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

RAJYA SABHA
UNSTARRED QUESTION NO. 294
TO BE ANSWERED ON 02ND DECEMBER, 2025

DEATHS DUE TO COUGH SYRUPS

294. DR. V. SIVADASAN:

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

(a) the findings of the inspections conducted by the CDSCO in six States following the recent cough syrup tragedy;

(b) the specific systemic changes implemented in the drug manufacturing, testing, and approval protocols especially for paediatric formulations, to prevent such incidents from recurring;

(c) the minimum audit/qualification protocol for excipient suppliers to cough-syrup manufacturers, and table how many suppliers have been blacklisted in 2024-26; and

(d) the number of children who have lost their lives in the tragedy, State-wise since 2020?

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

(a) to (d): 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.

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