

**GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA**

STARRED QUESTION NO:130
ANSWERED ON:13.12.2013
SPURIOUS SUB STANDARD AND EXPIRED DRUGS
Choudhary Shri Harish;Rama Devi Smt.

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

- (a) whether the existing laws, infrastructure and manpower are adequate to monitor and check manufacturing and marketing of spurious, sub-standard and expired drugs in the country;
- (b) if so, the details thereof and if not, the reasons therefor indicating the outcome of the review/assessment made in this regard;
- (c) the number of cases of manufacturing and marketing of spurious, sub-standard and expired drugs reported/ detected, raids conducted and action taken against the erring persons/drug manufacturers during each of the last three years and the current year, State/UT-wise;
- (d) the number of drug samples tested and those declared spurious/sub-standard/adulterated during the said period, State/ UT-wise; and
- (e) the measures taken/proposed by the Government to strengthen the existing laws, infrastructure, manpower and monitoring mechanism in order to check the menace of manufacturing and marketing of spurious, sub-standard and expired drugs in the country?

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 LOK SABHA STARRED QUESTION NO. 130 FOR 13TH DECEMBER, 2013

(a)&(b): The existing laws are adequate to monitor and check the manufacturing and marketing of spurious, sub-standard and expired drugs in the country. However, the regulatory infrastructure including manpower are considered inadequate and need upgradation. The Mashelkar Committee in 2003 had also recommended strengthening of the central and state drug control departments. Recently, the Public Health Foundation of India (PHFI) has conducted an assessment of the Central Drugs Standard Control Organisation (CDSCO) and recommended that there is an urgent need to strengthen the infrastructure and personnel in the organisation.

(c) & (d): The year-wise details of number of spurious, substandard and expired drugs reported, raids conducted and action taken during the last three years and the current year are at Annexure A. The year-wise details of number of samples tested as provided by the State Drugs Controllers and enforcement actions taken by them during the last three years and the current year are at Annexure B.

(e) The drug regulatory infrastructure of the country is being continuously upgraded. At the central level, the number of sanctioned posts in the Central Drugs Standard Control Organisation (CDSCO) has been increased from 111 in 2008 to 475. The Central Drugs Testing Labs are continuously being strengthened with new and sophisticated testing equipments.

During the 12th Five Year Plan, outlays of Rs.1800 crore for CDSCO and Rs.1200 crore for a new centrally sponsored scheme for strengthening of states` drug regulatory system have been made for upgradation of physical and manpower infrastructure of drug regulatory system, e-governance, overseas inspections, creating more drug testing labs, mobile drug testing labs, mini labs at port offices, pharmacovigilance programmes, training programmes, programmes on public awareness, etc.

The following measures have been taken by the Government to deal with the problem of spurious / not-of-standard drugs 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 were made cognizable and non-bailable.
- (ii) The amendment also enabled setting up of special designated courts for speedy disposal of cases to deal with the cases of offences under the Drugs and Cosmetics Act. 16 States/UTs have already set up these special Courts.
- (iii) Guidelines for taking action on samples of drugs declared spurious or not of standard quality in the light of enhanced penalties were forwarded to the State Drugs Controllers/ State Government for implementation. The guidelines are available on the web site of CDSCO (www.cdsc0.nic.in).

(iv) Whistle Blower Scheme has been announced by the Government of India to encourage vigilant public participation in the detection of movement of spurious drugs in the country. The details of policy are available at the website of CDSCO (www.cdsc0.nic.in).

(v) The inspectorate staff has been instructed to keep vigil and draw samples of drugs for testing analysis to monitor the quality of drugs moving in the country.