COMMENTARY

Rational use and regulatory stewardship for paediatric cough syrups in India: A public health imperative

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Abstract

Recurrent paediatric deaths from diethylene glycol (DEG)-contaminated cough syrups in India highlight critical failures in regulatory stewardship and rational medicine use. Despite global alerts and domestic advisories, children continue to be exposed to hazardous, non-essential multiple-drug combinations. This commentary analyses the intersection of clinical irrationality and regulatory gaps, arguing that persistent reliance on over-the-counter (OTC) cough syrups for self-limiting viral illnesses in children under five is ethically indefensible. We review recent incidents (2022–2025) and policy responses, identifying persistent weaknesses in supply-chain oversight and excipient testing. We propose a four-pillar stewardship roadmap: clinical restraint to curb unnecessary prescribing; rigorous quality assurance, including universal batch testing; intensified market surveillance; and public communication to counter misconceptions. Aligning India's paediatric pharmaceutical governance with WHO rational use principles is urgently needed to prevent further avoidable mortality and restore trust in the public health system.

Keywords: *diethylene glycol contamination, pharmacovigilance, public health policy India, paediatric cough syrups, regulatory stewardship, rational medicine use*

Clinical context and rationale

Acute cough and cold in children are usually viral, self limited illnesses that resolve without medicines. Systematic reviews, such as Cochrane analyses, have shown that antitussives and cough/cold combinations, purchased from pharmacies, do not have any clinically significant effect compared to placebo in young children. Importantly, this lack of efficacy is accompanied by potential harms such as sedation, respiratory depression, paradoxical excitation and dosing errors especially in children under 5 years [1-3]. The World Health Organization (WHO), Medicines and Healthcare products Regulatory Agency (MHRA), and national advisories discourage routine use of paediatric cough/cold syrups and favour non-pharmacological care as first-line treatment [1,4-6]. WHO's rational use principles emphasise that medicines should be used only when they offer a favourable balance of benefit, harm, and cost, and when safer alternatives are not available [4].This approach is particularly important in the context of paediatric over-the-counter (OTC) products, where both the evidence base and children's vulnerability to adverse effects (AEs) demand heightened caution. In other words, our concern is not that every paediatric cough syrup is uniformly harmful in every child, but that in young children the overall benefit-risk balance is unfavourable: clinically meaningful efficacy is unproven or minimal, whereas AEs, dosing errors, and exposure to irrational multi-ingredient formulations remain real and avoidable risks.

Strict regulatory control and rational prescribing is thus of paramount importance, particularly in India, where easy access to OTCs, and expectations among caregivers, encourage unnecessary use [5,7]. As these factors combine with the flaws in manufacturing control and supply-chain management, children are inadvertently exposed not just to preventable medicine-related harm but to the devastating consequences of contaminants/adulterants like diethylene glycol (DEG) and ethylene glycol (EG). Ethically and as a public-health matter, recurrent, avoidable paediatric fatalities from cough syrup contamination point to systemic weaknesses and, in many cases, failures in regulatory stewardship and justice, rather than solely individual technical misjudgement.

This commentary examines the experience of paediatric cough syrup in India between rational usage of medicine and regulatory stewardship. Drawing on WHO alerts, Indian regulatory and policy documents, peer-reviewed literature, and credible media reports from 2022–2025, we review recent paediatric DEG/EG incidents, analyse India's regulatory and clinical responses, and identify persistent gaps in domestic surveillance, OTC governance, and ethical accountability. We then propose a pragmatic four-pillar roadmap — clinical restraint, quality assurance, market surveillance, and public communication to realign India's approach to paediatric cough and cold management based on WHO rational use principles and the state's duty to protect children.

We propose a stewardship approach for safe and rational use of paediatric cough syrups, similar to that used in antimicrobial stewardship programmes, including (i) prescriber education for paediatricians and primary care physicians, (ii) policies to restrict use of OTC remedies for children under six years, (iii) periodic prescription audits, (iv) clinical decision support system integration, and (v) regulatory enforcement for adherence to evidence-based guidelines. These five operational interventions are practical measures to implement the clinical and systems aspects of our broader four pillar stewardship roadmap (clinical

restraint; quality assurance; market surveillance; public communication), which together form our recommended approach.

The term "stewardship" in this context refers to clinicians, regulators, manufacturers, and the public, working together to make sure medicines are used only when truly needed, are safe and of high quality, and do as little harm as possible. This includes careful prescribing, strict checks on quality, strict implementation of rules, and awareness building among people on using medicines wisely [4]. We have consistently used this term to signify that both clinicians and regulators share the duty to safeguard children's health.

For clarity, our stewardship proposal adopts a precautionary operational threshold for children under six years, while also acknowledging current advisories against use below two years [5] and broader recommendations discouraging routine use below five years [1,2].

