

**GOVERNMENT OF KERALA****Abstract**

Health & Family Welfare Department- Management of Cough in Children & Rational Use of Cough Medications - Technical Guidelines - approved - Orders- issued.

HEALTH & FAMILY WELFARE (F) DEPARTMENT

G.O.(Rt)No.3114/2025/H&FWD Dated,Thiruvananthapuram, 09-10-2025

Read 1 Email dated 07/10/2025 from Child Health Office of the State Mission Director, National Health Mission Kerala Thiruvananthapuram.

ORDER

In the context of diethylene glycol (DEG) contamination in cough syrups, recently been reported in India, resulting in significant paediatric mortality and renewed public health scrutiny, Government are pleased to issue the '*Technical Guidelines on the Management of Cough in Children & Rational Use of Cough Medications*', as annexed to this order.

(By order of the Governor)

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ADDITIONAL CHIEF SECRETARY

The State Mission Director - National Health Mission, Thiruvananthapuram.

The Director of Health Services, Thiruvananthapuram.

The Director of Medical Education, Thiruvananthapuram.

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Signed by

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Date: 09-10-2025 16:58:28

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TECHNICAL GUIDELINES

SUB: THE MANAGEMENT OF COUGH IN CHILDREN & RATIONAL USE OF COUGH MEDICATIONS

Background

A major incident of diethylene glycol (DEG) contamination in cough syrups has recently been reported in India, resulting in significant paediatric mortality and renewed public health scrutiny. Laboratory testing revealed that the implicated brand of cough syrup contained DEG at concentrations as high as 48.6%, far exceeding the permissible trace limit of 0.1%. Following nationwide alerts and global concern over the presence of harmful contaminants (such as diethylene glycol and ethylene glycol) in paediatric cough syrups, the Directorate General of Health Services issued a directive (F. No. 28025/52/2025–SAS.II/EMR dated 03.10.2025). In compliance, the Drugs Control Department, Kerala has initiated a targeted inspection and surveillance operation across the state. The Drugs Control Department, Kerala, has taken prompt and proactive measures to assess and ensure the safety of such drugs being marketed and sold in the state.

Diethylene glycol [DEG] is a toxic industrial solvent used in products like antifreeze and brake fluids not intended for pharmaceuticals. Its accidental substitution for safe excipients (like glycerol) in paediatric syrups is especially hazardous. Children exposed to DEG may develop acute renal failure, encephalopathy, metabolic acidosis, hepatic and pancreatic injury, and multiple organ dysfunction. Onset of kidney failure can occur within 24 hours of ingestion, with progression to severe systemic toxicity and death, particularly in those under five years due to lower body weight and metabolic capacity.

The current episode echoes previous toxic excipient tragedies in India and globally, highlighting persistent weaknesses in drug safety oversight, especially with over-the-counter paediatric formulations. Officials have reiterated not to use cough or cold syrups in children under two years, and to exercise caution up to age five, advocating for medical supervision and minimal use of combination preparations.

It is in this context that this technical guideline is being issued to optimize the management of cough and rationalize the use of cough syrup in children. The use of cough syrup in children should strictly follow the latest recommendations of the World Health Organization (WHO) and the Indian Academy of

Paediatrics (IAP). Both agencies currently emphasize minimizing pharmacological treatment and prioritizing non-drug supportive measures.

1. Clinical Approach to Management of Cough

Cough is a sound produced by an attempt to expel an irritant during a forceful exhalation, while the term “cold” is used to refer to a nasal discharge or a blocked nose. It is vital to confirm with the parents what they mean by cough. This is because parents often misinterpret noisy breathing, mucus spitted out or a vibratory feel on the chest as “cold and cough”. Cough can be dry or wet—at times, what sounds like a dry cough but is associated with a noisy chest could be a wet cough. Cough can be a symptom of primary respiratory disease or it can be secondary to cardiac, upper gastrointestinal, or neurological disease; occasionally, it may also be a habit disorder.

