GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

STARRED QUESTION NO:29
ANSWERED ON:06.12.2013
BANNED DRUGS
Singh Shri Mahabali

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 during each of the last three years and the current year, State/UT-wise;

(c) the action taken against the offenders during the said period, State/UT-wise;

(d) whether the Government proposes to put in place a comprehensive mechanism to stop manufacturing and marketing of banned/unapproved drugs across the country; and

(e) if so, the details thereof?

Answer

THE MINISTER 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 THE LOK SABHA STARRED QUESTION NO. 29 for 06.12.2013

(a)to(c): Yes. The Central Drugs Standard Control Organization (CDSCO) had conducted raids in 2011 in and around Delhi and in Mumbai to check the withdrawal of the drugs Gatifloxacin, Tegaserod and Rosiglitazone after these were prohibited by the Central Government under the provisions of the Drugs & Cosmetics Act, 1940 by notification in the Gazette of India. In 29 shops, banned drugs were found. Action was initiated in those cases as per the provision of the Drugs and Cosmetics Act, 1940.

Twenty three 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 SLAs for necessary action.

State / UT-wise information in this regard is not maintained centrally. However, during 2011, 27 cases in Delhi and 2 cases in Rajasthan were detected and action was initiated for sale of banned drugs. As far as the sale of unapproved Fixed Dose Combination (FDC) drugs is concerned, the information as available is annexed.

(d) & (e): The State Drug Controllers have been requested in the Drugs Consultative Committee meeting 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are not permitted without approval from the office of DCG (I) and the drugs prohibited by the Central Government are withdrawn from the market with immediate effect.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 their infrastructure for better enforcement and develop vigilance mechanism over the drugs moving in the market.

On 1st October, 2012, the Central Government issued statutory directions under Section 33 P of the Drugs and Cosmetics Act, 1940 to all State / UT Governments to instruct their respective drug licensing authorities to abide by the provisions prescribed under the Drugs and Cosmetics Rules for grant of manufacturing licenses for the 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 i.e. without prior approval of the DCG (I).