# Review Article Recent Cough-Syrup Disaster: epidemiology, causes, clinical course, regulatory failures and preventive actions

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***Abstract*—Over the past decade contaminated cough syrups for children that contain industrial glycols (ethylene glycol, or EG, and diethylene glycol, or DEG) have repeatedly resulted in mass poisonings and child fatalities in low- and middle-income nations throughout the last ten years. Over-the-counter (OTC) drugs are frequently used to treat common paediatric diseases like cough and cold symptoms (CCS). On the other hand, not enough is known about the toxicity and safety of these drugs in children. Therefore, protecting children's health requires an awareness of their clinical toxicological. This narrative review emphasises the value of clinical toxicology in assessing the toxicity profile and safety of over-the-counter drugs used to treat paediatric CCS.**

**A current outbreak in India in October 2025 has brought to light ongoing deficiencies in supply-chain supervision, quality control, and regulatory enforcement. This review provides practical suggestions to stop such catastrophes by summarising the available epidemiology, toxicological, clinical presentation, laboratory diagnosis, treatment, production, and regulatory failures. Priorities include quick adverse-event surveillance, enhanced traceability of raw materials, strengthened independent laboratory capability, required glycol testing of excipients and finished liquids, and international collaboration to prevent the import or export of suspect batches.**

## I. INTRODUCTION

The most well-established cause of mass poisonings worldwide is the contamination of oral liquid medications with industrial solvents, most frequently DEG and EG. Even at low concentrations, these substances are poisonous and can kill young children as well as cause acute kidney injury (AKI) and central nervous system depression. A new cluster of child mortality in India in October 2025 has sparked international alarm and triggered regulatory actions, following significant incidents in The Gambia, Uzbekistan, and India (2022–2023)

## II. EPIDEMIOLOGY

The poisoning incidents disproportionately affected young children, who are more vulnerable due to their lower body weight and limited physiological reserves

## III. MAJOR INCIDENTS INCLUDE

- The Gambia (2022): Over 70 children died from acute kidney failure after consuming contaminated cough syrups manufactured by Maiden Pharmaceuticals.
- Uzbekistan (2023): At least 18 children died after ingesting DEG-contaminated medicines made by Marion Biotech.
- Indonesia (2022): 99 children died from contaminated syrups, though the products were not linked to the Gambian incident.
- India (2025): At least 23 children died in Madhya Pradesh and Rajasthan after taking Coldrif cough syrup, manufactured by Sresan Pharmaceuticals [1–4]

In order to give doctors, public health officials, and policymakers a clear, evidence-based picture, this review summarises recent publications and recommendations [5].

## IV. WHAT IS COLDRIF?

- Sresan Pharmaceutical Manufacturer, based in Tamil Nadu, India, produces cough syrup under the Coldrif brand.

- The particular batch in question is SR-13, which was produced in May 2025 and has an expiration date of April 2027.
- According to reports, its commercial formulation contains popular cough syrup active components such paracetamol, phenylephrine hydrochloride, and chlorpheniramine maleate, which is frequently found in cough and cold medications (26).

## V. CAUSES

OTC medicine poisoning is especially dangerous for children because of their developing physiology and their undeveloped drug metabolism and excretion systems. Furthermore, there is a considerable chance of negative side effects when children use over-the-counter (OTC) drugs improperly or excessively.

These catastrophes are mostly caused by the unethical and unlawful replacement of pharmaceutical-grade excipients with less expensive, hazardous industrial solvents. Diethylene glycol (DEG) and ethylene glycol (EG), which are found in automotive brake fluid and antifreeze, are the most toxic adulterants. Without specific laboratory testing, it is challenging to identify the presence of these compounds because they are colourless, odourless, andsweet-tasting [25].

Immoral production methods: To cut production costs, manufacturers use cheaper, industrial-grade DEG instead of pharmaceutical-grade propylene glycol or glycerin.Contaminated supply chains: These harmful compounds are introduced into the supply chain through the employment of unreliable vendors and the absence of required batch-wise raw material testing [25].