Actual cough in early infancy is uncommon, so if an infant is coughing significantly, one must proactively rule out serious illnesses such as pneumonia, congenital heart disease, aspiration secondary to congenital malformations or gastroesophageal reflux, and cystic fibrosis.

For proper assessment of cough symptom, following questions need to be always asked for symptomatic assessment.

TABLE 1: Questions to be asked for clinical approach.		
Question		Interpretation
Is cough a predominant symptom?		If yes, it suggests an airway disease
If yes, is it dry or wet?		Upper airway—dry; lower airway—wet
Is there a past history of recurrent cough?		Suggests reactive airway disease
Is there a personal or family history of atopy?		Supports a diagnosis of atopic disease
Is the cough worse at night?	Soon after lying down	Postnasal drip
	Later in the night/early morning	Supports reactive airway disease
Onset	Sudden	Inhaled foreign body
	Over a few hours	Reactive airway disease
Progress	Recurrent episodic	Asthma
	Progressively worsening	Pertussis, mediastinal mass compressing airway
Sequence of appearance and disappearance of symptoms	High fever followed by cold and cough	Viral infection
	Cold and cough for 1–2 days followed by high fever	Prodrome followed by viral infection
	Cold and cough followed by mild fever	Reactive airway disease
	Cough subsiding soon after fever subsides	Viral infection
	Cough taking 5–7 days to subside after fever subsides	Viral infection on a background of reactive airway disease
Other symptoms—cold, fever, chest pain, breathlessness, palpitation, vomiting, and swallowing dysfunction		As per the symptom complex

2. What are the differentials to be considered if cough is the common symptom in children?

i. Viral infections:

- Often associated with prominent fever along with cough. Cough can be present throughout the day and night, often with history of contact with another person with influenza like illness [ILI].
- A hoarse loud cough suggests laryngeal involvement (almost always viral infection—croup); a dry hacking cough with throat irritation, with a postnasal drip suggests viral pharyngitis and minimal/no cough with painful swallowing (with submandibular lymphadenitis) denotes bacterial infection.
- A wet cough more than tachypnoea suggests proximal lower airway involvement—bronchitis which is commonly viral, often allergic and at times bacterial.

- Tachypnoea more than wet cough suggests distal lower airway involvement, i.e., bronchiolitis. It must be noted that cough may not be the prominent symptom in infants with classical viral bronchiolitis

ii. Reactive airway disease:

- No fever or mild fever later in the course of the illness
- Cough predominant during late night/early morning, may have associated cold/breathlessness, past h/o recurrent cough, well between episodes, personal or family h/o atopy.
- Presence of interval symptoms i.e, cough and breathlessness after exercise, crying or laughing also suggests asthma.

iii. Adenoid hypertrophy with secondary bacterial infection:

- High fever with a blocked nose, maybe snoring and mouth breathing at night, past h/o recurrent cough as well as cold (blocked nose), maybe h/o ear infections. A persistent thick nasal discharge may suggest sinusitis .

iv. Tuberculosis:

- Persistent cough for 2 weeks or more, with or without fever and/or weight loss
merits screening for tuberculosis.

v. Foreign body:

- Usually in the toddler age group —the sudden onset of cough without any history of upper respiratory infection often needs to be probed by leading questions and is crucial to the diagnosis.

3. Approach to Chronic/recurrent cough

- When cough persists for >3 weeks, it is arbitrarily classified as a chronic cough. Most of the acute diseases presenting with a significant cough often settle down within a week.
- **Tuberculosis** should always be considered in case of chronic cough. Reactive airway disease (asthma), aspiration due to congenital malformations, undiagnosed foreign body, and cystic fibrosis can all present as chronic/recurrent cough.
- **Habit cough** is diagnosed when the child has a loud honking dry cough, which is almost incessant at times, but is strikingly totally absent in sleep and during play.

