

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

**RAJYA SABHA
UNSTARRED QUESTION NO. 3622
TO BE ANSWERED ON 24TH MARCH, 2026**

**MEASURES TO PREVENT COUNTERFEIT DRUGS AND ENSURE DRUG
QUALITY**

3622. SMT. JEBI MATHER HISHAM:

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

- (a) whether Government has assessed the scale and spread of counterfeit medicines in view of reports indicating a significant rise in their circulation, the details thereof, State/UT-wise;
- (b) whether the volume and financial size of the counterfeit medicine market in the country has been estimated;
- (c) the steps taken to ensure the genuineness and quality of medicines distributed through Jan Aushadhi outlets amid concerns of counterfeit circulation;
- (d) the State/UT-wise details of quality tests conducted by CDSCO during the last five years; and
- (e) whether Government has examined the factors contributing to the influx of adulterated medicines and the corrective measures undertaken?

ANSWER

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

(a) to (e): 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 47,012 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.

Central Drugs Standard Control Organization (CDSCO) and Ministry of Health and Family Welfare have taken following regulatory measures to ensure the production of quality medicines across the country including those distributed through Jan Aushadhi outlets: -

- (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) Further, more than 1100 cough syrup manufacturers and 380 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.
- (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 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.
- (v) 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.
- (vi) 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.
- (vii) 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) 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.

As per information received from States/UTs Drugs Controllers, the number of drug samples tested by various States/U.Ts and their status 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
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

On the 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.
