GOVERNMENT OF INDIA MINISTRY OF CHEMICALS AND FERTILIZERS DEPARTMENT OF PHARMACEUTICALS

LOK SABHA

UNSTARRED QUESTION No. 258

TO BE ANSWERED ON THE 26th April, 2016

Spurious Medicines

258. PROF. RAVINDRA VISHWANATH GAIKWAD:

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

- (a) whether the Government has conducted any investigation into the production of spurious medicines in the country and if so, the details thereof;
- (b) the number of companies, persons or institutions found guilty of producing and distributing spurious medicines during the last three years; and
- (c) the concrete action taken/being taken/proposed to be taken by the Government to check this menace?

<u>ANSWER</u>

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI HANSRAJ GANGARAM AHIR)

- (a) The manufacturing, sale and distribution of drugs in the country is regulated under the provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945 made thereunder through a system of licensing and inspection. License for manufacturing sale and distribution of drugs are granted by State Licensing Authorities appointed by respective State Governments. State Licensing Authorities are legally empowered to take action against violations of any provisions of said Act.
- (b) As per the Office of Drugs Controller General (India), information received from various State/UTs Drugs Controllers mentions that 3648 raids were conducted during 1st April, 2015 to 31st March, 2016. These cases were investigated and FIR, Prosecution, Suspension/Cancellation of licenses were done where found guilty.

Contd.....2.

- (c) The Govt. of India has taken/taking following steps to check the menace of spurious medicines and to ensure that safe, efficacious and quality of medicines are made available in the country:-
 - (i) The Drugs and Cosmetics Act, 1940 was amended under Drugs & Cosmetics (Amendment) Act 2008 to provide stringent penalties for manufacture of spurious and adulterated drugs. Certain offences have also been made cognizable and non-bailable by setting of special Courts.
 - (ii) The States / UTs were requested to set up special Courts for trial of offences under the Drugs and Cosmetics Act for speedy disposal. So far, 22 States have already set up designated special Courts.
 - (iii) A Whistle Blower Scheme was announced by the Government of India to encourage vigilant public participation in the detection of movement of spurious drugs in the country. The scheme provides for suitably rewarding the informers for providing concrete information to the regulatory authorities in respect of movement of spurious drugs. The details of policy are available at the website of CDSCO (www.cdsco.nic.in).
 - (iv) Guidelines for taking action on samples of drugs declared spurious or not of standard quality in the light of enhanced penalties under the Drugs & Cosmetics (Amendment) Act, 2008 were forwarded to the State Drugs Controllers for uniform implementation.
 - (v) The inspectorate staffs have been instructed to keep a vigil and draw samples of drugs for test and analysis to monitor the quality of drugs moving in the country.
 - (vi) The number of sanctioned posts in Central Drugs Standard Control Organization (CDSCO) has been increased from 111 in 2008 to 474 in 2016.
 - (vii) The testina capacities of Central Drugs Testing under CDSCO are Laboratories being constantly strengthened to expedite testing of drug samples in the country.