GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE

LOK SABHA
UNSTARRED QUESTION NO. 239
TO BE ANSWERED ON 3RD FEBRUARY, 2017

REPORT ON SPURIOUS DRUGS

239. SHRI GUTHA SUKENDER REDDY:

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

(a) whether the National Institute of Biologicals and National survey of Drug have submitted their report conducted on Spurious drugs and if so, the details thereof;

(b) the steps taken by the Government to curtail the marketing of spurious drugs in the country; and

(c) the details of the action being taken by the Government on the erring companies which are responsible for the increase of spurious drugs in the market?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(FAGGAN SINGH KULASTE)

(a): The National Institute of Biologicals has submitted the report on Survey of Extent of Problems of Spurious and Not of Standard Quality Drugs in the Country to the Ministry of Health & Family Welfare on 25.01.2017. Based on a scientifically planned design, 47,954 samples of drugs were picked up by Sample Drawing officers from the designated outlets in the presence of representatives of Civil Society or the Pharmacy Council of India. Of these, 47012 drug samples were subjected to test/analysis in 10 NABL accredited laboratories of the Central and State Governments. The samples were drawn from retailers, Government sources and Ports. The overall percentage of Not of Standard Quality drugs was found to be 3.16% and spurious drugs around were 0.0245%.

(b): The Government is committed to ensuring the quality, safety and efficacy of drugs and with this in view, a series of measures have been taken. These include:

(i) stringent penalties including making certain offences cognizable and non-bailable;
(ii) establishment of special designated Courts for trial of offences under Drugs and Cosmetics Act for speedy disposal of cases;

Contd……..

(iii) announcement of a Whistle Blower Scheme to encourage vigilant public participation for detection of movement of spurious drugs in the country;
(iv) issuance of guidelines to the State Drugs Controllers for taking action on samples of drugs declared spurious, adulterated, misbranded or 'not of standard quality';
(v) 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;
(vi) increase in the number of posts in the Central Drugs Standard Control Organization (CDSCO);
(vii) re-equipping drug testing laboratories with state-of-the-art equipment;
(viii) conducting workshops and training programmes for skill enhancement in areas such as Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP), Good Distribution Practices (GDP), Good Clinical Practice (GCP) and Good Storage and Distribution Practices (GSP) to regulators and industry in partnership with other Departments, industry and regulators of other countries including USA and European Union;
(ix) Conducting training programmes for laboratory personnel of State and Central laboratories to upgrade their analytical capabilities and skill sets; and
(x) risk based inspection of manufacturing facilities.

(c): As per information available with CDSCO, during 2015-16, out of 74,586 drugs samples tested, 234 were declared as spurious/adulterated and 258 prosecutions were launched under the provisions of Drugs and Cosmetics Act, 1940.

……