

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

UNSTARRED QUESTION NO:4077

ANSWERED ON:20.03.2015

SPURIOUS SUBSTANDARD AND EXPIRED DRUGS

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

- (a) the quantum and value of spurious, substandard and expired drugs estimated to be in circulation in the country, State/UT-wise;
- (b) whether the existing laws, infrastructure and manpower are adequate to monitor and check the manufacturing and marketing of spurious, substandard and expired drugs in the country;
- (c) if so, the details thereof and if not, the reasons therefor indicating the outcome of the review/assessment made in this regard;
- (d) the number of cases of manufacturing and marketing of spurious, substandard 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; and
- (e) the measures being taken by the Government to strengthen/upgrade the existing laws, infrastructure, manpower and monitoring mechanism in order to check the manufacturing and marketing of spurious, substandard and expired drugs in the country?

Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI JAGAT PRAKASH NADDA)

- (a): The quantum and value of spurious, sub-standard and expired drugs in the country has not been estimated. Its extent can, however, be gauged from the findings of a survey conducted in 2009. Under this survey, 24,136 samples of 62 brands of drugs belonging to 9 therapeutic categories of 30 manufacturers from over 100 different pharmacy outlets in different regions of the country and located in each stratum viz. metros, big cities, districts, towns and villages were collected. The survey revealed that the extent of drugs found spurious was 0.046%.
- (b) & (c): India is one of the largest producers of drugs in the world and further augmentation of infrastructure and human resources, both at the Central and State levels, would be necessary for effective regulation of drugs.
- (d): Details of expired, adulterated, spurious and substandard drugs reported and action initiated/taken against the offenders during 2011-12, 2012-13, and 2013-14 and up to September, 2014 by Central Drugs Standard Control Organisation and States/Union Territories are annexed. (Annexures I, II & IIIA)
- (e): With a view to checking the marketing and manufacture 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. A 'Track and 'Trace' software has also been developed for authentication of drugs manufactured in India.