GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:1299
ANSWERED ON:18.07.2014
BANNED UNAPPROVED DRUGS
Dhruvanarayana Shri Rangaswamy;Patel Shri Devji Mansingram

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

(a) whether certain cases of manufacturing and marketing of banned/ unapproved drugs have been reported in the country;

(b) if so, the details thereof indicating the number of such cases reported and the action taken by the Government against the offenders during each of the last three years and the current year, State/UT-wise;

(c) the measures taken/proposed to be taken by the Government to stop manufacturing and marketing of banned/ unapproved drugs across the country;

(d) whether there is shortage of abortion drugs in the country; and

(e) if so, the details thereof and the reasons therefor along with the corrective measures being taken by the Government in this regard?

Answer

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

(a) to (c): Certain cases of sale of banned drugs were detected during the raids conducted by Central Drugs Standard Control Organization in 2011 in and around Delhi and in Mumbai to check the withdrawal of Gatifloxacin, Tegaserod and Rosiglitazone after their prohibition for marketing and sale in the country. These drugs were being sold in 29 shops after issue of notification of ban, 27 cases in Delhi and 2 cases in Rajasthan. The concerned State Licensing Authorities were asked to take action as per the provision of Drugs and Cosmetics Act, 1940. Further, 23 cases of new Fixed Dose Combinations (FDCs), considered as new drugs, were also found to be licenced by State Licensing Authorities (SLAs) without approval of the Drugs Controller General (India) [DCG (I)]. In all such cases, the office of DCG(I) took up the matter with respective State Licensing Authorities for necessary action. A Statement containing details of these 23 cases annexed.

Apart from these, following the statutory direction issued by the Central Government to all the State / UT Governments on 1.10.2012 under Section 33P of the Drugs & Cosmetics Act, 1940 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 i.e without prior approval of the DCG(I), the manufacturers of all FDC licensed before 1.10.2012 without the approval of DCG(I) have been asked to prove the safety and efficacy of such FDCs before the CDSCO within a period of 18 months failing which such FDCs will be considered for being prohibited for manufacture and marketing in the country. About 7000 applications in respect of such FDCs have been received by the CDSCO.

The State Drug Controllers have also been requested in the Drugs Consultative Committee meetings 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. States have also been advised to strengthen the infrastructure for better enforcement and develop vigilance mechanism over the drugs moving in the market.

(d) & (e): The Government regularly monitors shortages and availability of drugs on the basis of monthly reports received from State Drugs Control Administration and also complaints, if any, received from NGOs, individuals etc. On receipt of any report on shortage for a particular drug, the Government immediately takes up the matter with the concerned manufacturer and advises them to rush the stock in the affected area. The Government has not received any report regarding shortage of abortion drug in the country.