

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

**LOK SABHA
UNSTARRED QUESTION NO. 4823
TO BE ANSWERED ON 20TH MARCH, 2026**

MANUFACTURING OF SPURIOUS DRUGS

4823. SMT. SANJNA JATAV:

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

(a) whether the Government is aware of the fact that Himachal Pradesh accounts for one third of the drugs failing quality tests and is a major supplier of medicines to semi-urban areas, thereby allegedly putting the lives of millions in danger and if so, the details thereof along with the actions taken by the Central Drugs Standard Control Organization (CDSCO) so far and if not, the reasons therefor;

(b) the list of the drugs which failed quality tests, drug-wise, company-wise and State wise;

(c) whether the Government is contemplating checking the production of spurious drugs including cough syrups so as to have a stringent mechanism for the defaulters and if so, the details thereof along with the steps taken or proposed to be taken by the Government in this regard and if not, the reasons therefor; and

(d) whether the Government is planning to strengthen by establishing new testing Laboratories and increasing the workforce to deal with this situation and if so, the details thereof and if not, the reasons therefor?

**ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY
WELFARE**

(SMT. ANUPRIYA PATEL)

(a) & (b): As part of the monthly drug alert uploaded on the website of Central Drugs Standard Control Organization (CDSCO), in the last one year (Jan. 2025 to Dec. 2025), 1902 drug samples were declared as not of standard quality (NSQ). Out of these 590 drugs samples were manufactured in Himachal Pradesh. Details of these drugs are available on the CDSCO website under the heading of Drug Alert (www.cdsc.gov.in).

In all such cases, CDSCO directed the manufacturers (as per the label claim) for recall of such drugs. In such cases, based on investigation outcomes, actions are taken by the

concerned licensing authorities under the provisions of Drugs & Cosmetics Act & Rules made there under including prosecution in Court of law.

(c): 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 addition to the existing requirements of testing the raw materials, the Indian Pharmacopoeia Commission, Ghaziabad has issued an amendment to Indian Pharmacopoeia (IP) 2022, to also mandate the testing for DEG and Ethylene Glycol (EG) in oral liquids at finished product stage before market release.
- (iii) 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.
- (iv) 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.
- (v) 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.
- (vi) 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.
- (vii) 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.

- (viii) 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.
 - (ix) 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.
 - (x) 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.
- (d): For strengthening the drug regulatory system in the country, Ministry of Health and Family Welfare has implemented a Centrally Sponsored Scheme Strengthening of States' Drug Regulatory System (SSDRS). The scheme envisages upgrading existing State laboratories, setting up of new drug testing laboratories and upgradation of existing State drug control offices in the country. Under the SSDRS Scheme, funds totalling Rs. 756 Crore has been released to States/UTs as part of the Central Share and 19 New Drug Testing Labs have been constructed and 28 existing labs have been up-graded in various States/UTs.
