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THE DEADLY CONSEQUENCES OF CONTAMINATED MEDICINE: A LOOK INTO THE KILLER COUGH SYRUP CASE

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ABSTRACT

In 2025, India faced a major public health crisis following the deaths of several children who consumed a cough syrup contaminated with diethylene glycol (DEG), a highly toxic industrial chemical prohibited in pharmaceutical formulations. The affected product, intended for pediatric use, contained DEG due to the substitution of pharmaceutical-grade excipients with industrial-grade solvents, reflecting severe lapses in Good Manufacturing Practices (GMP) and quality control. DEG toxicity primarily targets the kidneys, leading to acute renal failure, metabolic acidosis, neurological complications, and multi-organ dysfunction, particularly in children due to their physiological vulnerability. The incident prompted immediate regulatory actions, including product bans, recalls, seizures, suspension of manufacturing licenses, and legal proceedings against the responsible manufacturer. The World Health Organization (WHO) issued a Medical Product Alert, highlighting the global risk posed by contaminated liquid medicines and urging heightened international vigilance.[31] This tragedy underscores the critical importance of strict excipient quality assurance, robust regulatory oversight, and strengthened pharmacovigilance systems to ensure the safety of pediatric medicines and prevent similar incidents in the future.

KEYWORDS: Diethylene glycol, pediatric drug toxicity, acute renal failure, pharmaceutical adulteration.

INTRODUCTION

In 2025, India—particularly the state of Uttar Pradesh—witnessed a serious public health tragedy involving the deaths of several children after the consumption of a cough syrup contaminated with diethylene glycol (DEG). DEG is a highly toxic chemical commonly used as an industrial solvent and antifreeze agent and is strictly prohibited in medicines intended for human use.[1] This tragic incident raised widespread concern among regulatory authorities,

pharmaceutical manufacturers, healthcare professionals, and the general public regarding the safety, quality, and regulatory oversight of pharmaceutical products. The event was especially alarming because the contaminated medicine was a pediatric formulation, intended for use in children, who are particularly vulnerable to toxic substances.[2]

Diethylene Glycol (DEG)

Diethylene glycol is not approved for use in any pharmaceutical formulation meant for human consumption. It is widely used in various industrial applications, such as solvents in paints, inks, brake fluids, and antifreeze formulations. DEG may also function as a humectant or plasticizer in certain non-pharmaceutical products. However, in some instances, DEG has been accidentally or deliberately substituted for safer pharmaceutical-grade solvents like glycerol or propylene glycol, which are commonly used in oral liquid medicines. This substitution may occur due to inadequate quality checks or as a cost-cutting measure, as DEG is significantly cheaper than pharmaceutical-grade excipients. Such practices represent a serious violation of Good Manufacturing Practices (GMP) and pose grave risks to patient safety.

BACKGROUND

Cough syrups are among the most frequently prescribed medicines for children to relieve symptoms of cough, cold, and mild respiratory infections. The tragic outcome of the contaminated cough syrup incident highlights critical failures in pharmaceutical manufacturing and quality assurance. The use of non-pharmaceutical-grade raw materials, combined with inadequate testing for toxic contaminants, allowed DEG to enter the final formulation. DEG is extremely toxic even when ingested in small quantities. Once consumed, it can cause acute kidney failure, liver damage, severe metabolic acidosis, neurological complications, and death, with children being at the highest risk due to their lower body weight and underdeveloped detoxification systems. This incident underscores the urgent need for strict excipient quality control, rigorous testing of raw materials, and robust regulatory oversight, particularly for medicines intended for pediatric use.

KEY EVENTS THAT LEAD TO THE BAN

September–October 2025: Pediatric Deaths Reported: Between September and October 2025, several children in Madhya Pradesh and Rajasthan died after consuming a cough syrup that was later found to be contaminated.[21] The syrup had been manufactured in Tamil Nadu and was prescribed to treat common respiratory symptoms such as cough and fever. Instead of providing relief, the medicine caused severe toxicity, leading to acute kidney failure and death in multiple pediatric patients. These deaths raised immediate concerns about the safety of the product and prompted investigations by state health authorities.

