CODEN [USA]: IAJPBB ISSN : 2349-7750

INDO AMERICAN JOURNAL OF
PHARMACEUTICAL SCIENCES

SJIF Impact Factor: 7.187

https://doi.org/10.5281/zenodo.17457026

Available online at: http://www.iajps.com Review Article

A CRITICAL REVIEW OF PAEDIATRIC DRUG SAFETY, REGULATORY OVERSIGHT AND PUBLIC HEALTH RESPONSE IN INDIA 2025

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Abstract:

A number of children died and were hospitalized as a result of upsetting public health concerns regarding pediatric cough syrups in India in 2025. These occurrences brought to light significant pharmacovigilance procedures and regulatory shortcomings. They also underscored the urgent need for reform to enhance medication safety in India, with a particular focus on pediatric formulations. In order to improve medication regulation, manufacturing monitoring, and public health policy in India, this review provides the available data, regulatory reactions, toxicological findings, and lessons learned. This article's goals are to give a general overview of pediatric pharmacovigilance, illustrate its differences from adult pharmacovigilance, and offer real-world instances. The Food and Drug Administration in the US has a reputable division dedicated to overseeing the development of pharmaceuticals for children. Similarly, the Central Drugs Standard Control Organization (CDSCO) in India has the authority to impose rules tailored to the production of pediatric medications. There is an urgent need to address the problem and introduce particular drug development guidelines in order to control and safeguard the interests of the pediatric population in light of the planned revisions to India's drug development guidelines.

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Please cite this article in press Kartik Devidas Chavhan et al., ***A critical review of paediatric drug safety,Regulatory oversight and public health response in india 2025****, Indo Am. J. P. Sci, 2025; 12(10).*

INTRODUCTION:

India is the world's second most populated country. Millions of children are born in India each year. Many children under five pass away each year from neonatal causes, pneumonia, and diarrhea. Safe and effective medications could be used to treat many of these problems. As a result, the demand for different vaccines and medications tailored to children has skyrocketed. These necessary medications, however, are frequently inappropriate for usage in youngsters. However, the lack of pediatric-specific criteria for drug development in India and the inappropriate use of currently available medications have resulted in adverse drug reactions, drug resistance to common pathogens, and infections by uncommon organisms. In India, it is urgently necessary to promote the use of safe and suitable medications in children.

Paediatric drug safety as a public health priority:

ADRs are particularly dangerous for children because of their developing physiology, undeveloped organ systems, and fluctuating metabolism. Pediatric patients frequently receive off-label drugs or formulations that have not been specially evaluated for their age group, in contrast to adults. ADRs in children are underreported worldwide, despite being a major contributor to pediatric morbidity and mortality, according to the WHO. In India, where about 30% of the population is under the age of 14, it is crucial for public health to guarantee safe access to medications However, due to a lack of clinical trials, age-appropriate formulations, and low awareness among healthcare professionals and caregivers, pediatric pharmacovigilance is still in its infancy.

Importance of pediatric drug safety:

Pharmacovigilance in pediatrics is crucial for identifying dangers that may be overlooked due to the difficulties. Adverse medication reactions in children require a targeted and meticulous approach to detect and analyze. Pharmacovigilance is important for pediatric medication safety for the following primary reasons:

1. **Early Detections of ADR's**
   Early detection of adverse medication reactions is made possible by pediatric pharmacovigilance, especially those that might not have been noticed during clinical trials because of age-specific variations or small sample sizes. Early detection can result in prompt treatment, preventing child harm and informing decision-makers about the safety profile of a medication.

2. **Informed Decision-Making for Healthcare Providers**
   Healthcare providers can use the useful information provided by ongoing ADR tracking and reporting to guide their prescription decisions. Pediatricians and other healthcare professionals can make better decisions about children's medication use when appropriate pharmacovigilance systems are in place, particularly when weighing the advantages and disadvantages of various treatment options.

3. **Improvement of Drug Labelling and Safety Information**
   Pharmacovigilance helps to improve drug labeling and safety warnings as post-marketing data on pediatric drug use builds up. With updated dose recommendations, age-specific restrictions, and warning labels, this helps guarantee that the pharmaceutical instructions for pediatric use are appropriate. Additionally, it gives regulatory bodies the ability to advise or restrict children's usage of specific drugs.

