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

LOK SABHA
UNSTARRED QUESTION NO. 1003
TO BE ANSWERED ON 05TH DECEMBER, 2025

SUBSTANDARD QUALITY OF MEDICINES

1003. SHRI ABHISHEK BANERJEE:

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

(a) the number of pharmaceutical manufacturing units inspected by Central Drugs Standard Control Organization (CDSCO) in 2023–24 and 2024–25 that were found to be non-compliant with quality norms and the number of units ordered to shut, State-wise;

(b) the quantity (in number of batches) of medicines rejected for substandard quality in those inspections and the value of such batches; and

(c) the steps taken/proposed to be taken by the Government to strengthen quality control, including augmentation of labs, digital traceability, and stricter oversight of Active Pharmaceutical Ingredient (API) sourcing, particularly in view of scholar criticisms about India's dependence on imported APIs and quality lapses?

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

(a) to (c): In order to assess the regulatory compliance of drug manufacturing premises in the country, the Central Drugs Standard Control Organization (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 as per the provisions of the Drugs Rules 1945.

Further, 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 Central Drugs Standard Control Organization (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.

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) 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.

(iii) 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.

(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 making it mandatory that, in case the applicant intends to market the drug under a brand name or trade name the applicant shall furnish an undertaking in Form 51 to the licensing authority that such or similar brand name or trade name is not already in existence with respect to any drug in the country and the proposed brand name or trade name shall not lead to any confusion or deception in the market.

(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.

****