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

RAJYA SABHA
STARRED QUESTION NO. *29
TO BE ANSWERED ON 22ND JULY, 2025

PREVALENCE OF SPURIOUS DRUGS

***29. DR. ASHOK KUMAR MITTAL:**

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

(a) whether Government acknowledges the alarming prevalence of substandard and spurious drugs in the country, as highlighted by recent inspection of Central Drugs Standard Control Organisation (CDSCO), if so, the details thereof;

(b) whether adequate measures have been taken to ensure accountability among pharmaceutical manufacturers who repeatedly fail quality standards;

(c) whether Government plans to enhance transparency by publishing a list of compliant drug manufacturers to rebuild public trust; and

(d) whether any significant resources have been allocated to combat the systemic issues leading to drug quality violations?

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

(a) to (d): A Statement is laid on the Table of the House.

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STATEMENT REFFERRED TO IN REPLY TO RAJYA SABHA STARRED QUESTION NO. *29 FOR 22.07.2025

(a) & (b) : Isolated cases regarding spurious/ adulterated/ sub-standard drugs are received from time to time.

As a part of quality monitoring and in order to assess the regulatory compliance of drug manufacturing premises in the country, the Central Drugs Standard Control Organization (CDSCO), in collaboration with state regulators, initiated risk-based inspections of drug manufacturing and testing firms in December 2022. Firms have been identified based on risk criteria like number of drugs declared as not of standard quality, complaints, criticality of the products etc. As of now, 905 units have been inspected, resulting in 694 actions being taken. These actions include Stop Production Orders (SPO), Stop Testing Orders (STO), license suspensions/cancellations, warning letters, and showcause notices, depending on the severity of non-compliance. This initiative has provided valuable insights into the manufacturing practices and has led to relevant corrective actions, resulting in noticeable improvements in the regulatory framework.

As per information received from various States/Union Territories Drugs Controllers, number of drug samples reported Not of Standard Quality/spurious/adulterated by the States/UTs Drugs Controller during the last three years is given below:

Year (April to March)	No. of drugs samples tested	No. of drugs samples declared Not of Standard Quality	No. of drugs samples declared Spurious/ Adulterated
2022-23	96,713	3,053	424
2023-24	1,06,150	2,988	282
2024-25	1,16,323	3,104	245

(c): All the drug manufacturers are required to comply with the conditions of licence, including Good Manufacturing Practices (GMP) as prescribed under the Drugs Rules, 1945, to ensure the quality, safety, and efficacy of drugs.

Further, CDSCO uploads list of drugs of various companies, which are declared Not of Standard Quality/ Spurious/ Misbranded/ Adulterated by the Central Drugs Testing Laboratories, on its website under the heading of Drug Alert (www.cdsco.gov.in).

In case of drug samples declared as NSQ by the Drugs Testing laboratories under CDSCO, the respective manufacturing firms are asked for immediate recall and stop further distribution of the not of standard quality drugs in the market. Further, based on investigation outcome, actions are taken by the licensing authorities concerned under the provisions of Drugs & Cosmetics Act & Rules made thereunder such as stop production orders, stop testing orders, license suspensions/cancellations, warning letters and showcause notices.

(d): The Government is implementing Strengthening of Pharmaceutical Industry (SPI) Scheme in the country. The Scheme has 3 components / sub-schemes:

(i) Assistance to Pharmaceutical Industry for Common Facilities (APICF): To strengthen the existing infrastructure facilities by providing financial assistance to pharmaceutical clusters for creation of common facilities;

(ii) Revamped Pharmaceutical Technology Upgradation Assistance Scheme (RPTUAS): To facilitate and upgrade of production facilities of existing small and medium pharmaceutical companies having average turnover of less than ₹ 500 crore, to attain the standards specified in the revised Schedule M to the Drugs Rules, 1945 and the World Health Organization – Good Manufacturing Practices (WHO-GMP); and

(iii) Pharmaceutical and Medical Devices Promotion and Development Scheme (PMPDS): To promote knowledge and awareness in and about the pharmaceutical industry by taking up studies, building databases and sponsoring events for knowledge and experience sharing within the pharmaceutical industry.

Further, for strengthening the drug regulatory system in the country, Ministry of Health and Family Welfare is implementing a Centrally Sponsored Scheme 'Strengthening of States' Drug Regulatory System (SSDRS) with an approved outlay of Rs. 850 Crore. The scheme envisages upgrading existing State laboratories, setting up of new drug testing laboratories and upgradation of existing State drug control offices in the country. So far under the SSDRS Scheme, funds totalling Rs. 756.00 Crore has been released to States/UT's as part of the Central Share and 17 New Drug Testing Labs have been constructed and 24 existing labs have been up-graded in various States/U.T's.