4. **Risk Management strategies**
   The creation of risk management strategies, which may involve extra monitoring, special warnings, or limitations for pediatric usage, is made possible by pharmacovigilance. In certain situations, children may be prescribed alternative medications with a better safety record, and the advantages and disadvantages of particular prescriptions can be better recognized.

5. **Public Health and safety**
   Children are given safe and effective medications because of efficient pharmacovigilance procedures. Pharmacovigilance safeguards the public's health and makes sure that kids aren't put through needless risks by keeping an eye out for and responding to possible adverse drug reactions.

Points to consider in the development of a paediatric safety specification:

1. **Non-clinical research**

- Is there evidence of developmental toxicity?
  - Examine studies on young animals.

2. Pharmacodynamic and pharmacokinetic information

- What data are available to help choose the right dosage for children?
- What are the possible adverse effects on children?
- If data for children is lacking, take into account PK/PD modeling and simulation as well as an adaptive trial design.
- Take into account the danger of drug-drug interactions and common co-medications in children.
- Take into account the risk of drug-food interactions in children.

3. Pharmacogenetics

- Is there evidence that children have pharmacogenetic risk factors?
- Examine the information on pharmacogenetics development that is currently available.
- If data is lacking, think about incorporating data gathering into a pediatric trial.

4. Risks associated with formulation selection

- Take medication errors into account.
- Try to use formulations with as few or no excipients as possible.
- Evaluate the possibility of daily and overall cumulative excipient exposure from the research drug and co-medications.

5. Clinical safety information (such as observational studies, spontaneous reports, and clinical trials)

- Sort data according to age groups and other criteria, such as ADR risk factors, dosage, and indications.
  - Examine combined safety data (ages +/- indications).
- Examine information from extensive safety databases, such as VigiBase, EudraVigilance, and FAERS.

Data from pharmacoepidemiology

- Are there statistics on drug use among kids?
- Are there pharmacoepidemiological safety data available for both adults and children that shed additional light on risk factors, outcomes, and, if relevant, the efficacy of risk-minimization initiatives?
- Take into account the limits of administrative databases and pediatric electronic health records.

6. Class effects

- Analyze the effects of literature on both adults and children.

7. Literature

- Examine the literature and data about the dangers of the study drug on websites run by health authorities.

8. Adverse drug responses in clinical settings

- Take into account how ADRs manifest in the study population's age group and how this varies from that of other pediatric and adult age groups.
- How a child's clinical presentation may evolve over time (for example, during long-term follow-up).
- Take into account how different biomarkers are employed for safety monitoring in children and adults.

9. Co-medication in the research group of children

- Examine the pediatric safety specifications of co-medications and how they may affect safety data for the study drug.
- Take into account variations from adult co-medications (e.g., type of co-medications).
  - Recognize the increased risk of medication errors from the use of

  co-medications (including off-label/unlicensed) and the types of adverse drug reactions (ADRs) that may result from this.
- Take into account the hazards, interactions, and/or additive effects of the co-medication excipients.

Case studies of pediatric drug safety failures:

India has witnessed multiple pediatric drug safety failures in recent years.

● COLDRIF COUGH SYRUP TRAGEDY (2025)

After using a cough medication called Coldrif, a number of children in Madhya Pradesh's Chhindwara area started exhibiting symptoms of acute renal failure in the middle of 2025, which rapidly got worse. Sresan Pharmaceuticals, based in Tamil Nadu, made the cough syrup.

The Tamil Nadu Drugs Control Department tested a box of Coldrif syrup (Batch SR-13, Mfg. May 2025) after establishing probable cause. The findings were unsettling: the syrup had a 48.6% diethylene glycol (DEG) concentration. DEG is a highly hazardous solvent that is frequently used as brake fluid and industrial antifreeze. It is strictly forbidden to consume DEG or use it in medications. Particularly in youngsters, ingesting DEG can result in immediate kidney damage, metabolic acidosis, neurological aftereffects, and even death.

