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

**RAJYA SABHA**
**UNSTARRED QUESTION NO. 1919**
**TO BE ANSWERED ON 16TH DECEMBER, 2025**

# CIRCULATION OF ADULTERATED MEDICINES

**1919. SMT. JEBI MATHER HISHAM:**

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

(a) whether Government has assessed the current volume and estimated market size of counterfeit medicines amid the reported 50 per cent spike in their circulation;

(b) the steps taken to ensure the genuineness and quality of medicines distributed through Jan Aushadhi outlets amid rising counterfeit circulation;

(c) the details of quality tests conducted by CDSCO over the last five years and the trends that have emerged, State/UT-wise; and

(d) whether Government has examined the reasons behind the influx of adulterated medicines, including discount-driven demand and the corrective actions have been taken thereon?

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

(a) : 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. Presently, there is no specific study conducted to assess the current volume and estimated market size of counterfeit medicines. However, a nation-wide survey (2014-16) was conducted to assess the extent of Not of Standard Quality (NSQ)/Spurious drugs. Out of a total 47012 drug samples drawn from both Governments and private sources, the estimated percentage of NSQ and spurious drugs from Retail outlets was 3% and 0.023% respectively, while that from Government sources was 10.02% and 0.059% respectively.

(b): 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) 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.

(ii) List of drugs of various companies, which are declared Not of Standard Quality/ Spurious/ Misbranded/ 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.

(iii) 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.

(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.

(c): As per information received from States/UTs Drugs Controllers, the number of drug samples tested during last five years by various States/U.Ts and status regarding number of drug samples declared Not of Standard Quality/spurious/ adulterated 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 |
|---|---|---|---|
| 2020-21 | 84,874 | 2,652 | 263 |
| 2021-22 | 88,844 | 2,545 | 379 |
| 2022-23 | 96,713 | 3,053 | 424 |
| 2023-24 | 1,06,150 | 2,988 | 282 |
| 2024-25 | 1,16,323 | 3,104 | 245 |

(d): Isolated complaints regarding sale of not of standard quality and spurious/adulterated drugs, as and when received, action is initiated by the licensing authority as per the provisions of Drugs & Cosmetics Act, 1940 and rules thereunder.

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