GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

STARRED QUESTION NO:176
ANSWERED ON:02.12.2011
BANNED DRUGS
Saha Shri Anup Kumar;Tagore Shri Manicka

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

(a) whether the Government has recently suspended the manufacture, sale and distribution of some medicines including Letrozole across the country;

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

(c) whether sale of certain unapproved Fixed Dose Combinations and medicines banned or unapproved in/outside the country has recently come to the notice of the Government;

(d) if so, the details thereof alongwith the action taken thereon; and

(e) the measures taken/proposed by the Government to keep a strict vigil on manufacture, sale and distribution of unapproved^anned drugs in the country?

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. 176 FOR 2ND DECEMBER, 2011

(a)&(b): Yes. The manufacture, sale and distribution of letrozole for induction of ovulation in anovulatory infertility has been suspended by the Central Government recently through a Gazette Notification G.S.R.752(E) dated 12.10.2011 because of the doubts raised about the safety of the drug for this indication. The Government has also, in the recent past, prohibited the manufacture, distribution and sale of the following drugs through Gazette Notifications:

Gazette Notification 82(E) dated 10.02.2011:

(I) Nimesulide formulations for human use in children below 12 years of age: The drug has been reported to be haepatotoxic and children are considered more susceptible to haepatotoxicity.

(2) Cisapride and its formulations for human use: The drug is reported to be associated with increased risk of serious cardiac arrhythmia.

(3) Phenylpropanolamine and its formulations for human use: The drug is associated with risk of hypertensive episodes like cardiac congestive failures and hemorrhagic strokes.

(4) Sibutramine and its formulations for human use: The drug is associated with increased risk of cardiovascular events such as heart attacks and stroke.

(5) R-Sibutramine and its formulations for human use: The drug is associated with increased risk of cardiovascular events such as heart attacks and stroke.

(6) Human Placental Extract and its formulations for human use (amended vide GSR No.418 (E) dated 30.05.2011) except its-

(i) Topical application for wound healing, and

(ii) Injection for pelvic inflammatory disease.

There are safety concerns like transmission of blood borne infections, immunoreactions and unwanted exposure to hormones associated with the use of this drug in other formulations.

Gazette Notification 218(E) dated 16.03.2011:

(1) Gatifloxacin formulation for systemic use in human by any route including oral and injectable; The drug is associated to cause significant disturbance of blood glucose level.

(2) Tegaserod and its formulations: The drug is associated with risk of increasing cardiovascular events.

However, the Madras High Court has quashed banning of the drug Phenylpropanolamine and granted an interim stay in respect of prohibition of the drugs Gatifloxacin and Tegaserod.

(c)&(d): Yes. The Central Drugs Standard Control Organization (CDSCO) conducted raids in and around Delhi and in Mumbai to assess the withdrawal of the banned drugs, namely, Gatifloxacin, Tegaserod and Rosiglitazone, from the market. The safety issues of Dextropropoxyphene and its formulations which has been withdrawn/restricted in some countries have been examined recently by an Expert Committee. The Committee has recommended that since the drug is more than three decades old in the market, it will be worthwhile to allow continuing the drug for the time being and data shall be generated on cardiovascular toxicity and dependence potential.

(e): In the meetings of the Drugs Consultative Committee, the State Drug Controllers have been requested to ensure that New Drugs and FDCs without approval from DCG (I) office should not be permitted and the drugs prohibited by the Central Government are withdrawn from the market with immediate effect. The Central Government has already enhanced the manpower strength of the CDSCO from 111 in February, 2008 to 327 in December, 2009. The State / Union Territory Governments have also been advised to strengthen their infrastructure for better vigilance over the drugs moving in the market.