carefully before and during treatment because the risk of bladder cancer increases with age. Elderly patients should start on the lowest possible dose and be regularly monitored because of the risks of bladder cancer and heart failure associated with pioglitazone.

(2) Analgin and its formulations were permitted to be manufactured and sold, subject to the condition that the manufacturers shall mention the following on their package insert and promotional literature of the drug:

`The drug is indicated for severe pain or,pain due to tumor and also for bringing down temperature in refractory cases when other antipyretics fail to do so.`

(3) In the case of the Fixed dose combination of Flupenthixol + Melitracen, the Hon`ble High Court of Karnataka in their order dated 14.8.2013 in the case of WP. No. 28354/2013 (GM-RES) quashed the notification of Government for suspension of the drug and remanded the matter back to reconsider afresh and take decision in accordance with the law. Accordingly, the issue of suspension of the drug was re-examined by the DTAB and based on its recommendation, the manufacture, sale and distribution of the drug for human use have again been prohibited in the country vide gazette notification dated 11.07.2014.

(e) Pharmacovigilance Programme of India (PvPI) through its 150 Adverse Drug Reaction (ADR) monitoring centres monitors the health risk associated with adverse drug reactions of the drugs in the country.