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

LOK SABHA
UNSTARRED QUESTION NO. 2382
TO BE ANSWERED ON 13TH FEBRUARY, 2026

DISTRIBUTION OF SUBSTANDARD COUGH SYRUPS

2382. SHRI RAHUL GANDHI:

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

(a) the number of deaths linked to contaminated cough syrups during the last five years along with details of brands and manufacturers, State-wise;

(b) the total number of cough syrup samples tested/number found containing diethylene glycol (DEG) and/or ethylene glycol (EG) beyond permissible limits during the last five years, year-wise and State-wise along with the details of data is available;

(c) the action taken against manufacturers and regulatory officials responsible for manufacture, approval and distribution of substandard cough syrups;

(d) whether the Government is aware of alerts by the World Health Organization regarding Indian made contaminated cough syrups linked to child deaths in Gambia and Uzbekistan and if so, the details thereof;

(e) the steps taken/proposed to be taken by the Government to strengthen drug testing protocols to prevent such incidents from recurring; and

(f) whether any compensation has been provided to families of victims of contaminated cough syrups and if so, the details thereof?

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

(a) to (f): Upon receipt of reports of a cluster of child deaths from Chhindwara, Madhya Pradesh, a Central team of experts comprising an epidemiologist, a microbiologist, an entomologist, and drug inspectors from the National Centre for Disease Control (NCDC), National Institute of Virology (NIV), and Central Drugs Standard Control Organisation (CDSCO), respectively visited Chhindwara and Nagpur and undertook a detailed investigation of the reported cases and deaths in coordination with the Madhya Pradesh State

Authorities. A total of 19 drug samples, reportedly consumed by the affected children, were collected from the treating private practitioners and nearby retail stores for testing. Chemical analysis of these 19 samples indicated that 15 samples were of Standard Quality, while 4 samples were declared Not of Standard Quality (NSQ). As per the test report, the content of Diethylene Glycol (DEG) in Syrup Coldrif (B.No. SR-13) manufactured by M/s Sresan Pharmaceutical located in Kancheepuram, Tamil Nadu and consumed by the deceased children was found to be 46.28% w/v.

The premises of M/s Sresan Pharmaceuticals was inspected. Several critical and major Good Manufacturing Practices (GMP) violations including unhygienic storage conditions were observed. The matter regarding the criminal action against the manufacturer was taken up by CDSCO with the State Government of Tamil Nadu. The State Drugs Controller, Tamil Nadu cancelled the manufacturing licence. Further, following the incident, the States of Madhya Pradesh, Tamil Nadu, Odisha and the Union Territory of Puducherry to which the impugned cough syrup batches were supplied, ordered immediate ban and recall of the same. Criminal case has been registered in the matter by the State of Madhya Pradesh and strict action has been taken including the arrest of persons involved.

As per information received from States/UTs Drugs Controllers, the number of drug samples tested including cough syrups during the last five years by various States/U.Ts and status regarding number of drug samples declared Not of Standard Quality/spurious/ adulterated including enforcement actions taken 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	Number of prosecution launched for manufacturing, sale and distribution of spurious/adulterated drugs
2020-21	84,874	2,652	263	236
2021-22	88,844	2,545	379	592
2022-23	96,713	3,053	424	663
2023-24	1,06,150	2,988	282	604
2024-25	1,16,323	3,104	245	961

The World Health Organisation, on an ongoing basis, issues medical product alerts as and when quality related incidents are reported to it by its member nations. Such alerts relate to incidents pertaining to various member nations, including Gambia and Uzbekistan, and are accessible to the member nations.

In case of Gambia, joint investigation was undertaken by CDSCO and State Drug Controller, Haryana. Based on investigations conducted, which revealed violation of Good Manufacturing Practices (GMP), State Drugs Controller, Haryana issued show cause notice to M/s Maiden Pharma under Rule 85(2) of the Drugs Rules, 1945 and order was issued for stopping all the manufacturing activities of M/s Maiden Pharmaceuticals at Sonipat, Haryana with immediate effect for violation of GMP.

In the case of Uzbekistan, CDSCO in coordination with State Drugs Controller, Uttar Pradesh conducted a joint investigation at M/s. Marion Biotech Pvt. Ltd., Noida, Uttar Pradesh. Drug samples were drawn from the manufacturing premises under the provisions of Drugs & Cosmetics Act, 1940 for test & analysis. Further, manufacturing license of the firm was suspended by State Licensing Authority, Uttar Pradesh on 09.01.2023. Further, an FIR was lodged in the concerned police station and three persons were arrested.

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 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.

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