October 2, 2025: Confirmation of Adulteration: On 2 October 2025, Drug Control authorities in Tamil Nadu officially confirmed that the cough syrup was adulterated with dangerously high levels of diethylene glycol (DEG)[23]. DEG is a toxic industrial chemical not permitted in pharmaceutical formulations. This laboratory confirmation provided clear evidence that the product failed to meet safety and quality standards and posed a serious public health risk.

October 4, 2025: State-Level Bans and Seizures: Following the confirmation of contamination, the Madhya Pradesh government imposed an immediate ban on the sale and distribution of the affected cough syrup on 4 October 2025[21]. As a precautionary measure, the governments of Tamil Nadu and Kerala also initiated bans and conducted widespread stock seizures to prevent further exposure. These actions aimed to quickly remove the contaminated product from the market and limit additional harm.[23]

October 10, 2025: Ban by Delhi Government: On 10 October 2025, the Delhi government issued its own ban on the cough syrup after official testing declared it "Not of Standard Quality (NSQ)" under drug regulatory guidelines. This step reinforced the seriousness of the issue and demonstrated the spread of regulatory concern across major regions of the country.

October 13, 2025: WHO Medical Product Alert: The situation escalated to the international level on 13 October 2025, when the World Health Organization (WHO) issued a Medical Product Alert.[1] The alert warned against specific batches of the contaminated cough syrup and other related products. WHO cautioned that the syrups posed a severe risk to public health, particularly to children, and urged global vigilance to prevent their circulation through both regulated and unregulated supply chains.

INTENDED ACTIVE INGREDIENT

- Paracetamol
- Chlorpheneramine maleate
- Phenylephrine HCl
- Sodium citrate

IDENTIFIED KILLER TOXICANT AND ITS ROLE

The toxic substance responsible for the loss of several children's lives was identified as diethylene glycol (**DEG).**[11] Under normal pharmaceutical practice, pharmaceutical-grade propylene glycol or glycerol is used as a solvent in cough syrup formulations because of their proven safety and compliance with pharmacopeial standards. However, in this tragic incident, the approved pharmaceutical-grade solvent was replaced with an industrial-grade solvent, which was later found to be heavily contaminated with diethylene glycol. The presence of DEG at such an excessive concentration indicates gross negligence, inadequate raw material testing, and serious violations of Good Manufacturing Practices (GMP). This extreme deviation from accepted safety standards directly contributed to the severe toxicity observed in affected children. The limit of diethylene glycol present in the contaminated cough syrup was found to be 46.28%W/V this exceeds the safer limit.[32] The acceptable limit of diethylene glycol is not more than 0.10% by weight according to USP. This exceeded limit produced the serious side effects and leads to death of the children.

WHAT HAPPENED AFTER CONSUMPTION

The children consumed the contaminated cough syrup to relieve symptoms of cough and fever, unaware of the lethal toxicant present in the formulation. Shortly after ingestion, they began to exhibit symptoms of diethylene glycol poisoning, primarily affecting the kidneys. One of the earliest clinical manifestations was **oliguria** (markedly reduced urine output) or **anuria** (complete absence of urine production), which are hallmark signs of acute renal failure. Diethylene glycol is metabolized in the body to toxic compounds that damage renal tubules, leading to the rapid deterioration of kidney function.[10] As renal failure progressed, toxic metabolites accumulated in the bloodstream, causing metabolic acidosis and planning immense stress on other vital. This cascade of events ultimately resulted in multiple organ dysfunction syndrome (MODS), a life-threatening condition in which multiple organ systems fail simultaneously. In many cases, despite medical intervention, the damage was irreversible, leading to the death of affected children.

WHY DEG IS TOXIC?

