GOVERNMENT OF INDIA HEALTH AND FAMILY WELFARE LOK SABHA

UNSTARRED QUESTION NO:1586 ANSWERED ON:13.12.2013 BAN ON DRUGS Bali Ram Dr. ;Saroj Shri Tufani;Sivakumar Alias J.K. Ritheesh Shri K.

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

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

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

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

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

(e) the steps taken/proposed by the Government to keep continuous vigilance on the drugs causing health risks in the country?

Answer

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

(a) & (b): The manufacture for sale, sale and distribution of following drugs had been suspended in 2013 as the use of these drugs was likely to involve risk to the human health:

1. Dextropropoxyphene and formulations containing Dextropropoxyphene for human use.

2. Analgin and all formulations containing analgin for human use.

3. Fixed Dose Combination of Flupenthixol+Melitracen for human use.

4. Pioglitazone and all formulations containing Pioglitazone for human use.

(c): Apart from the above drugs suspended during the current year, the following drugs were prohibited / suspended during the last three years:

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

(d): The suspension of Pioglitazone and all formulations containing Pioglitazone for human use was revoked on the recommendation of Drugs Technical Advisory Board (DTAB). Accordingly a revised notification permitting the manufacture for sale, sale and distribution of Pioglitazone and all formulations containing Pioglitazone for human use subject to the conditions as recommended by DTAB was published vide notification G.S.R. 520 (E) dated 31-07-2013.

(e): The Government is already running the Pharmacovigilance Programme of India for keeping a continuous vigilance on the drugs causing health risks through monitoring, recording and reporting Adverse Drug Reactions (ADRs) in the country.