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Review Article

The Coldrif Cough Syrup Tragedy: A Review of Diethylene Glycol Contamination and Pediatric Safety Failures in India

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ABSTRACT:

In October 2025, India experienced a tragic outbreak of paediatric deaths linked to consumption of the cough-and-cold liquid formulation Coldrif Syrup, manufactured by Sresan Pharmaceuticals. The present review examines the event in the wider context of paediatric cough-syrup usage, regulatory vulnerabilities, formulation factors and pharmacology, adverse toxicology, public-health response and future prevention. The review first outlines the history of paediatric cough syrups and regulatory frameworks in India, then analyses the composition of Coldrif, its pharmacological rationale, and evidence of usage in children aged 2-8 years. Next, we summarise clinical and epidemiological evidence of efficacy and safety, followed by detailed discussion of the toxic contamination event: detection of diethylene glycol (DEG) in the batch, mechanisms of DEG toxicity, mortality outcomes (at least 20–24 children under five died), and key lapses in manufacturing and oversight. We then review regulatory and public-health responses: immediate product recalls, manufacturing shutdowns, arrests, revision of testing norms (incorporation of DEG/EG testing in monograph), and advisory-against use in very young children. The article closes with recommendations for clinicians, pharmacists and caregivers around rational prescribing of cough-cold syrups in children, safer alternative strategies, and calls for strengthened pharmacovigilance, manufacturing oversight and supply-chain traceability. Although cough and cold remain common in children, this calamity emphasises that benefit-risk balance demands rigorous manufacturing quality and regulatory vigilance. Keywords: paediatric cough syrup, Coldrif, diethylene glycol, contamination, drug safety, India.

Keywords: aediatric cough syrup · Coldrif · diethylene glycol · contamination · drug safety · India

INTRODUCTION

The cough and cold combination syrup Coldrif has recently become the subject of a major public-health crisis in India, after a cluster of deaths in children aged under 5 years. This review examines why the crisis occurred, how it happened, the main causes, how dangerous it was and how such events may be prevented in the future. The purpose is to place this incident in a broader framework of paediatric cough-cold therapy, manufacturing and regulatory oversight, and to draw lessons for clinicians, pharmacists, regulators and caregivers.

2. Background

Cough and cold combination syrups have long been used in paediatric medicine to relieve symptoms such as cough, nasal congestion, allergic rhinitis and fever. In many low- and middle-income countries, such syrups are widely prescribed and dispensed. Regulatory frameworks exist to ensure quality, efficacy and safety (e.g., monographs in national pharmacopoeias, good manufacturing practice (GMP) requirements). However, numerous past incidents (for example, syrup-poisoning outbreaks in Africa and Asia) have demonstrated that sub-standard manufacturing or contamination can have catastrophic consequences. The Indian regulatory

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structure is dual: the central agency (Central Drugs Standard Control Organisation, CDSCO) and state controllers share oversight, which introduces variability in enforcement and capacity. (Vision IAS)

3. Composition and Formulation of Coldrif

According to available information, Coldrif is a paediatric cough/flu syrup containing typical active ingredients for such an indication (for example an antihistamine, decongestant, analgesic/antipyretic). One batch (SR-13, May 2025) has been implicated. While the manufacturer claimed standard excipient and formulation processes, laboratory investigations found contamination with diethylene glycol (DEG) far above permissible limits. The excipients, solvent systems or glycerin substitutes used appear to be the likely vehicle of contamination. (mint)

4. Pharmacological Actions

Each active ingredient in a cough-and-cold syrup typically acts via distinct mechanisms: antihistamines block H1-receptors (reducing rhinorrhea and sneezing), decongestants (e.g., phenylephrine) produce vasoconstriction of nasal mucosa, analgesics/antipyretics (e.g., paracetamol) reduce fever and pain. Combination therapy aims at symptomatic relief. In children, pharmacokinetics differ from adults: reduced glomerular filtration, different body water compartments, immature hepatic metabolism and renal excretion all affect drug half-life and elimination. Yet regulatory approval for children normally hinges on well-controlled studies — which are often lacking for many over-the-counter cough syrups.

5. Therapeutic Indications

Coldrif was marketed for children with upper-respiratory tract infection symptoms: cough, cold, nasal congestion, fever and associated discomfort. Dosage recommendations were presumably stratified for age groups (2-8 years, etc.) though specific publicly-available dosing data are limited. Contraindications likely included severe renal/hepatic impairment, known hypersensitivity to components, and caution in very young children (infants under two).

6. Clinical Evidence of Efficacy

There is limited peer-reviewed evidence specific to Coldrif in the paediatric population. Many cough syrups rely on symptom relief without robust randomized controlled trials in young children. Hence the efficacy data are weak. Comparison with placebo or alternative symptomatic remedies is scarce. The shortcomings in available evidence include small sample sizes, non-age-stratified data, and lack of long-term safety outcomes.