At least 11 child fatalities have been reported by Madhya Pradesh health officials.

For symptoms resembling DEG poisoning, about a dozen additional kids were admitted to the hospital. Children reportedly showed signs of oliguria that resulted in multi-organ failure, vomiting, and changed mental status.

- **MAIDEN PHARMACEUTICALS CASE (2022):**

The tragic deaths of seventy children in The Gambia as a result of ingesting tainted cough syrups made in India are known as the Gambia cough syrup scandal. The World Health Organization (WHO) urged health authorities to stop the distribution of specific Maiden Pharmaceuticals goods in October 2022 by issuing a medical alert.

Promethazine Oral Solution, Kofexmalin Baby Cough Syrup, Makoff Baby Cough Syrup, and Magrip N Cold Syrup were among the impacted syrups.

A top officer in the health department of Haryana allegedly received a payment in April 2023 to change test samples of the tainted syrups before they were analyzed in a state laboratory. This sparked questions about whether Maiden Pharmaceuticals knew their products were contaminated. Although independent laboratory testing for the WHO verified the presence of diethylene glycol and ethylene glycol, two dangerous chemicals, Indian authorities found problems with the syrups' labeling but reported no toxins. Naresh Kumar Goyal, the creator of Maiden Pharmaceuticals, has denied any misconduct in the production process in spite of these findings.

PAEDIATRIC PHARMACOVIGILANCE:

Enhancing knowledge of known (i.e., identified) and possible dangers is the goal of pharmacovigilance, which also gathers any incomplete or missing safety information (e.g., risk factors for identified risks; further safety information on potential risks). A variety of risk-minimization techniques are used to manage identified risks.

ADRs Associated with Children's Irrational Drug Use :

There are several instances of unpleasant yet preventable side effects. These incidents mostly happened as a result of children using drugs irrationally. Usually occurring at lower dosages than in adults, these adverse drug reactions (ADRs) might cause unusual symptoms and may impact normal growth and development.

- Hepatotoxicity linked to sodium valproate use is one of the serious adverse drug reactions (ADRs) associated with regularly used medications in children.
- Using salicylates increases the risk of Reye's syndrome in kids who have viral infections.
- Chloramphenicol-induced "grey baby" condition in newborns.
- Effects of long-term corticosteroids on adrenal function and growth suppression.
- NSAID-induced gastrointestinal bleeding.
- Children who use ciprofloxacin run the risk of developing arthropathy.

Unpleasant experiences can result from the usage of excipients in formulations as well as active compounds. The following are some frequently used excipients and their ADRs:

- Antiasthmatic medications that cause benzalkonium chloride-induced bronchospasm.

- Aspartame-induced headaches and seizures.
- Children with sulphonamide allergies who experience cross-sensitivity reactions to saccharin.
- Benzyl alcohol toxicity in neonates receiving high-dose continuous infusion with preserved medications.
- Propylene glycol-induced hyperosmolality and lactic acidosis.

REGULATORY FRAMEWORK & ANALYSIS OF REGULATORY OVERSIGHT IN INDIA:

Central Drug Standard Control Organisation (CDSCO):

India's National Regulatory Authority (NRA) is called CDSCO. It operates under the Ministry of Health & Family Welfare, Directorate General of Health Services (DGHS), Government of India. In order to carry out the duties delegated to the central government under the Drugs and Cosmetics Act, the CDSCO serves as the primary drug regulating authority. The headquarters of CDSCO are in New Delhi. The CDSCO and state regulatory agencies share responsibility for granting licenses for intravenous fluids, vaccinations, sera, and blood and blood products. The Drug Controller General of India (DCGI) is in charge of regulating pharmaceuticals and medical devices within the CDSCO. The DCGI is advised by the Drug

Consultative Committee (DCC) and the Drug Technical Advisory Board (DTAB). The Central Licensing Approval Authority (CLAA) is responsible for the licensing and classification of medical equipment. It is also in charge of issuing warnings, conducting post-market surveillance, establishing and implementing safety standards, and recalling pharmaceutical products for adverse events.