Current landscape: Incidents, oversight gaps, and policy actions

Recent deaths involving paediatric cough syrup in India and abroad reveal system-wide failures across product development, manufacturing, approval, prescribing, dispensing, and post-marketing surveillance. WHO's rational use principles — appropriate medicine, dose, duration, and cost — should guide India's approach to paediatric cough and cold management, particularly in children under five years [4]. Yet, in practice, children in this age group continue to remain vulnerable to irrational products and to unacceptable manufacturing and supply-chain risks. This perspective examines how shortcomings at the interface of rational use and regulatory stewardship in paediatric therapeutics have allowed unsafe and unnecessary cough syrups to persist in routine care.

In October 2025, a state investigation reported DEG-adulterated syrup and extensive non-compliance with good manufacturing and laboratory practices/Schedule L-1 (GMP/L-1) at a manufacturing facility, including failures in excipient control, documentation, and testing, and underscored the need for universal excipient controls, advanced laboratory testing methods to detect toxic impurities (ie lot-level impurity testing), and risk-based inspections [8]. In response to the series of international deaths linked to contaminated Indian-made cough syrups, the Central Drugs Standard Control Organisation (CDSCO) initiated stringent monitoring of high-risk pharmaceutical solvents such as propylene glycol (PG), glycerin, and sorbitol. Manufacturers are now required to register and upload comprehensive batch-level data — including manufacturing details, vendor information, and supply records — on the One Nation One Drug Licensing System portal to enhance traceability and ensure quality control across the supply chain [9]. However, traceability of excipients such as glycerine and PG should extend beyond manufactured pharmaceutical products, further up the chemical supply chain to manufacturers, distributors and re-packagers. Regulatory oversight on chemical trade practices such as mandatory supplier audits and certification should be strengthened to prevent adulteration and substitution with toxic industrial-grade solvents [5,6,10]. Glycerine, PG and similar substances are commonly used as ingredients in cough syrups when pharmaceutical-grade standards are maintained. However, toxic substances such as DEG/EG may enter the supply chain as contaminants, particularly in settings with inadequate quality control. This underscores the importance of strict regulatory oversight, supplier verification, and routine testing of raw materials [6,11]. Glycerine is a common and generally safe excipient in paediatric syrups when it is of pharmaceutical grade; however, contamination risk arises when non pharmaceutical or industrial grade glycerine is used, underscoring the regulator's role in supplier auditing and lot level testing [12].

Since 2022, international alerts on child deaths, including those from Gambia, Uzbekistan and within India, have highlighted serious regulatory breaches. Antitussives and multiple-drug combinations offer little benefit to children, while adulterated or insufficiently tested excipients pose severe preventable risks [13,14]. These recent fatalities add to a long history of DEG poisonings in India, and in spite of much debate on why such deaths continue to occur and responses by the regulatory authorities, the underlying failures in deterrence and accountability still persist [15].

Paediatric cough syrups, in particular, often marketed as inoffensive medications for seasonal colds, have turned out to be deadly products of failed quality systems. Human beings are very sensitive to DEG — outbreak studies have reported fatalities at exposures as low as 14 mg/kg, even making trace contamination lethal [16]. DEG and EG are not permitted as intentional components of paediatric oral liquids; however, they may occur as contaminants in high risk excipients (eg, glycerin, propylene glycol, sorbitol, maltitol), which is why regulators emphasise stringent testing of raw materials and finished formulations [17]. WHO guidance for oral liquid preparations recommends screening for DEG/EG and specifies that concentrations of DEG and EG should each be *not more than 0.10% (m/m)* [18]. Recent paediatric deaths in the Gambia were associated with the use of DEG-contaminated syrups, a symptom of supply chain and testing failure, which is in direct contravention of the policies of WHO and the US Centers for Disease Control and Prevention (CDC) [19]. Such recurrent events reflect gaps in implementation and enforcement across the regulatory–manufacturing–supply chain continuum, rather than any regulatory acceptance of unsafe excipients [15].

India has responded with several regulatory measures such as mandating pre export testing of cough syrups at government and National Accreditation Board for Testing and Calibration Laboratories, with batch level certificates required before export [20]. Schedule M of the Drugs Rules

was revised to align with WHO GMP, tightening expectations around pharmaceutical quality systems, quality risk management, validation, supplier qualification, and recall processes. However, phased timelines for full compliance were subsequently extended for micro, small & medium enterprises (MSME) [21]. The repeated occurrence of DEG toxicity has been traced to adulteration or process impurities in high-risk excipients, fragmented supply chains, inadequate supplier qualification and lack of lot-by-lot identity testing: a systemic failure to check DEG contamination. However, the major priority of the authorities seems to be restoring confidence in the export markets, and not so much securing safety in the domestic paediatric market. Surely, Indian children deserve the same assurance of safety at home as overseas buyers.