4. Clinical Examination in a child presenting with cough:

The following table elucidates anatomical localization of cough based on symptomatology and auscultatory findings.

TABLE 2: Anatomical localization related to cough.					
Anatomical localization	Airways	Lung parenchyma	Pleura	Interstitium	Heart
Symptoms/signs					
Cough	+++	+	+/-	+/-	++
Fever	+/-	++	++	+/-	-
Breathlessness	+/-	++	++	+	+/-
Chest pain	-	+/-	++	-	-
Distribution of signs	Generalized	Localized	Localized	Generalized	Generalized/ Localized
Audible sound	Stridor/wheeze	Grunt	-	-	-
Retractions	Suprasternal/ subcostal	Intercostal	-	-	Intercostal/ subcostal

5. Investigations in a child presenting with Cough:

- Complete blood count:** Limited utility in diagnosis; eosinophilia may support a diagnosis of atopic airway disease but is not specific and its absence does not rule out the diagnosis.
- Chest X-ray:** More often than not, it is either normal or demonstrates nonspecific findings like prominent broncho vascular markings or ill-defined haziness which do not point to a particular diagnosis. However, in the case of chronic cough, a chest X-ray may suggest tuberculosis, a mediastinal mass pressing on a bronchus, or signs of a retained foreign body.
- A **tuberculin test** should no longer be used to diagnose tuberculosis.
- Computed tomography (CT) scan** is rarely necessary in routine office practice and is reserved for suspected uncommon conditions presenting with cough.
- Spirometry:** Though ideal to confirm the diagnosis of asthma, it needs the child's cooperation and the technician's patience, and is hence, difficult to implement in all suspected cases. In routine practice, asthma is a clinical diagnosis.

6. Management of Cough in children:

It should always be remembered that cough is a symptom and not a disease. Curative treatment in the form of antibiotics is possible only in case of bacterial infections such as bacterial pharyngitis, complicated sinusitis/otitis media, and pneumonia. Majority of diseases presenting with cough need only symptomatic and supportive therapy. **There is no role for over the counter (OTC) cough medicines/other preparations in children.** Rational use of cough syrups is recommended in children avoiding use of irrational combinations and inappropriate formulations. Nonprescription oral OTC medicines for cough have different modes of action based on their active ingredients and should be avoided in children.

For supportive management of acute cough, the following categories of drugs are available in the market:

- i. Antitussives e.g., centrally acting nonopioid derivatives (dextromethorphan) or other peripherally active agents (levodropropizine) act by reducing the cough reflex.
- ii. Expectorants i.e., drugs leading to increased bronchial mucus production, make secretions easier to remove by cough or ciliary transport (guaifenesin).
- iii. Mucolytics i.e., drugs aiming to decrease the viscosity of bronchial secretions, act to make secretions easier to clear through coughing (bromhexine/ambroxol).
- iv. Antihistamine-decongestant combinations i.e., drugs that are combined antihistamine H1-receptor antagonists and alpha-adrenoceptor agonists, act by causing vasoconstriction of mucosal blood vessels thus reducing congestion.
- v. Antihistamines i.e., antihistamine H1-receptor agonists, act by reducing histamine release and thus reducing local congestion and production of secretions. (cetirizine, levocetirizine, fexofenadine, chlorpheniramine maleate, promethazine, diphenhydramine)
- vi. Other drug combinations i.e., fixed drug combinations using different ingredients, have mechanisms of action based on individual ingredients—mostly highly irrational combinations which are NOT recommended.
- vii. Demulcents —Demulcents form a coating and soothe the inflamed pharyngeal mucosa, thereby reducing the frequency and strength of the afferent impulses transmitted to the cough centre—honey.