Functions of CDSCO:

Central licensing authorities are responsible for -

- Acceptance of new medications
- Conducting clinical studies
- Setting drug standards
- Import registration, licensing, and quality control of imported medications
- Coordinating state drug control authorities' efforts by providing expert advice to ensure consistent D&C Act enforcement

State licensing authorities are responsible for -

- Control over the manufacture, distribution, and marketing of pharmaceuticals.

Other Functions:

- Licenses are given for large volume parenteral (LVP), blood banks, recombinant DNA products, vaccines, and some medical equipment.
- Modification of the D&C Act regulations
- Old medications and cosmetics are prohibited.
- Granting a test license, personal license, and No Objection Certificate (NOC) for exports
- New medication and cosmetics testing

Role of central drug testing laboratory:

- Acts as a body that makes decisions about drug quality.
- Acquisition, storage, and dissemination of pharmaceutical materials that meet international reference standards.
- Establishing microbiological cultures and national reference standard pharmaceutical substances for use in pharmaceutical analysis, as well as providing standard drugs and cultures to state QC labs and pharmaceutical manufacturing plants.
- State drug control labs and other organizations train their analysts.
- International WHO staff members receive advanced analytical training.
- Informs the central drug control authorities on the toxicity and quality of drugs that are pending licenses.
- To determine the analytical requirements for the Indian Pharmacopoeia and Indian Homoeopathic Pharmacopoeia monograph development.
- Furthermore, the CDL collaborates with the WHO to develop International Pharmacopoeia standards and specifications.
- Drug and cosmetics research and analysis.
- Analysis of registration samples in accordance with Good Manufacturing Practices (GMP) for site registration approval.
- To begin conducting analytical study on medication standardization.

Drugs & Clinical trials new rules 2019:

The new rules reduce the time to one month for approving drugs manufactured in India and to 90 days for those developed in foreign countries. The rules also waive off the need for conducting a local Clinical Trial (CT) if the drug is approved for marketing in countries mentioned by the

DCGI. The DCGI has waived off the CTs for the drugs approved in the European Union, United Kingdom, Australia, Canada, Japan and the United States. The new rules aim to encourage clinical research in India by providing transparent and effective regulations for CT and by assuring faster accessibility of new drugs to the Indian population.

Importance of regulatory oversight in safeguarding children:

The Central Drugs Standard Control Organization (CDSCO) and state-level drug control authorities are in charge of managing India's drug regulatory system. These organizations are in charge of approving, examining, and keeping an eye on pharmaceutical producers.
Nevertheless, the system is beset by fragmentation, inadequate funding, and uneven Good Manufacturing Practice (GMP) compliance.

Effective oversight is especially critical for pediatric drugs, which require:

- Rigorous pre-approval testing
- Age-specific dosage and formulation standards
- Post-marketing surveillance for ADRs
- Transparent recall mechanisms

Without these protections, children are vulnerable to harmful or subpar drugs, which frequently have deadly results.

Regulatory and Manufacturing Failures:

A terrible incident involving the deaths of children in India in 2025 involved the use of Coldrif cough syrup, which was tainted with diethylene glycol (DEG) and contained the active component dextromethorphan hydrobromide.

During an inspection of the production site, the Tamil Nadu Drug Control Department found over 350 Good production Practices (GMP) infractions. Among these are

- The use of rusted and unsterilized equipment
- The lack of validation for testing protocols
- The lack of written records attesting to the raw materials used in manufacturing
- Inadequate batch release records
- The absence of standard operating procedures (SOPs)

These results point to a systemic operational failure and strongly imply that, even though contamination might have happened, it probably could have been avoided with regular quality inspections.

Despite Coldrif syrup's distribution throughout India's states, no central batch testing revealed contamination before the unfavorable event. This suggests that strong interstate coordination between state and federal narcotics agencies has broken down.

A crucial step of requiring toxicity testing prior to batch release was overlooked. Pharmacovigilance was delayed, with no warnings or recalls issued prior to the report. A regulatory concentration on reporting adverse occurrences rather than being proactive with testing and batch release practices is evident in the fact that India's Central Drugs Standard Control Organization, or CDSCO, only gave notice after children's deaths were recorded.

