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

RAJYA SABHA
UNSTARRED QUESTION NO. 417
TO BE ANSWERED ON 03RD FEBRUARY, 2026

STRENGTHENING REGULATORY FRAMEWORK FOR OTC MEDICINES

417. SHRI RANDEEP SINGH SURJEWALA:

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

(a) whether Government has detected harmful manufacture/sale of over the counter (OTC) Medicines/liquid syrups being sold in the country, if so, the details of such medicines and syrups;
(b) whether Government has reviewed the existing standards and protocols for the manufacturing/sale of over-the-counter (OTC) medicines including liquid syrups in light of the recent incidents involving contaminated cough syrups; and
(c) if so, the specific changes made, protocols enforced or enhancements made to the regulatory framework?

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

(a) to (c): The manufacturing, sale and distribution of drugs in the country are regulated under the provisions of Drugs & Cosmetics Act, 1940 and rules thereunder. The regulatory control over the manufacture, sale and distribution of drugs in the country is exercised through a system of licensing and inspection by the State Licensing Authorities (SLAs). Compliance with the conditions of licence granted under the said Act and Rules is mandatory for manufacture, sale and distribution of drugs in the country. SLAs are legally empowered to take action against violation of provisions of the said Act and Rules.

Isolated complaints regarding quality of drugs are received from time to time. As and when such complaints are received, the matter is referred to the concerned licensing authority for taking action as per the provisions of the said Act and Rules.

As per the Drugs and Cosmetics Act, 1940 and Rules thereunder the drugs covered under various Schedule like Schedule X, Schedule H and Schedule H1 are required to be sold by retail on the prescription of a Registered Medical Practitioner (RMP) only. Accordingly, any syrup preparation containing a drug classified under these schedules is required to be sold by retail on the prescription of a RMP only.

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) More than 1100 cough syrup manufacturers 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) 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.

(iv) 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.

(v) 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.

(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) 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.

(viii) 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.

(ix) 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.

(x) 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.

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