7. Evidence from Systematic review of Randomised control trials shows that

- i. Over the counter (OTC) antitussive medications/other preparations are no more effective than placebo for reducing cough from viral upper respiratory infections in children.
- ii. OTC antitussives should not be used in children under 6 years of age because of lack of demonstrated efficacy and potential adverse effects.
- iii. The peripheral antitussive levodropropizine improved elimination of cough compared with antibiotics at day 6 of presumed viral illness
- iv. Bronchodilators (salbutamol and levosalbutamol) only useful in case of wheeze associated cough like bronchiolitis, Viral induced wheeze, or asthma. Inhaled drugs are preferred over oral preparations.

8. Guidelines to be followed while managing cough in children

Current evidence does not support the use of cough syrups. In case cough is very distressing, the following best practice statements must be adhered to.

- i. Regarding use of antitussives: prescribing antitussives like dextromethorphan as a single night time dose (0.5 mg/kg) or levodropropizine 1–2 mg/kg dose once or twice if indicated in children above age of 4 years.
- ii. The public and healthcare professionals should be educated about the natural history of cough associated with upper respiratory tract infection (URTI) as in the majority of cases, cough resolves within 2 weeks.
- iii. Parents should be educated about red flag signs and when to return to a doctor.
- iv. Medicines prescribed once for management of cough should not be used on another occasion without consulting a doctor.
- v. Cough persisting beyond 2 weeks needs proper evaluation. Treatment should be customized based on the identified aetiology.
- vi. Symptomatic therapy should be used judiciously in older children and avoided in infants and children below 2 years.
- vii. Bronchodilators are indicated in case of bronchospasm. Inhalation therapy is always preferred in such cases. In cases of bronchial asthma with allergic rhinitis as comorbidity, antihistamines may be used in children above 6 months on a case-to-case basis. Mucolytics (bromhexine,

ambroxol, and acetylcysteine) are useful in bronchiectasis, cystic fibrosis. Cough suppressant is indicated only for dry cough where caution should be exercised (dextromethorphan or pholcodine may be preferred) use only on SOS basis in indicated situations. Local demulcents maybe a safer option. Expectorant, guaifenesin, maybe used only for productive cough.

- viii. For symptomatic relief in children without red flag signs, home remedies are useful. These include hydration, propped up position, open ventilation, honey with a drop of lime, sips of hot water, or hot water gargling. Honey should be avoided in infants due to risk of botulism.
- ix. Proper counselling is extremely important especially when the cough may be recurrent or take time to be relieved and also when long-term compliant treatment is necessary as in the case of tuberculosis or asthma.

9. Non-Pharmacological First-Line Measures

- Ensure adequate hydration and rest during recovery.
- Use saline nasal drops and supportive measures for symptomatic relief.
- Reassure caregivers about the benign and self-limiting nature of most childhood coughs.

10. Core Recommendations

- Cough syrups and cold medications must not be prescribed or dispensed to children under two years of age.
- For children under five years, these medications are generally not recommended; their use (if any) must follow careful clinical evaluation, close supervision, and strict adherence to the lowest effective dose and shortest duration possible.
- Most acute cough illnesses in children are self-limiting and resolve without any pharmacological intervention; hydration, rest, and saline nasal drops should be the first-line approach.
- Combination cough and cold syrups are explicitly discouraged for children under two years and should not be used beyond this age unless clinically specifically indicated.
- Medicines such as bronchodilators may be indicated but only for conditions with bronchoconstriction (e.g., asthma), preferably delivered by inhalation rather than as syrup.
- Antihistamines may be selectively considered for children above six months old with allergic rhinitis and cough, after clinician evaluation.

- **Parents and caregivers should not self-medicate; all cough syrup prescriptions must be supervised by a qualified healthcare provider.**

11.Dosage and Safety Considerations

- Strict attention to proper dosing is required, as inappropriate use of drugs like dextromethorphan or codeine can lead to serious adverse effects.
- Dose calculations for permitted agents must follow strictly weight-based pediatric formulary guidance; avoid generic manufacturer dose labeling based on age alone.
- The risk of adverse effects—such as sedation, respiratory depression, and death—is especially high with opioid and certain antitussive medications in young children.
- All cough syrup products dispensed in healthcare settings must adhere to proper manufacturing standards and be free of harmful contaminants such as diethylene glycol (DEG) and ethylene glycol (EG].