Several suggestions for resolving the problems:

The developmental, physiological, and psychological profiles of children and adolescents differ significantly from those of adults, making them a vulnerable demographic. These developmental differences must be taken into account and addressed throughout the pharmacological research and development process.

A paediatric drug development regulation is imperative as part of the Central Drugs Standard Control Organisation's (CDSCO) ongoing organisation and revision of regulatory guidelines to align with international standards. This will improve outcomes without jeopardising the safety of the population in question.

Pediatric Drug Safety Challenges in India (2025):

- **Drug Toxic Contamination in Children**

  Cough syrups containing industrial solvents that are deadly to humans, diethylene glycol (DEG) and ethylene glycol (EG), were implicated in a number of well-publicized child fatalities in Madhya Pradesh and Rajasthan. Kidney failure and mortality resulted from the usage of these compounds as low-cost alternatives to pharmaceutical-grade solvents. Coldrif, Respifresh TR, and ReLife syrups were identified as the main offenders in worldwide alerts issued by the WHO.

- **Inadequate Regulation Monitoring**

  The Central Drugs Standard Control Organization (CDSCO) of India has come under fire for its disjointed enforcement, sluggish inspections, and absence of local batch testing requirements before retail sales. Because they have less oversight, smaller firms frequently avoid quality checks. Implementation is still difficult even though the government is now requiring all cough syrups to have a Certificate of Analysis prior to sale and to adhere to WHO-compliant criteria.

- **Increase in Unauthorized and Subpar Drugs**

  Unlicensed pharmacies and unapproved pediatric formulations, frequently promoted without prescriptions, are common in rural and urban peripheral areas. Because of inadequate oversight and constrained laboratory capabilities, these regions are more likely to provide inferior or fake medications.

- **Drug Abuse and Misuse in Children**

  Children are increasingly abusing over-the-counter (OTC) medications, especially cough syrups with codeine, Tramadol, and Alprazolam, which are taken for their psychoactive effects. The Indian government is strengthening pharmacy surveillance and database tracking measures as a result of this social and regulatory dilemma.

- **Insufficient Pharmacovigilance in Pediatrics**

  India underreports safety signals because it lacks comprehensive methods to monitor adverse drug reactions (ADRs) in children. The majority of children's medications in India are merely adult formulations that have been scaled down without adequate pediatric trials or kid-friendly excipients, despite the fact that pediatric pharmacology acts differently from adult pharmacology.

- **Disjointed Public Health Reaction**

  Although the government has implemented a number of public health initiatives, including bulk recalls of suspected pediatric medications, digital tracking for high-risk chemicals, and stricter GMP enforcement under Revised Schedule M, states continue to exhibit significant differences in the quality of compliance. Although it is still uneven, coordination across national agencies such as CDSCO, ICMR, and NCDC is getting better.

- **Impact on the World and Reputation**

  The image of India as the "pharmacy of the world" has suffered due to a series of contamination episodes. Following past catastrophes in The Gambia and Uzbekistan, the WHO and importing countries now keep a close eye on pediatric formulations made in India. India is prioritizing alignment with the WHO's Global Accelerator for Pediatric Formulations (GAP-f) Roadmap 2025–2030 in response to this scrutiny, which aims to improve the accessibility and quality of safe child medications.

DISCUSSION:

In order to improve medication manufacturing standards and rebuild confidence in India's healthcare system, this analysis highlights the urgent need for systemic change. The suggestions made in this paper have the potential to prevent future catastrophes of this kind if they are implemented with good intentions.

