GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:3958
ANSWERED ON:20.03.2015
BANNED UNAPPROVED DRUGS
Bhamre Dr. Subhash Ramrao

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

(a) the details of the drugs banned/ unapproved by the Government during the iast three years and the current year indicating the reasons therefor;

(b) whether certain cases of manufacturing and marketing of drugs banned/unapproved inside/outside the country have been reported in the recent past;

(c) if so, the details thereof indicating the number of such cases reported and the action taken by the Government against the offenders during the said period, State/ UT-wise; and

(d) the measures taken/proposed to be taken by the Government to stop manufacturing and marketing of banned/ unapproved drugs in the country?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRIJAGAT PRAKASH NADDA)

(a): The following drugs have been banned/suspended during last three years and current year keeping in view the likely risk to human beings and availability of safer alterna- tives in the country:

1. Serodiagnostic test kits for diagnosis of tuberculosis on 7 June, 2012.

2. Dextropropoxyphene and formulations containing Dextropropoxyphene for human on 23rd May, 2013.

3. Analgin and all formulations containing Analgin on 18th June, 2013. [Suspension of this drug was subsequently revoked on 13lil February, 2014 subject to the certain con- ditions.]

4. Suspension of fixed dose combination of Flupenthixol + Melitracen on 18`h June, 2013. It was subsequently prohibited on 11th July, 2014.

(b) & (c): No case of manufacturing and marketing of unapproved New Drugs/Fixed Dose Combinations (FDCs) has been reported in the recent past. The manufacturing and marke- ting of banned drugs is a punishable offence under the Drugs & Cosmetics Act, 1940 and the State Licensing Authorities are empowered to take action in such cases.

(d): The Central Government has, on 1st October 2012, issued statutory directions under Sections 33P of the Drugs and Cosmetic Act, 1940 to all the State / Union Territory Gove- rnments to instruct their respective Drug Licensing Authorities to abide by the provi- sions of the Drugs and Cosmetics Rules, 1945 while granting manufacturing licenses for drugs falling under the definition of the term "New Drug" and not to grant licenses for manufacture, for sale or for distribution or for export of such new drugs, except in accordance with the procedure laid down under the said Rules including obtaining approval of the Drugs Controller General (India) before granting such licences. The State Drug Controllers have also been requested to ensure that New Drugs and FDCs are not permitted without approval from the office of DCG (I) and the drugs prohibited by the Central Government are withdrawn from the market with immediate effect.