Age Group	Recommendation	Remarks
<2 years	No cough syrup or cold medication	Use only after specialist assessment
2–5 years	Generally, avoid	Use after clinical evaluation, under supervision
>5 years	Use only if indicated after thorough assessment	Stick to lowest effective dose, shortest duration

12.Key Directives Issued via Circular (dated 04.10.2025) by Drugs controller of Kerala:

Based on the Directorate General of Health Services’s instructions and local risk assessment, the following directives were issued to all field officers and stakeholders:

- Monitoring of Cough and Cold Medications Given to Children Under 2 Years

- Extra vigilance is required for products administered to children under the age of two.
- Special attention to be paid to formulation types and excipient safety.
- Safety Evaluation for Children Under 5 Years before prescribing cough medications.
- Drugs intended for children under five must be verified for: Proper dosage, Safe concentration levels, Appropriate duration of treatment
- Surveillance must ensure these drugs do not result in overdose due to formulation errors.

13.Directives to Pharmacists

- Cough syrup comes under schedule H/H1 and hence should be dispensed only based on prescription of a qualified doctor. The presence of registered pharmacist is mandatory while dispensing schedule H/H1 drugs.
- All enforcement officers as well as stake holders must ensure that drugs are sourced only from GMP (Good Manufacturing Practices) certified manufacturers.
- Drugs from non-GMP-certified firms should not be stocked, sold, or distributed.
- Drugs should not be dispensed based on outdated prescriptions.
- As per directive from Central Government Health Ministry [S.O.1717[E] dated 14.4.2025] cough syrup containing formulation of chlorpheniramine maleate + pheniramine hydrochloride should not be prescribed or dispensed in children below 4 years of age.

14.Directives for Public

- Cough is a symptom not a disease and hence don't self-medicate.
- Do not demand cough syrups or formulations. Use them only as per directions of a paediatrician.
- Don't use leftover medicines or use outdated prescriptions.
- Medicine prescribed for one child should not be used for another child without consulting a Paediatrician.
- In children with cough, in case of red flag signs like chest pain, breathlessness, haemoptysis, excessive fatiguability, seizure, cyanosis or altered sensorium, immediately contact a paediatrician.
- Medications prescribed by doctor should be used at the prescribed dose for prescribed duration.

Conclusion

The current episode echoes previous toxic excipient tragedies in India and globally, highlighting the importance of stewardship while using cough syrups, especially with over-the-counter paediatric formulations. Scientific evidence clearly has reiterated not to use cough or cold syrups in children under two years, and to exercise caution up to age five, advocating for medical supervision and minimal use of combination preparations. It is in this context that this technical guideline is being issued to optimize the management of cough and rationalize the use of cough syrup in children.

References:

1. Standard Treatment Guidelines 2022: Management of Cough in Office Practice
Yeshwant Amdekar, Rajesh Chokhani, Ramamurthy Palaniraman
2. WHO guidelines on Cough and Cold Remedies for the treatment of ARI in young children.
3. An expert consensus on managing cough in Indian paediatric practice: Intl J of Basic & Clinical Pharmacology. 2024 Nov 13(6): 941-952
4. Bavdekar SB, Vora A, Karekar S. Paediatric cough as a symptom: Tips for management. Indian J Child Health. 2022;9(9):158-63.
5. Brodlie M, Graham C, McKean MC. Childhood cough. BMJ. 2012;344:e1177.
6. Chang AB. Cough. Paediatric Clinics of North America. 2009;56:19-31.
7. Kasi AS, Kamerman-Kretzmer RJ. Cough. Paediatrics Review. 2019;40(4):157-67.