

Supplementary Table 1. A Four-Pillar Stewardship Roadmap for Pediatric Cough Syrup Safety in India

| Framework Pillar | Strategic Priority & Recommended Action | Core Stakeholders |
|-------------------------------|---|------------------------------------|
| Quality Assurance | Independent Batch Verification: Mandate laboratory testing of all high-risk liquid drug components (e.g., glycerine, propylene glycol) for toxic contaminants before they are used in production[6], [11], [25]. | Manufacturers & Regulators (CDSCO) |
| Market Surveillance | Supply-Chain Transparency: Implement end-to-end digital tracking for chemical suppliers and repackagers to prevent industrial-grade solvents from entering the pharmaceutical supply chain[5], [11], [16]. | State & Central Regulators |
| Clinical Restraint | Rational Pediatric Prescribing: Progressively withdraw non-essential multi-ingredient cough/cold combinations from the market for children under age six, as they offer no proven benefit[1], [2], [4]. | Ministry of Health (MoHFW) |
| Clinical Restraint | Stricter Access Controls: Reclassify pediatric cough syrups as "Prescription Only" to prevent over-the-counter (OTC) misuse and facilitate professional clinical supervision[1], [20]. | Drug Controllers & Pharmacists |
| Clinical Restraint | Evidence-Based Supportive Care: Promote non-drug measures (e.g., hydration, saline drops, honey ≥ 1 year) as the first-line standard for childhood coughs[2], [26]. | Pediatric Associations (IAP) |
| Public Communication | Transparent Risk Communication: Maintain a searchable national portal for product recalls and laboratory test failures to empower clinicians and caregivers[9], [24]. | Regulators (PvPI/CDSCO) |
| Ethical Accountability | Victim Compensation Mechanisms: Establish a statutory fund to provide rapid financial redress to families of children harmed by contaminated medications, ensuring manufacturer liability[7] | National Government & Judiciary |

- This table outlines a multi-sectoral stewardship roadmap to prevent avoidable pediatric mortality from contaminated or irrational cough syrups. The framework emphasizes "Clinical Restraint" to reduce unnecessary medicine exposure in young children and "Quality Assurance" to address structural supply-chain risks.

Abbreviations and Technical Specifications:

- **Contaminants:** Diethylene Glycol (DEG) and Ethylene Glycol (EG).
- **Testing:** Methods include Thin-Layer Chromatography (TLC) and Gas Chromatography with Flame Ionization Detection (GC-FID) as per WHO/International Pharmacopoeia standards.
- **Stakeholders:** CDSCO: Central Drugs Standard Control Organisation; MoHFW: Ministry of Health and Family Welfare; IAP: Indian Academy of Pediatrics; PvPI: Pharmacovigilance Programme of India.