Diethylene glycol (DEG) is a highly dangerous industrial chemical that is not intended for human consumption. When accidentally or intentionally ingested through contaminated medicines, DEG produces severe and often fatal toxic effects. Its toxicity is mainly due to its metabolism into harmful compounds and its damaging effects on vital organs.

Metabolic Toxicity of DEG: After ingestion, DEG is rapidly absorbed from the gastrointestinal tract into the bloodstream. In the body, it is metabolized primarily in the liver by the enzyme alcohol dehydrogenase (ADH), the same enzyme involved in alcohol metabolism. DEG is converted into toxic metabolites, mainly 2-hydroxyethoxyacetic acid and diglycolic acid.[7] These metabolites are responsible for most of the clinical toxicity. They disrupt normal cellular metabolism and acid–base balance, leading to: Severe metabolic acidosis, where excess acid accumulates in the blood, impairing enzyme function and cellular activity, Acute kidney injury, particularly due to renal tubular necrosis, which severely reduces the kidneys' ability to filter waste and produce urine**.** Neurological toxicity, manifesting as headache, confusion, seizures, reduced consciousness, and eventually coma.[9] The severity of toxicity increases as these metabolites accumulate, especially in children, who have limited detoxification capacity.

Target Organs and Organ-Specific Effects: DEG affects multiple organ systems[8], but the kidneys are the primary target, making renal failure the leading cause of death.[10] Severe acute renal failure due to tubular damage; leads to oliguria or anuria and accumulation of toxins, Central nervous system depression, seizures, altered mental status, and coma[9], Elevated liver enzymes and, in severe cases, hepatic necrosis due to metabolic stress, Secondary respiratory distress caused by severe metabolic acidosis and fluid overload. The combined failure of these vital organs often progresses rapidly to multi-organ failure, which is frequently fatal if not treated promptly.

TIMELINE AND IMPACT

Clinical Progression and Health Impact on Children: Children who consumed the contaminated Coldrif syrup initially presented with common symptoms such as fever and cough, for which the medication was prescribed. However, within a short period, their condition deteriorated rapidly. Many children developed oliguria or anuria, indicating severely reduced or absent urine output, which is a hallmark of acute kidney injury.[10] This progressed to acute renal failure, followed by multi-organ failure, ultimately leading to death in several cases. One documented case involved a four-year-old girl who remained hospitalized for nearly a month while undergoing intensive treatment before succumbing to complications. Such cases highlight the severe and irreversible toxicity associated with diethylene glycol exposure in children.[5]

Mortality and Scale of the Incident: Official reports confirmed that at least 17 child deaths in Madhya Pradesh were directly linked to the contaminated Coldrif batch. However, some sources have suggested that the total death toll may be as high as 24 children, indicating that the full extent of the tragedy may still be under investigation. The high number of fatalities underscores the extreme danger posed by contaminated pediatric medicines.[19]

Regulatory and Legal Actions Against the Manufacturer: In response to the incident, law enforcement authorities arrested the owner of the manufacturing company, reflecting the seriousness of the regulatory violations involved. The company's manufacturing license was suspended, effectively halting its operations. These actions were taken due to evidence of gross negligence, violation of Good Manufacturing Practices (GMP), and failure to ensure product safety.

Government Response and Public Health Measures: The state government took immediate steps to control the crisis. These included ordering a recall of the affected Coldrif batch, stopping further distribution of the product, and initiating criminal investigations against those responsible. Additionally, a public health alert was issued to inform healthcare professionals and the public about the risks associated with the product and to prevent further use.[19]

WHO RESPONSE TO CONTAMINATED COUGH SYRUP

Following reports of child deaths linked to contaminated cough syrups in India, particularly the product Coldrif-the World Health Organization (WHO) has taken several important steps to address the situation. These actions aim to protect public health, prevent further harm, and support national and international regulatory efforts in controlling the spread of unsafe medicines.[13]

