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

LOK SABHA
UNSTARRED QUESTION NO. 1094
TO BE ANSWERED ON 05TH DECEMBER, 2025

REGULATORY ACTIONS ON CONTAMINATED MEDICINES

1094. DR. SHASHI THAROOR:

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

(a) the immediate actions that have been taken by the Government in response to the World Health Organization's alert of 13 October 2025 regarding contaminated cough syrups manufactured in the country, which were linked to child deaths and found to contain Diethylene Glycol (DEG) far the above permissible limits;

(b) the current status of regulatory reform for oral-liquid medicines, especially syrups for children;

(c) whether domestic products requires the same testing standards as exported ones in the country and if so, the details thereof;

(d) whether the licences of implicated companies have been suspended and if so, the details thereof;

(e) the number of manufacturing units in India have failed to comply with revised Schedule M/Good Manufacturing Practices (GMP) standards as of October 2025; and

(f) the enforcement mechanisms like recall, licence cancellation, prosecution are being used by the Ministry and the Central Drugs Standard Control Organization (CDSCO) to prevent further public-health harm?

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.

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.

****