No doubt the Indian authorities have taken some important corrective steps from time to time. In December 2023, the national regulator had ordered a widely used anti-cold combination (chlorpheniramine maleate + phenylephrine) to display a clear warning against use in children below four years [10, 22]. In addition, pre-export government laboratory testing and certification for cough syrups were mandated from June 2023, an important step to protect importing countries and restore confidence in Indian pharmaceutical exports [22]. Following repeated episodes of DEG-related child fatalities, including those reported as recently as October 2025, and the resulting international outcry [22], Indian regulators moved beyond advisory-level measures to restrict OTC sales of certain cough and cold preparations, marking a shift toward prescription-only status [23]. More recently, central advisories reiterated that cough and cold medications should not be prescribed or dispensed to children under two years and are generally not recommended for children below five years of age; and that non-pharmacological measures should be the first line treatment [5]. These advisories are consistent with WHO's advice that OTC cough/cold medicines are NOT recommended in children under five years of age [2] and the warnings of other regulators on paediatric OTC use and labelling (eg FDA and MHRA) [1,6]. Taken together, this emerging policy framework affirms that routine paediatric cough syrup use in young children is neither evidence-based nor ethically defensible.

However, three urgent gaps persist:

1. ***Prescription practices and OTC access***

   For most viral upper respiratory infections (URIs) in children, pharmacological antitussives and multi-ingredient syrups offer little benefit and carry serious risks including those of sedation, respiratory depression, and dosing errors. Regulatory warnings must therefore be matched by strict OTC controls, pharmacist stewardship, and prescriber education. In spite of the evolving guidance, multi-ingredient cough/cold preparations are still readily accessible and a ubiquitous part of young children's treatment.

2. ***Misuse potential and inadequate prescription-only enforcement***

   Furthermore, codeine, or other such drugs contained in cough syrups, could be abused resulting in addiction, especially among teens and young adults [24]. The danger of abuse also requires tightening of the reins, and increased regulation of prescription of such products is hence a significant constituent of rational and safe use [1]. Due to the safety risks and abuse potential, several jurisdictions, including India, have restricted access to codeine-containing products (and other antitussive formulations), limiting them to prescription-only status, since even therapeutic doses (100ml bottle equivalent to 30mg tablet of morphine)can cause sedation, respiratory depression, and misuse; stringent dosage limits are enforced under narcotics control regulations [21,25].

3. ***Domestic quality oversight and post-marketing surveillance gaps***

   While export testing has been tightened, domestic market surveillance, routine GMP inspections, and batch testing of excipients (eg, glycerin, PG) need further strengthening. WHO has explicitly stated that DEG/EG events demand comprehensive excipient qualification and risk-based targeted testing throughout the supply chain, rather than narrow, one-time measures focused only on finished-product testing [7]. Without such system level reforms, new clusters of avoidable paediatric deaths remain a foreseeable risk. The implementation of comprehensive post-marketing surveillance in India is faced with certain practical issues such as lack of laboratory capacity, limited workforce, and funding. Integrating domestic market surveillance, routine GMP inspections, excipient batch testing, recall monitoring, and adverse-event reporting with existing systems such as the drug safety monitoring programmes (Pharmacovigilance Programme of India [PvPI]), while leveraging digital reporting platforms, and risk-based prioritisation could improve feasibility and optimise resource utilisation [6,26]. A potentially feasible financing model would be to prioritise high-risk paediatric oral liquids within existing central and state drug-regulatory budgets, while integrating laboratory testing, recall monitoring, and adverse-event reporting into existing platforms such as CDSCO systems and the PvPI. A phased, risk-based approach —rather than universal untargeted sampling of all products — would make post-marketing surveillance more implementable and financially sustainable in the Indian setting.

   An important ethical dimension that remains under-addressed is that of compensation for the affected families. When children die due to contaminated medicines, manufacturers bear both the legal and moral responsibility to ensure product safety. Regulatory authorities also have a duty to enforce accountability and

facilitate timely compensation. Establishing clear mechanisms for liability, compensation funds, and rapid legal redress is essential to uphold justice and repair public trust [7]. We propose that regulators mandate a statutory compensation mechanism analogous to established no-fault vaccine injury compensation programmes such as the United States National Vaccine Injury Compensation Program [27], whereby manufacturers provide financial guarantees or insurance to enable prompt compensation; and regulators expedite claims adjudication while pursuing legal and criminal liability where negligence is established.

