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

LOK SABHA
UNSTARRED QUESTION NO. †967
TO BE ANSWERED ON 24TH JULY, 2026

SPURIOUS DRUGS

†967. SHRI SANJAY HARIBHAU JADHAV:

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

(a) the steps taken/proposed to be taken by the Government to curb spurious drugs;
(b) the number of drug testing laboratories functioning in various States, to check the trade in spurious drugs, especially in Maharashtra;
(c) the number of samples tested by these laboratories during the last three years along with the number of spurious or sub-standard drugs found in these samples;
(d) whether the Government is considering to bring a new law to award strict punishment to those involved in the manufacturing and sale of spurious drugs and if so, the details thereof; and
(e) the manner in which the supply of spurious drugs is being checked in view of the increasing online sales of medicines, along with the details thereof?

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

(a): The manufacture, sale and distribution of drugs in the country is regulated under the provisions of Drugs and Cosmetics Act, 1940 and Rules, 1945 thereunder through a system of licensing and inspection. Licenses for manufacture, sale and distribution of drugs are granted by the State Licensing Authorities (SLAs) appointed by respective State Governments.

Central Drugs Standard Control Organization (CDSCO) and Ministry of Health and Family Welfare have taken following regulatory measures to ensure the import and manufacture of safe, efficacious and quality medicines across the country:

(i). An advisory has been issued on 03.10.2025 to all State/UT Health Departments and healthcare facilities to ensure rational use of paediatric cough syrups. Further, the Drugs Controller (India) directed all State/UT Drug Controllers on 07.10.2025 to ensure strict compliance with testing requirements under the Drugs Rules, 1945, and on 27.10.2025 instructed them to maintain heightened vigilance against spurious and substandard drugs and take prompt action under the Drugs & Cosmetics Act, 1940.

(ii). 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 1040 premises since December, 2022 and based on findings, more than 950 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.

(iii). Further, more than 1100 cough syrup manufacturers and 420 blood centres 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.

(iv). 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.

(v). 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.

(vi). 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.

(vii). The Drugs Rules, 1945 have been 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.

(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.

(b): As per information available, there are 80 drugs testing laboratories functioning in various States/UTs across the country including 8 in Maharashtra.

(c) to (e): 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.

As per information received from various States/Union Territories Drugs Controllers (SDCs), number of drug samples reported Not of Standard Quality/spurious/adulterated by the States/UTs Drugs Controller during the last five years is as follows:

Financial Year	No. of drugs samples tested	No. of drugs samples declared Not of Standard Quality	No. of drugs samples declared Spurious/ Adulterated
2023-24	1,06,150	2,988	282
2024-25	1,16,323	3,104	245
2025-26	1,41,322	3,012	283

The Drugs and Cosmetics Act, 1940 has provisions for penalties in case of contraventions to various provisions of the said Act and Rules. The Act was amended by way of Drugs & Cosmetics (Amendment) Act 2008 to provide for more stringent penalties for manufacture of spurious and adulterated drugs. Certain offences have also been made cognizable and non bailable.

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