7. Adverse Effects and Safety Profile

Common side-effects of standard cough-cold combinations include drowsiness, irritability, nausea, dry mouth, palpitations (with decongestants) and paradoxical excitation (in young children). More serious effects, especially when mis-used or in overdose, may include seizures, cardiovascular disturbances (tachycardia, hypertension) and respiratory depression. Drug interactions must also be considered (for example antihistamines + sedatives, decongestants + MAO inhibitors). Careful dosing is essential in children due to narrower safety margins and immature elimination.

8. Recent Toxicity and Contamination Reports

In October 2025, the crisis peaked with at least 20–24 children (all under age 5) dying in the district of Chhindwara (in the central Indian state of Madhya Pradesh) after consuming the Coldrif cough syrup. (chemistryworld.com) Laboratory tests revealed that the contaminated batch contained diethylene glycol (DEG) in amounts nearly 500 times the permissible limit. (Sky News) DEG is a toxic industrial solvent; ingestion in children leads to acute kidney injury, multi-organ failure, brain damage and death. (Deccan Herald) The cluster of deaths triggered urgent investigations; arrests were made of the owner of the manufacturing firm, G. Ranganathan, and manufacturing licences were revoked. (The Financial Express) The contamination apparently resulted from substitution of glycerin/solvent with DEG (or inadequate purification) — a formulation failure compounded by deficient oversight. The main causes include poor manufacturing practice, inadequate raw-material testing, insufficient batch-release testing for toxic solvents, weak regulatory enforcement and supply-chain lapses. Delay in recognising the link (two weeks between first deaths and regulatory action) also exacerbated the toll. (The Times of India)

9. Public Health and Regulatory Actions

Responding to the tragedy, Indian state governments (Madhya Pradesh, Uttar Pradesh, West Bengal among others) banned Coldrif and ordered product recalls. (News on Air) The central agency (CDSCO) notified the World Health Organization (WHO) and issued Medical Product Alert N°5/2025 for contaminated oral liquid medicines in India. (World Health Organization) New manufacturing and testing norms were mandated — including mandatory testing for DEG/EG (ethylene glycol) in finished pharmaceutical products, insertion in

Indian Pharmacopoeia monograph and stricter GMP compliance, with a deadline for all plants to upgrade by year-end. (India Today) Arrests of manufacturer and prescriber occurred (also a doctor alleged to have received commissions for prescribing Coldrif). (www.ndtv.com) The WHO flagged a regulatory gap in domestic (non-export) syrup batches, and emphasised strengthening surveillance, especially in informal/unregulated supply-chains. (Reuters)

10. Clinical Implications and Recommendations

For paediatricians and pharmacists:

- Avoid routine use of multi-component cough/ cold syrups in children under 5 (and especially under 2), unless clinically warranted.
- Verify batch numbers and product recalls when using any paediatric syrup; stop use of any batch that is subject to recall or alert (e.g., Coldrif batch SR-13).
- Consider safer alternatives: non-medicated symptomatic relief (humidified air, hydration), single-ingredient formulations with established safety profiles.
- Report any unusual adverse effects (e.g., rapid onset kidney-injury after cough syrup) to pharmacovigilance authorities.

For caregivers/parents:

- Be aware that not all medication is risk-free for children; store medicines safely, verify prescriptions, and avoid administering cough syrups without consulting a qualified paediatrician.
- Return any suspect bottles of syrup if a recall notice has been issued.
- Practice non-pharmacological symptom relief (e.g., rest, fluids, saline nasal drops) before resorting to combination syrups in young children.

11. Future Research Directions

There remains a critical need for:

- Rigorous clinical trials of paediatric cough/cold syrups (age-stratified) to establish benefit vs. harm in children 2–8 years.
- Systematic pharmacokinetic and safety data in younger age groups (infants, toddlers).
- Research into manufacturing chain vulnerabilities (raw material sourcing, excipient substitution, solvent purification) and supply-chain traceability.
- Evaluation of national/regional regulatory implementation and monitoring of GMP compliance in the Indian manufacturing sector.
- Development of rapid on-site assays for toxic solvent contamination (DEG/EG) accessible to state regulators and manufacturing QA labs.

12. CONCLUSION

The Coldrif tragedy underscores a sobering truth: even widely-used paediatric medications must be manufactured and regulated with utmost integrity. While the symptomatic relief of cough/ cold in children is an important therapeutic goal, the risk of fatal contamination steeply alters the benefit-risk equation. The incident in Madhya Pradesh and beyond serves as a stark warning that manufacturing quality, regulatory oversight and supply-chain vigilance cannot be compromised. For children's health, the dictum must be: medicine meant to heal must never harm.

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