

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

STARRED QUESTION NO:297

ANSWERED ON:12.12.2014

SPURIOUS AND SUB STANDARD DRUGS VACCINES

Kamaraaj Dr. K.;Sahu Shri Tamradhwaj

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

- (a) The number of spurious, sub-standard and expired drugs/vaccines reported and investigated, raids conducted and the action initiated/taken against the offenders during each of the last three years and the current year, State/UT-wise;
- (b) The number of drugs/vaccine samples tested and those declared spurious/ sub-standard/adulterated during the said period indicating the drug testing laboratories established by the Government for the purpose, State/UT-wise;
- (c) The measures taken/proposed to be taken by the Government to strengthen the monitoring mechanism to check the marketing and manufacturing of spurious, sub-standard and expired drugs/vaccines and the funds earmarked, allocated and utilised for the purpose during the said period, State/UT-wise;
- (d) Whether certain instances of supply of spurious and sub-standard drugs/ vaccines to the hospitals or States/UTs under various programmes have also been reported and if so, the details thereof along with the action taken/ proposed to be taken by the Government thereon, State/UT-wise; and
- (e) The measures being taken by the Government to check the sale and marketing of drugs/vaccines by illegal online pharmacies in the country?

**Answer**

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI SHRIPAD YESSO NAIK)

(a) to (e): A statement is laid on the Table of the House

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 297 FOR 12TH DECEMBER, 2014

(a) & (b): The details of the number of expired, spurious and substandard drugs/vaccines reported and action initiated/taken against the offenders during last three years and the current year by the Central Drugs Standard Control Organisation (CDSCO) and States/UTs is at Annexure I and IIA & B, respectively. The details of the existing Drugs Testing Laboratories in the country are given in Annexure III.

(c): With a view to checking the marketing and manufacturing of spurious, sub-standard and expired drugs/vaccines in the country, a series of measures have been taken. These include stringent penalties including making certain offences cognizable and non-bailable; establishment of special designated Courts for trial of offences under the Drugs and Cosmetics Act for the speedy disposal of cases; announcement of a Whistle Blower Scheme to encourage vigilant public participation for detection of movement of spurious drugs in the country; issuance of guidelines to the State Drugs Controllers for taking action on samples of drugs declared spurious or not of standard quality; and instructions to the concerned staff to keep a vigil and draw samples of drugs for test and analysis for monitoring the quality of drugs moving in the country.

(d): The number of cases of spurious drugs reported in Government hospitals in various parts of the country and action taken thereon, as per information received from States/ Union Territories is at Annexure IV.

(e): The sale and distribution of drugs is regulated in terms of the provisions of the Drugs & Cosmetics Act, 1940 and Rules made thereunder through a system of licensing and inspection. As per the provisions of the Act and Rules, drugs included in Schedule H, H1 and X are required to be sold by retail only on the prescription of Registered Medical Practitioners (RMP). The State Licensing Authorities are empowered for taking action on any violation of the conditions of sale license. In order to check illegal online pharmacies, the State Drug Controllers have also been directed to maintain a close vigil in their States in the Drugs Consultative Committee (DCC) meeting held in July, 2014.