Issuance of a Medical Product Alert: On 13th October 2025, WHO issued an official Medical Product Alert concerning certain oral cough syrups manufactured in India that were found to contain diethylene glycol (DEG). DEG is a highly toxic industrial chemical that should never be present in pharmaceutical products. The syrups specifically identified in the alert included Coldrif (manufactured by Sresan Pharmaceuticals), and ReLife (Shape Pharma Pvt Ltd).[4] WHO warned that these contaminated products pose a serious risk to human health, particularly for infants and young children, and can lead to severe illness or death event at low levels of exposure.[29]

Coordination with Indian Regulatory Authorities: WHO was formally informed by India's national drug regulatory authority, the Central Drugs Standard Control Organization(CDSCO), on 8 October 2025 that DEG contamination had been detected in at least three and liquid medicines associated with reported child deaths. In response, WHO began working closely with CDSCO and expressed its readiness to provide technical and regulatory support. This collaboration focuses on investigating the source of contamination, strengthening quality control measures, and ensuring appropriate regulatory actions are taken against the responsible manufacturers.[17]

Global Alert and Call for Heightened Vigilance: Recognizing the risk of international distribution. WHO urged regulatory authority worldwide to remain alert. It emphasized that contaminated syrups could enter both formal and informal supply chains, making detection difficult. WHO specifically warned countries to closely monitor and liquid medicines originating from the same manufacturing facilities, particularly those produced from December 2024 onward. Health systems were advised to promptly report any detection of these products or similar suspicious formulations to WHO.[15]

Public Health Advice and Safety Warnings: WHO strongly advised the public to stop using the identified cough syrups immediately. Individuals who had already used these products and experienced adverse reactions were urged medical attention or contact a poison control center. Additionally, WHO encouraged healthcare professionals and patients to report any adverse drug reactions, unexpected side effects, or treatment failures through national pharmacovigilance systems. Such reporting is essential for early detection of unsafe medicines and for preventing further harm.[31]

SIMILAR CASE HISTORY RELATED TO BANNED COUGH SYRUP

1. The Gambia (2022): The deaths of 70 children were attributed to cough syrups contaminated with DEG and EG. This incident led to heightened scrutiny on Maiden Pharmaceuticals, an Indian company. The contamination was linked to unsafe manufacturing practices and poor-quality control.[24]
2. Indonesia (2022): After nearly 100 children died from kidney failure linked to similar toxic substances in liquid medications, Indonesia's health authorities temporarily banned the sale of syrup and liquid-based medicines. This case raised alarms about the quality control processes in the production and distribution of medicines.[25]
3. Uzbekistan (2022): The deaths of 18 children from consuming a contaminated cough syrup called Dok-1 Max, produced by Marion Biotech, led to further investigations. It was found that the syrup contained industrial-grade propylene glycol, which had not undergone proper testing for contaminants. This case exemplifies the risks associated with using untested raw ingredients in pharmaceuticals.[26]
4. Cameroon (2023): A WHO alert was issued after several child deaths were linked to the Naturcold cough syrup, which contained high levels of DEG. This product, manufactured by Riemann Private Ltd, was found to be misrepresented as being produced by a non-existent UK company, raising questions about the company's authenticity and accountability.[27]
5. Marshall Islands and Micronesia (2023): The Guaifenesin TG syrup from QP Pharmachem, another Indian manufacturer, was also found to be contaminated with harmful substances and distributed to these regions, prompting further international concern.[28]

CONCLUSION

The 2025 diethylene glycol–contaminated cough syrup tragedy highlights a serious failure in pharmaceutical manufacturing and regulatory oversight. The use of an industrial toxicant in a pediatric formulation led to acute renal failure and the death of several children, emphasizing the critical importance of strict adherence to Good Manufacturing Practices and rigorous excipient quality control.[31] Strengthened regulatory surveillance, mandatory raw material testing, and effective pharmacovigilance are essential to prevent such incidents and ensure the safety of medicines, especially for vulnerable populations like children.

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