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

RAJYA SABHA
UNSTARRED QUESTION NO. 1089 #
TO BE ANSWERED ON 09TH DECEMBER, 2025

UNABATED TRADE OF FAKE MEDICINES

1089 # SHRI NEERAJ DANGI:

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

(a) the total value of counterfeit medicines seized by Government during the last two years;

(b) the number of persons arrested during the said period in connection with the trade of counterfeit medicines, along with the number of medical stores and wholesale traders whose licences have been cancelled for their involvement in such activities, the details thereof State-wise;

(c) whether the major reason behind the trade in counterfeit medicines is a weak monitoring mechanism; and

(d) if so, the stringent measures taken by Government to prevent the manufacture and circulation of counterfeit and substandard medicines and to ensure quality assurance?

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

(a) to (d): The terminology “Counterfeit Medicines” is not defined under the Drugs and Cosmetics Act, 1940 and Rules made thereunder. However, the Drugs and Cosmetics Act defines spurious, adulterated and misbranded drugs which includes counterfeit drugs.

The details of number of drug samples reported Not of Standard Quality/spurious/ adulterated and enforcement action taken by the States/UTs Drugs Controller during last two years of various States/U.Ts is as under:

Year (April to March)	Number of drugs samples tested	Number of drugs samples declared Not of Standard Quality	Number of drugs samples declared Spurious/ Adulterated	Number of prosecution for manufacturing, sale and distribution of spurious/adulterated drugs
2023-24	1,06,150	2,988	282	604
2024-25	1,16,323	3,104	245	961

The manufacture, sale and distribution of drugs in the country are regulated under the provisions of Drugs & 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. SLAs are legally empowered to take stringent action against violation of any provision of the Act and Rules.

CDSCO and the Ministry of Health and Family Welfare in recent years have taken following measures to prevent the manufacture, sale and distribution of spurious/adulterated/not of standard quality drugs in the country.

(i) In order to assess the regulatory compliance of drug manufacturing premises in the country, the CDSCO, in collaboration with state regulators, initiated risk-based inspections of drug manufacturing and testing firms. This provides for various regulatory actions such as issuance of show cause notices, stop production orders, and suspension or cancellation of licenses/product licenses.

(ii) The Drugs Rules, 1945 have been amended in 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.

(iii) As part of quality monitoring, CDSCO uploads details of drug samples that fail quality checks on its website as monthly Drug Alerts. For samples declared Not of Standard Quality (NSQ) by the Drugs Testing laboratories under CDSCO, manufacturers are directed to immediately recall the product and stop further distribution. Based on investigation findings, licensing authorities concerned take action under the Drugs & Cosmetics Act and Rules, including stop-production/testing orders, license suspension or cancellation, warning letters, and showcause notices.

(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. However, for manufacturers having turnover of less than Rs. 250 Cr, conditional extension up to 31.12.2025 is currently operational for those who submitted their upgradation plan for the extended compliance period.

(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 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.

(viii) The 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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