Beyond contamination control, India's paediatric cough/cold care faces a rational use deficit. Non-prescription access to antitussives and multiple-drug combinations, heterogeneous state-level enforcement, and persistent promotional influences normalise pharmacologic treatment of self-limited viral URIs in under-fives, contrary to WHO and national advisories discouraging these products in young children. Weak OTC controls and fragmented regulatory capacity allow irrational products to remain widely available, undermining prescriber guidance and caregiver education despite limited benefit and real harms to this age group [1,2,4,5]. These are structural problems in how medicines are regulated, not merely individual-level prescribing errors [15]. In the following sections, we propose a pragmatic stewardship roadmap spanning clinical restraint, quality assurance, market surveillance, and public communication to address these intertwined ethical and regulatory failures.

Pragmatic stewardship road map

We propose four mutually reinforcing pillars:

1) *Clinical restraint:* Avoid routine OTC cough/cold syrups in children <6 years; emphasise symptomatic care (fluids, saline; honey ≥1 year), safety-net advice, and documentation of shared decision-making.

2) *Quality assurance:* Implement strict vendor qualification, excipient certificate of analysis (CoAs), risk-based DEG/EG testing for each oral liquid batch, digital batch records, and release-only-after-results.

3) *Market surveillance:* Intensify risk-based inspections; random sampling of syrups at state laboratories; strengthen drug safety monitoring (pharmacovigilance) and near-real-time public recall notices.

4) *Public communication:* Ensure clear labelling, caregiver education, myth-busting campaigns, and a national portal that archives alerts and recalls in searchable form. Risk communication should be transparent, factual, and proportionate: it should explain which products or batches are affected, what caregivers should do, and why most childhood coughs remain self-limiting illnesses, best managed with supportive care. Coupling clear warnings with visible regulatory action can reduce misinformation and panic while preserving public trust [28].

The accompanying Supplementary Figures 1 and 2 (available online only) summarise milestones between 2022 and 2025, and operational actions for each pillar, respectively.

Operationalising rational use requires horizontal measures that apply across paediatric products — aligning the National List of Essential Medicines (NLEM) and state Essential Medicines Lists (EMLs), enforcing OTC and age cut-offs, protecting WHO-standard compositions (eg, WHO-ORS) via labelling and retail enforcement, strengthening risk-based inspections (targeted inspections based on higher-risk products and manufacturers), and embedding electronic health records-based prescribing alerts ("nudges") and mandatory prescribing blocks ("hard-stops") to prevent unsafe or age-inappropriate use.

Repeated DEG poisonings reflect persistent structural gaps rather than ignorance: complex, globalised excipient supply chains with repackaging and fraud risk; over reliance on supplier CoAs instead of lot level testing; weak deterrence and fragmented regulatory capacity; lowest bid procurement that rewards cost cutting; and underpowered surveillance and laboratory infrastructure. India's inability to prevent recurring DEG deaths even after multiple earlier episodes reflects deep failures in regulatory deterrence and follow-through, not a lack of knowledge about the risks [15]. Preventing recurrences requires mandatory Gas Chromatography-Mass Spectroscopy (GC–MS) testing of glycerin/PG and finished syrups, independent pre release batch testing and random market sampling, excipient GMP certification and vendor audits, quality weighted tenders, risk based inspections with public compliance reporting, stronger penalties and recall effectiveness checks, and investments in poison centres and acute kidney injury sentinel surveillance, consistent with recommendations in the *New England Journal of Medicine* and recent analyses [6]. Economic pressures within pharmaceutical supply chains also require explicit policy attention. Price competition, low-margin procurement, cost-cutting in the sourcing of excipients can incentivise purchasing from poorly qualified suppliers and discourage robust lot-by-lot quality testing. A realistic stewardship response must therefore include quality weight procurement criteria, mandatory supplier qualification, independent batch verification and penalties that make non-compliance more costly than compliance [6].

The WHO alerts were an alarm; India's export testing mandate was a start. Our children deserve the fullest measure of safety and rational care within and beyond our borders. Implementing the measures as mentioned in Supplementary Table 1 (available online only) will save lives, restore trust, and recentre paediatrics on evidence, not habit. The recent fatal incidents were preventable. They must catalyse a zero-tolerance approach to substandard paediatric products, end the casual use of cough/cold mixtures in infants and toddlers, and align India's practice with WHO's rational use framework. Operationalising

rational use now requires aligning NLEM/state EMLs, enforcing OTC restrictions and age cut-offs on cough/cold products, embedding EHR e-prescribing nudges and hard-stops, and protecting WHO standards (eg, WHO-ORS) in the retail market through compositional, labelling, and enforcement safeguards [1,4,5,6,21]. These are globally applicable lessons for regulators confronting cross-border excipient risks and paediatric OTC governance.

India lacks robust data on paediatric cough and cold prescribing and AEs, highlighting the need to strengthen pharmacovigilance and to study national use patterns, compliance with age-based restrictions, and outcomes of regulatory reforms.

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