REFERENCE:

1. Jasso-Gutiérrez L, Castellanos-Solís EC, Santos-Preciado JI. The importance of pharmacovigilance in the pediatric population. *Bol Med Hosp Infant Mex.* 2009;66(3):221–228.
2. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). *Medical Dictionary for Regulatory Activities (MedDRA)—MedDRA® Term Selection: Points to Consider. Endorsed Guide for MedDRA Users Release 4.19 based on MedDRA Version 23.0.* 1 Mar 2020. Available from: admin.new.meddra.org/sites/default/files/guidance/file/000401_termselptc_r4_19_mar2020_13.pdf [Accessed 2020 Sep 30].
3. The Times of India. *11 children dead after consuming Coldrif cough syrup in Madhya Pradesh.* 2025. Available from: timesofindia.indiatimes.com
4. The Times of India. *WHO issues medical product alert on four cough syrups made by India's Maiden Pharmaceuticals* [Internet]. 2022. Available from: timesofindia.indiatimes.com/india/who-issues-medical-product-alert-on-four-cough-s yrups-made-by-indias-maiden-pharmaceuticals/articleshow/94665994.cms
5. Council for International Organizations of Medical Sciences (CIOMS). *Practical aspects of signal detection in pharmacovigilance: Report of CIOMS Working Group*

VIII. Geneva: CIOMS; 2010. Available from: cioms.ch/working_groups/working-group-viii/ [Accessed 2020 Aug 28].

6. European Medicines Agency (EMA). *Guidelines on Good Pharmacovigilance Practices (GVP)—Introductory cover note, last updated with Chapter P.III on pharmacovigilance for the use of medicines by pregnant and breastfeeding women.* 2019. www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guidelinesgood-pharmacovigilance-practices-gvp-introductory-cover-note-lastupdated-chapter-piii_en. pdf [Accessed 2020 Aug 17].
7. European Medicines Agency (EMA). *Guideline on Good Pharmacovigilance Practices (GVP): Product- or population-specific considerations IV—Paediatric population.* 2018. Available from: www.ema.europa.eu/en/documents/scientific-guideline/guideline-good-pharmacovigilancepractices-gvp-product-population-specific-considerations-iv_en0.pdf [Accessed 2020 Aug 17].
8. European Medicines Agency (EMA). *Guidance on the format of the risk management plan (RMP) in the EU—in integrated format, EMA/164014/2018 Rev.2.0.1 accompanying GVP Module V Rev.2, Human Medicines Evaluation.* Published 2018 Oct 31. www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guidance-formatriskmanagement-plan-rmp-eu-integrated-format-rev201_en.pdf [Accessed 2020 Aug 17].
9. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). *ICH harmonised guideline—Integrated addendum to ICH E6(R1): Guidelines for good clinical practice E6(R2)*. Current Step 4 version dated 2016 Nov 9. Available from: database.ich.org/sites/default/files/E6_R2_Addendum.pdf [Accessed 2020 Nov 14].
10. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). *ICH harmonised guideline—Addendum to ICH E11: Clinical investigation of medicinal products in the pediatric population E11(R1), final version.* Adopted 2017 Aug 18. Available from: database.ich.org/sites/default/files/E11_R1_Addendum.pdf [Accessed 2010 Nov 14].
11. Mankar SD, Gholap VD, Zende TP, Dighe RS. Drug regulatory agencies in India, USA, Europe and Japan—a review. *Int J Inst Pharm Life Sci.* 2014;4(2):288–297.
12. Central Drugs Standard Control Organization (CDSCO). *Homepage*. Available from: www.cdscoonline.gov.in/CDSCO/homepage [Accessed 2025 Oct 24].
13. Anusha T, Nagabhushanam MV. Role of regulatory affairs for new drug approval procedure in India. *Int J Pharm Anal Res*. 2017;6(2):431–441. Available from:
14. The Gazette of India. *New Drugs and Clinical Trial Rules, 2019.* Available from: www.iscr.org [Accessed 2025 Oct 24].
15. Sharma P, Gupta S. Regulatory gaps in India's pharmaceutical industry: a review. *Indian J Pharmacol*. 2023;55(2):98–104.
16. BBC News. *WHO warning: contaminated cough syrup linked to child deaths in India* [Internet]. 2025. Available from: https://www.bbc.com/news/articles/c3vzgz794wro 17. Deutsche Welle (DW). *India's cough syrup tragedy shows huge drug safety gaps* [Internet]. 2025. Available from: www.dw.com/en/indias-cough-syrup-tragedy-shows-huge-drug-safety-gaps/a-74352862
18. CNN. *WHO warning over contaminated cough syrup linked to India deaths* [Internet]. 2025. Available from: www.cnn.com/2025/10/14/world/who-warning-contaminated-cough-syrup-india-deaths-intl-hnk Available from:
19. Vision IAS. *Cough syrup deaths in India: understanding the contamination crisis and regulatory response* [Internet]. 2025. Available from: www.visionias.in/blog/current-affairs/cough-syrup-deaths-in-india-understanding-thecontamination-crisis-and-regulatory-response
20. BBC News. *WHO raises alarm over new cases of toxic cough syrup contamination* [Internet]. 2025. Available from: https://www.bbc.com/news/articles/ceq28jey1xwo 21. World Health Organization (WHO). *Medical product alert No. 5/2025: Substandard (contaminated) oral liquid medicines* [Internet]. 2025 Oct 13. Available from: www.who.int/news/item/13-10-2025-medical-product-alert-n-5-2025--substandard-(c ontaminated)-oral-liquid-medicines
22. Reuters. *WHO issues alert over contaminated cough syrups in India* [Internet]. 2025. Available www.reuters.com/business/healthcare-pharmaceuticals/who-issues-alert-over-contami nated-cough-syrups-india-2025-10-13/