## VI. BACKGROUND AND URGENCY

A cough syrup (batch SR-13, Coldrif) contaminated with diethylene glycol (DEG) was implicated in several child fatalities in India in October 2025. There are reports of large poisonings in other nations due to DEG/ethylene glycol contamination in liquid medications, therefore this is not an isolated incident. The catastrophe highlights structural flaws in post-market surveillance, regulatory supervision, and pharmaceutical supply chains.

| Risk | Consequence |
|---|---|
| Use of non-pharmaceutical grade glycols or adulteration | Introduction of toxic solvents into medicines |
| Inadequate testing of excipients & finished products | Failures to detect contamination before distribution |
| Weak traceability and recall capacity | Inability to isolate and remove harmful lots |
| Delayed adverse-event detection | Loss of critical time in initiating public health response |
| Regulatory gaps / fragmented lab capacity | Inconsistent enforcement and oversight |

## VII. RECOMMENDED URGENT ACTIONS

### A. Regulatory & Quality Assurance Measures

1 Mandatory DEG/EG examination Require all manufacturers of oral liquid formulations, particularly those for children, test their final products and excipients (glycerine, propylene glycol) for DEG/EG using approved chromatographic techniques (e.g. GC, LC-MS).

Enforce certificates of analysis at the batch or lot level that specifically attest to the absence (or permissible limit) of industrial glycols.

2 Facilitate audits of good manufacturing procedures (GMP)

Increase the regulatory inspection capabilities to examine internal quality control records, the glycol supply chain, and excipient suppliers. Cross-check supplier certifications and implement "surprise audits" of liquid formulation facilities.

3 Establish centralised reference labs.

Establish or assign regional chemical analysis and toxicology labs with GC/MS or LC/MS capabilities. Require manufacturers to submit a sample of every lot for independent testing on a regular basis.

4 Serialisation & traceability

To allow for accurate recalls, all bottles and pack units must be serialised (have unique identifiers). Keep digital records that trace the origins of final product lots to the suppliers of raw materials, production dates, shipping, and distribution networks.

5 Quick recall, alert, and compensation procedures
Establish legal deadlines for sample testing, public notice, suspect lot recalls, and victim compensation. As soon as contaminated stock is discovered, give authorities the authority to confiscate, destroy, and stop its sale.

B. Surveillance, Reporting & Response
6. Constant monitoring of adverse events
Use sentinel reporting in paediatric hospitals, particularly in nephrology and paediatrics: groups of deaths or unexplained AKI should prompt an investigation. Require doctors to notify the appropriate regulatory body right away if they suspect medication-associated poisoning.

7. Public & clinician communication systems
Provide a real-time recall/alert site with a list of questionable items and safe substitutes that is available to pharmacies and clinicians Conduct periodic public awareness efforts regarding the dangers of using paediatric syrups safely, for example, through the media or drugstore notes.

C. Legal, Institutional & Cross-Border Controls
8. Criminal Responsibility and Liability
Establish laws that make business executives (manufacturers, importers, and suppliers) criminally accountable for deliberate carelessness or adulteration. To improve compliance capacity, however, combine enforcement with assistance

9. International coordination
Interact with WHO, international pharmaco-vigilance networks, and trade partners' drug regulatory bodies to exchange supplier intelligence, banned lot information, and alerts. Implement strict controls on the import and export of liquid medications and excipients; refuse or test shipments that seem questionable.

10. Capacity building and funding
Provide funding to improve the infrastructure for chemical analysis at national regulatory laboratories. Teach inspection teams, QC chemists, and regulatory personnel how to identify adulterants in liquid formulations

Recent Outbreak(S) And Epidemiology (Oct 2025)
Consumption of a product advertised as Coldrif (batch SR-13), produced by Sresan/Shreesan (Tamil Nadu), has been linked to child deaths in several Indian states. About 20–23 children died in Madhya Pradesh and other areas, according to reports in October 2025; the product apparently tested highly positive for diethylene glycol [8]. While conducting sample testing, authorities have banned the batch and detained company leaders [6, 7].
These incidences are the most recent in a string of global occurrences (most notably The Gambia, 2022) where syrups made in India were implicated; previous WHO medical product alerts revealed DEG/EG contamination connected to child deaths. WHO and government cautions were prompted by the cumulative worldwide impact of previous incidents, which surpassed dozens of infant deaths [2, 4, 9]

## VIII. TOXICOLOGY AND MECHANISM OF INJURY

DEG and EG are small, sweet-tasting solvents that are occasionally used illegally as low-cost alternatives to pharmaceutical glycols (such as propylene glycol and glycerine) [10]. After intake, they undergo metabolism to produce hazardous metabolites (oxalic and glycollic acids), which result in renal tubular necrosis, metabolic acidosis, and central nervous system depression [11, 12]. Due to their low body weight and diminished renal clearance, children are particularly at risk. Usually, the clinical course starts with CNS and gastrointestinal symptoms and advances over the period of 24 to 72 hours to AKI and, if left untreated, death [13].

