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

RAJYA SABHA
UNSTARRED QUESTION NO. 427
TO BE ANSWERED ON 03RD FEBRUARY, 2026

FAILURE OF DRUG SAMPLES

427. SHRI HARSH MAHAJAN:

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

(a) whether Government is aware of how many drug samples have failed in laboratory tests in the country so far, causing serious risks to public health;
(b) if so, the details of such cases recorded, drug samples failed and the actions taken against the offenders, in the last three years, State-wise, including Himachal Pradesh; and
(c) whether Government is considering measures to strengthen the drug supply chain tighten penal provisions and run public awareness campaigns to address this problem, if so, the details thereof?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(SMT. ANUPRIYA PATEL)

(a) to (c) : List of drugs of various companies, which are declared Not of Standard Quality/ Spurious/ Adulterated by the Central Drugs Testing Laboratories is uploaded and available on the website of CDSCO under the heading of Drug Alert (www.cdsco.gov.in) and actions initiated as per provisions of the Drugs and Cosmetics Act, 1940 and rules thereunder.

As per information received from States/UTs Drugs Controllers, the number of drug samples tested in last three years by various States/U.Ts including Himachal Pradesh and status regarding number of drug samples declared Not of Standard Quality/spurious/ adulterated including enforcement actions taken is as under:

Financial Year	No. of drugs samples tested	No. of drugs samples declared Not of Standard Quality	No. of drugs samples declared Spurious/ Adulterated	Number of prosecution launched for manufacturing, sale and distribution of spurious/adulterated drugs
2022-23	96,713	3,053	424	663

2023-24	1,06,150	2,988	282	604
2024-25	1,16,323	3,104	245	961

Central Drugs Standard Control Organization (CDSCO) and the Ministry of Health and Family Welfare in recent years have taken following measures to ensure the quality and safety of medicines in the country.

(i) On 17.11.2022, the Drugs Rules, 1945 were amended vide G.S.R. 823(E) which has come into force from 1st of August, 2023 providing that the manufacturers of top 300 brands of drug formulation products, as specified in Schedule H2, shall print or affix Bar Code or Quick Response Code on its primary packaging label or, in case of inadequate space in primary package label, on the secondary package label that store data or information legible with software application to facilitate authentication.

(ii) On 18.01.2022, the Drugs Rules, 1945 were amended vide G.S.R. 20 (E) providing that every Active Pharmaceutical Ingredient (bulk drug) manufactured or imported in India shall bear Quick Response Code on its label at each level of packaging that store data or information readable with software application to facilitate tracking and tracing. The stored data or information shall include the minimum particulars including unique product identification code, Batch Number, Manufacturing date, Expiry Date etc.

CDSCO has made the said requirements regarding QR Codes available to the general public by publishing the notification in this regard on its website (https://cdsco.gov.in/opencms/opencms/en/Notifications/Gazette-Notifications) and has also advised industry stakeholders for public awareness campaigns in this regard.

(iii) 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.

(iv) In order to assess the regulatory compliance of drug manufacturing premises in the country, the CDSCO along with State Drugs Controllers (SDCs) have conducted Risk-Based Inspections of more than 960 premises since December, 2022 and based on findings, more than 860 actions like issuance of show cause notices, stop production order, suspension, cancellation of licenses /product licenses, warning letters have been taken by the State Licensing Authorities.

(v) More than 1100 cough syrup manufacturers have been subjected to intense audit in coordination with State authorities. Increased market surveillance sampling of syrup formulations by Central and State drugs regulators has also been done.

(vi) 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.

(vii) An online portal, SUGAM labs is in place since September 2023 for integrating the drug testing labs of the CDSCO. It automates the entire workflow for testing of Medical Products (Drugs, Vaccine, Cosmetics & Medical devices) to meet the quality specification and tracing the testing status in the laboratories.

(viii) Central regulator coordinates activities of State Drug Control Organisations and provides expert advice through the Drugs Consultative Committee (DCC) meetings held with State Drugs Controllers for uniformity in administration of the Drugs and Cosmetics Act.

(ix) Central government is providing regular residential, regional training and workshops to officials of CDSCO and State Drug Regulatory Authorities on Good Manufacturing Practices. In the Financial Year 2023-24 CDSCO has trained 22854 persons while in Financial Year 2024-25, 20551 persons have been trained.

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