23. Reuters. *India to force drugmakers to upgrade plants after fatal cough syrup crisis* [Internet]. 2025. www.reuters.com/business/healthcare-pharmaceuticals/india-force-drugmakers-upgrade-plants-after-fatal-cough-syrup-crisis-2025-10-17/
24. ScanX Trade. *India tightens regulations on cough syrup manufacturing following child deaths* [Internet]. 2025. Available from: scanx.trade/stock-market-news/stocks/india-tightens-regulations-on-cough-syrup-manufacturing-following-child-deaths/22830083
25. Study IQ. *Drug safety issues in Indian pharmaceutical sector* [Internet]. 2025. Available from: www.studyiq.com/articles/drug-safety-issues-in-indian-pharmaceutical-sector/
26. Medstown. *How drug abuse among children is driving India's pharmacy surveillance and trade policies in 2025* [Internet]. 2025. Available from: www.medstown.com/how-drug-abuse-among-children-is-driving-indias-pharmacy-surveillance-and-trade-policies-in-2025/
27. Health Policy Watch. *Toxic cough syrup, weak oversight: India's unending drug safety crisis* [Internet]. 2025. Available from: healthpolicy-watch.news/toxic-cough-syrup-weak-oversight-indias-unending-drug-safety-crisis/
28. PubMed Central (PMC). *Article reference: PMC12351480* [Internet]. Available from: pmc.ncbi.nlm.nih.gov/articles/PMC12351480/
29. International Journal of Contemporary Pediatrics. *Downloadable article on pediatric safety* [Internet]. Available from: www.ijpediatrics.com/index.php/ijcp/article/download/6624/4060/30840
30. Press Information Bureau (PIB). *Press release PRID 2175135* [Internet]. 2025. Available from: www.pib.gov.in/PressReleasePage.aspx?PRID=2175135
31. World Health Organization (WHO). *WHO launches global accelerator for paediatric formulations: strategic roadmap 2025–2030* [Internet]. 2025 May 20. Available from: www.who.int/news/item/20-05-2025-who-launches-global-accelerator-for-paediatric-formulations-strategic-roadmap-2025-2030
32. The Wire. *WHO flags persisting regulatory gaps that put Indians at risk from toxic cough syrups* [Internet]. 2025. Available from: m.thewire.in/article/health/who-flags-persisting-regulatory-gaps-that-put-indians-at-risk-from-toxic-cough-syrups
33. PW Only IAS. *Drug safety concerns in India* [Internet]. 2025. Available from: pwonlyias.com/current-affairs/drug-safety-concerns-in-india/
34. US Embassy India. *Health alert: recall of specific children's cough and cold medicines in India* [Internet]. 2025. Available from: in.usembassy.gov/health-alert-recall-of-specific-childrens-cough-and-cold-medicinesin-india/
35. World Health Organization (WHO). *WHO publications catalogue item: B09475* [Internet]. Available from: www.who.int/publications/i/item/B09475