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

RAJYA SABHA UNSTARRED QUESTION NO. 263 TO BE ANSWERED ON 02ND DECEMBER, 2025

COUGH SYRUP CONTAMINATION

263 DR. JOHN BRITTAS:

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

- (a) the number of people who have died or hospitalised after consuming spurious cough syrups in the country during the past three years;
- (b) the names of companies which manufactured these cough syrups;
- (c) the extent of domestic and international distribution of these contaminated syrups;
- (d) whether the Central Drugs Standard Control Organisation (CDSCO) have confirmed the presence of toxic chemicals in the syrup samples;
- (e) if so, whether such findings were officially communicated to the State Governments; and
- (f) the actions taken by Government against the delinquent pharmaceutical companies during past five years?

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

(a) to (e): 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.

Further, 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.

More than 700 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.

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.

(f): The details of number of drug samples reported Not of Standard Quality/spurious/ adulterated and enforcement action taken by the States/UTs Drugs Controller during last five years of various States/U.Ts is as under:

Year	Number of	Number of	Number of	Number of prosecution for
(April to	drugs	drugs	drugs samples	manufacturing, sale and
March)	samples	samples	declared	distribution of
	tested	declared	Spurious/	spurious/adulterated drugs
		Not of	Adulterated	
		Standard		
		Quality		
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
