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

LOK SABHA
UNSTARRED QUESTION NO. †1051
TO BE ANSWERED ON 05TH DECEMBER, 2025

INSPECTION OF LIFE SAVING MEDICINES

†1051. SHRI AMRA RAM:

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

(a) the names of life-saving drugs found to be substandard during the inspection along with the action taken by the Department against the concerned manufacturing companies;

(b) whether many children have died in Rajasthan and Madhya Pradesh due to cough syrup and if so, the details thereof; and

(c) whether these medicines were found to be up to standard, if so, the details thereof and if not, the reasons therefor along with the action taken by the Department thereon?

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

(a) to (c): Central Drugs Standard Control Organization (CDSCO) and State Drugs Control Authorities draw drug samples from the supply chain, including during inspections of manufacturing/ sales units, for test and analysis. 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 Central Drugs Standard Control Organization (CDSCO) under the heading of Drug Alert (www.cdsco.gov.in) and actions initiated as per provisions of the Drugs and Cosmetics Act, 1940 and rules thereunder.

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 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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