GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:4932
ANSWERED ON:16.12.2016
Track and Trace Mechanism for Medicines
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Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

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

(a) whether the Government has implemented the Track and Trace mechanism to check the authenticity of medicines in the country;

(b) if so, the salient features of the system;

(c) whether the cases of manufacturing spurious and adulterated drugs have come to the notice of the Government;

(d) if so, the State/UT-wise details thereof during each of the last three years and the current year along with the action taken against such manufacturers; and

(e) the other steps taken/being taken by the Government to keep a check on spurious medicines in the country?

Answer

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND
FAMILY WELFARE
(SHRI FAGGAN SINGH KULASTE)
(a) & (b): The Ministry of Health & Family Welfare had, with a view to establish trackability and traceability of drugs, issued a draft notification issued on 03.06.2015 to make barcoding compulsory on the Primary, Secondary and Tertiary packs to be marketed in the country and invited objections and suggestions from the stakeholders. The notification was, however, not finalized keeping in view the reservations of manufacturers regarding high cost of bar coding.

(c) & (d): State/UT-wise details of 'Not of Standard Quality' (NSQ)/Spurious/adulterated drugs detected in the country along with the action taken thereon during last three years and the current year, as per the information received from various State/UT Drugs Controllers are given in Annexure.

(e): The Government is committed to ensuring that the quality, safety and efficacy of drugs are not compromised. With this in view, the Government has taken a series of measures. These include:
I. stringent penalties including making certain offences cognizable and non-bailable;

II. establishment of special designated Courts for trial of offences under the Drugs and Cosmetics Act for speedy disposal of cases;

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 Standards Control Organization (CDSCO);

VII. re-equipping of drug testing laboratories with state-of-art equipment;

VIII. large scale nation-wide survey to determine the 'not of standard quality' drugs;

IX. 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 Practices (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.

X. Conducting training programmes for laboratory personnel of State and Central laboratories to upgrade their analytical capabilities

and skill sets.

XI. risk based inspections of manufacturing facilities.