Clinical Features, Diagnosis and Management
Clinical alert signs include vomiting, lethargy, decreased urine output, oliguria/anuria, fast respiratory compensation for metabolic acidosis, and elevated creatinine in children who have just consumed cough syrup [11]. Laboratory: increasing azotaemia, elevated osmolar gap, high anion gap metabolic acidosis; toxicologic assays identify DEG/EG when they are available [12].

Principles of management:
Airway, respiration, circulation, convulsions, and fluid status should all be managed immediately Fomepizole, which inhibits alcohol dehydrogenase, is the primary antidotal medication; ethanol provides a backup in case fomepizole is not available [14]. Improved

elimination: early haemodialysis in cases of high toxicant levels, renal failure, or severe metabolic acidosis [15]. Public health: identify and eliminate contaminated lots; active case finding and notify the public and medical professionals [8, 16].

Manufacturing, supply-chain and regulatory failures patterns and lessons

Across outbreaks, recurring root causes have been found to include: Sometimes caused by financial strains or inadequate supplier screening, adulteration or substitution of industrial glycols (DEG/EG) for pharmaceutical excipients (glycerine/propylene glycol) occurs. Lack of regular screening for DEG/EG in raw materials and final liquid formulations is an example of inadequate incoming quality testing at manufacturers [5, 17, 18]. Failures in detection and enforcement are caused by dispersed laboratory capacity and inadequate regulatory monitoring [19]. Recalls are made more difficult by the inability to trace raw ingredients and completed units across domestic distribution and export. In outpatient paediatrics, inadequate adverse event monitoring delays the identification of unusual clusters [19].

India's regulatory body, DCGI, has tightened regulations in reaction to the October 2025 incident, requiring DEG/EG testing of raw materials and finished products as well as rapid sample testing. These measures are similar to WHO recommendations but must be implemented rigorously [20].

## IX. PUBLIC-HEALTH AND REGULATORY RESPONSES (RECENT)

- Immediate action: stock seizures, product bans, targeted testing of additional lots and manufacturers, and, if appropriate, the arrest of responsible company personnel [3, 21].
- Tighter regulations include centralised reporting, increased laboratory capacity, and required testing for DEG/EG in excipients and final goods (announced by DCGI and echoed by international authorities) [7, 20, 22].
- International coordination: Several national regulators, including the US FDA, have publicly monitored the situation and released recommendations for import/export surveillance; WHO has previously issued medical product alerts and asked member states to investigate supply chains [23]

## X. RECOMMENDATIONS CLINICALLY ACTIONABLE AND POLICY LEVEL

Clinical / public health

High index of suspicion: Any group of paediatric AKI cases or unidentified fatalities should raise questions about recent medication use very away. Children with metabolic acidosis or oligouria should receive triage and early dialysis; if fomepizole is available, give it to them. Quick communication: Parents and physicians should receive clear instructions from local health authorities regarding suspect lots and safe substitutes.

Supply Chain and Manufacturing

All glycerine/propylene glycol lots and all completed oral liquids meant for children must undergo mandatory DEG/EG screening (regulator-mandated, with batch certifications). Vendor qualification and traceability: suppliers' chains and certificates of analysis must be recorded by manufacturers, and these records should be audited by regulators [20, 23]. Periodic blind testing by government labs to confirm industry conformity is known as independent third-party testing

International And Regulatory

Fast-track alerts and standardised testing procedures: establish cross-border rapid-alert systems and align national pharmacopoeia standards to mandate glycol limits. Analytical lab capacity building: Invest in regional reference labs' chromatography and mass spectrometry capabilities.

System reforms must be combined with legal and criminal accountability; while criminal enquiries are justified in cases of intentional neglect, systemic regulatory strengthening is necessary for prevention [3, 21].

Limitations Of Current Evidence

Rapid news reporting and early lab advisories provide a large portion of the immediate information; in many countries, definitive case counts and forensic laboratory confirmations are still pending. There aren't many longitudinal studies that measure the actual global burden. Official WHO, national regulator, and major news agency sources are cited wherever

possible in this study; nevertheless, certain details may change as a result of continuing investigations [18, 24]

## XI. CONCLUSION

The cough syrup poisonings in October 2025 serve as an alarming reminder that avoidable paediatric medication contamination still results in a devastating mortality rate. Technical solutions (lab capacity, traceability, and mandated DEG/EG testing) can be put into place, but they need to be combined with consistent regulatory enforcement, open public reporting, and international collaboration. Public health officials should give priority to removing problematic lots and assisting affected families, and clinicians should continue to be on the lookout for the distinctive clinical condition. Future tragedies can be avoided by taking urgent policy action now.

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