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

LOK SABHA
UNSTARRED QUESTION NO. 1282
TO BE ANSWERED ON 06TH FEBRUARY, 2026

DEATHS BY COUGH SYRUP

1282. DR. BACHHAV SHOBHA DINESH:

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

(a) whether the Government is aware of reports of deaths allegedly linked to the consumption of cough syrups in certain parts of Uttar Pradesh and if so, the details thereof;

(b) the standard procedure followed for approval, licensing and quality certification of cough syrups and other liquid oral medicines in the country, indicating the respective roles of the Central and State Drug Regulatory Authorities;

(c) the mechanism for quality control, random sampling, laboratory testing and post-market surveillance of such medicines after they are approved and released into the market;

(d) the circumstances under which sub-standard or contaminated medicines are able to reach consumers despite existing regulatory safeguards; and

(e) the steps taken/proposed to be taken by the Central Government to strengthen regulatory oversight, coordination with States and prevent recurrence of such incidents in future?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(SHRI PRATAP RAO JADHAV)

(a): As informed by the State Drugs Controller, Uttar Pradesh, there have been no reports of child deaths linked to the consumption of the alleged cough syrups.

(b) to (d): There is a regulatory framework under the provisions of Drugs and Cosmetics Act and Rules to regulate drugs, medical devices and cosmetics. Manufacture, sale and distribution of Drugs is primarily regulated by the State Licensing Authorities (appointed by respective State Governments) through a system of licensing and inspection while the Central Licensing Authority is responsible for approval of New Drugs, Clinical Trials in the country, laying down the standards for Drugs, control over the quality of imported Drugs, coordination of the activities of State Drug Control Organizations and providing expert advice with a view of bring about the uniformity in the enforcement of the Drugs and Cosmetics Act.

approval of New Drugs, Clinical Trials in the country, laying down the standards for Drugs, control over the quality of imported Drugs etc.

Under the Drug and Cosmetics Act 1940, drugs inspector randomly draws drug samples from the supply chain for quality checks. List of drugs of various companies, which are declared Not of Standard Quality/ Spurious/ Misbranded/ Adulterated by the Central Drugs Testing Laboratories are regularly uploaded on the website of Central Drugs Standard Control Organization (CDSCO) under the heading of Drug Alert (www.cdsco.gov.in). In case of drug samples failing in quality check, regulatory, actions are taken by the concerned licensing authorities under the provisions of Drugs & Cosmetics Act & Rules thereunder.

Further, with respect to post-market surveillance, the Pharmacovigilance Programme of India (PvPI) is in place to ensure the safety of drugs by monitoring adverse drug reactions (ADRs) and reducing the risks associated with their use in India.

(e): 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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