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

RAJYA SABHA
STARRED QUESTION NO. 170*
TO BE ANSWERED ON THE 04th AUGUST, 2026

SPURIOUS DRUGS

***170 SHRI RAMJI LAL SUMAN:**

Will the **MINISTER OF HEALTH AND FAMILY WELFARE** be pleased to state:

(a) whether the Central Drugs Standard Control Organisation (CDSCO) has detected 157 fake and substandard drugs in the country recently;

(b) if so, the details of such cases, including names of the drugs and manufacturers, Statewise; and

(c) the action taken against the erring manufacturers, suppliers and officials along with steps proposed to strengthen drug quality control, testing labs and enforcement mechanism to prevent recurrence of such incidents?

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

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

STATEMENT REFERRED TO IN REPLY TO RAJYA SABHA
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(a) to (c) The manufacture, sale and distribution of drugs are primarily regulated in the country under the provisions of Drugs & Cosmetics Act & Rules thereunder through a system of licensing and inspection by State Licensing Authorities appointed by respective State Governments while the Central Drugs Standard Control Organization (CDSCO), as the National Regulatory Authority, is responsible for approval of new drugs and clinical trials, laying down the standards for drugs, regulating the quality of imported drugs and coordination with the State Governments.

As part of the regulatory strengthening efforts, CDSCO regularly publishes details regarding samples tested by it and by the States on a monthly basis on its website as Drug alerts.

As part of the monthly Drug Alert for May 2026, details of 155 medical products declared as Not of Standard Quality (NSQ) and 02 drugs declared as Spurious by the Central CDSCO and the State Drug Testing Laboratories, including the names of the drugs and their manufacturers, State-wise, is available under the heading of Drug Alerts (https://cdsco.gov.in/opencms/opencms/en/Alerts/).

Whenever a drug is declared as a Spurious or NSQ by the Government Analyst, the Licensing Authority concerned is empowered to take actions under the provisions of the Drugs and Cosmetics Act, 1940 and the Rules made thereunder. Based on the outcome of the investigation, appropriate action such as suspension or cancellation of licences, prosecution, product recall and other penal action as provided under the Act is initiated against the erring manufacturers, suppliers and other persons.

In order to strengthen the supply of quality, safe and efficacious drugs in the country, several measures have been taken by CDSCO and Ministry of Health and Family Welfare including the following:

1) The Central Government has amended the Drugs Rules 1945 vide G.S.R. 922 (E) dated 28.12.2023 to revise the schedule M to the said rules related to Good Manufacturing Practices and requirements of premises, plant and equipment for pharmaceutical products. Revised Schedule M has become effective for the drug manufacturers with turnover > Rs. 250 crores from 29.06.2024 and for manufacturers having turnover of less than Rs. 250 Cr from 01.01.2026.

2) The Drugs Rules, 1945 were amended in year 2023 to mandate that manufacturers of the top 300 drug formulation brands listed in Schedule H2 shall print or affix a Bar Code or QR Code on the primary packaging label, or on the secondary label where space is insufficient, to store data readable through software applications for authentication. Similarly, the Rules have also been amended to require that every Active Pharmaceutical Ingredient (bulk drug), whether manufactured or imported, shall bear a QR Code on each level of packaging containing data readable through software applications to facilitate tracking and tracing

3) Further, the Central Government vide G.S.R. 506 (E) dated 22.06.2026, has extended the provision of QR code to all vaccine, all antimicrobials, all narcotic & psychotropic substance, listed under the Narcotic Drugs and Psychotropic Substance Act, 1985 and rules made thereunder and all anticancer drugs by bringing them under Scheduled H2. The provisions relating to vaccines, narcotic and psychotropic drugs, and anti-cancer medicines shall come into force from 1st July 2027, while the provisions relating to antimicrobials shall become effective from 1st July 2028.

4) In February 2024, CDSCO published regulatory guidelines for the sampling of drugs, cosmetics, and medical devices by Central and State Drugs Inspectors. These guidelines provide a structured approach to ensure the quality and efficacy of products available in the market through uniform drug sampling methodology.

5) Further, for strengthening the drug regulatory system in the country, Ministry of Health and Family Welfare has implemented a Centrally Sponsored Scheme 'Strengthening of States' Drug Regulatory System (SSDRS). 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. Under the SSDRS Scheme, funds totalling Rs. 756 Crore has been released to States/UTs as part of the Central Share and 24 New Drug Testing Labs have been constructed and 32 existing labs have been up-graded in various States/UTs.

6) Central Government has provided regular residential, regional training and workshops to more than 40,000 officials of CDSCO and State Drug Regulatory Authorities on Good Manufacturing Practices.

7) Regulatory compliance of drug manufacturing premises and private testing laboratories in the country is also assessed by CDSCO along with State Drugs Controllers (SDCs) through conduct of Risk-Based Inspections, and actions such as issuance of show cause notices, stop production order, suspension, cancellation of licenses /product licenses, issuance of warning letters, are taken by the State Licensing Authorities.

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