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Review Article: Role of Pharmacovigilance in Over-the-Counter (OTC) Medications for the Pediatric Population

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Abstract: Over-the-counter (OTC) medications are widely used in children for the symptomatic management of minor ailments such as cough, cold, fever, and pain. However, children are not "small adults" — differences in body composition, organ maturity, metabolic capacity, and the near-total absence of pediatric-specific clinical trial data make this population uniquely vulnerable to adverse drug reactions (ADRs) and medication errors from products that are freely available without a prescription. Pharmacovigilance (PV), defined as the science of detecting, assessing, understanding, and preventing adverse effects of medicines, plays a pivotal role in safeguarding pediatric patients from the risks associated with unsupervised or inappropriate OTC drug use. This article reviews the rationale for pediatric pharmacovigilance, the specific vulnerabilities of children to OTC-related harm, landmark regulatory events that shaped current safety practices, the tools and reporting systems used for pediatric ADR surveillance, and the persistent challenges and future directions for strengthening drug safety monitoring in this population.

Keywords: Pharmacovigilance, OTC drugs, pediatrics, adverse drug reactions, drug safety, off-label use

1. Introduction

Self-medication with OTC products is a global public health behaviour, and caregivers frequently use these agents to manage common childhood complaints like cough, cold, fever, and minor pain without consulting a physician. While OTC status implies an established safety margin for the general population, this assumption is far less secure in children, especially infants and toddlers. Pediatric patients differ from adults in drug absorption, distribution, metabolism, and excretion, and these differences change continuously as a child grows — meaning a dose that is safe at one age or weight may be toxic at another. Because most OTC formulations were never specifically tested in children, much of pediatric dosing has historically been extrapolated from adult data, a practice increasingly recognized as unreliable and sometimes dangerous.

Pharmacovigilance provides the systematic framework needed to identify these risks after a product reaches the market, where real-world use — including misuse, accidental ingestion, and dosing errors — reveals safety signals that pre-marketing trials could never capture.

2. Historical Milestones That Shaped Pediatric Pharmacovigilance

The evolution of pharmacovigilance as a discipline is closely tied to pediatric drug safety disasters:

The 1937 Sulphanilamide Elixir Tragedy: A liquid antibiotic formulation prepared using diethylene glycol as a solvent caused the deaths of more than 100 patients, many of them children, due to unrecognized toxicity of the excipient. This tragedy directly led to the U.S. Food, Drug, and Cosmetic Act

of 1938, which introduced mandatory pre-market safety testing. The Thalidomide Disaster (1957–1961): Thalidomide was originally marketed as an OTC sedative and later used to control nausea in pregnancy. Its severe teratogenic effects, including limb malformations in thousands of children, were formally linked to the drug in 1961. This catastrophe prompted the World Health Organization to establish its Programme for International Drug Monitoring in 1968, followed by the founding of the WHO Uppsala Monitoring Centre in 1978 — events widely regarded as the formal birth of modern pharmacovigilance. The 2007–2008 FDA Review of Pediatric Cough and Cold Medicines: Following years of reported adverse events — including convulsions, rapid heart rates, and fatalities — an FDA advisory committee reviewed OTC cough and cold products and found that efficacy data from adults could not be reliably extrapolated to children. Emergency department data from 2004–2005 estimated that around 1,500 children under age 2 were treated annually for adverse events, including overdoses, linked to these products. As a result, manufacturers voluntarily withdrew infant formulations from the market in late 2007, and in January 2008 the FDA formally advised against using OTC cough and cold products in children younger than 2 years, with later labelling changes extending caution to children under 4. Dosing Device Recalls: More recent pharmacovigilance-driven actions include recalls of pediatric cough syrups due to dosing cups with inaccurate or missing graduation markings, illustrating that safety risks in OTC pediatric products extend beyond the active ingredient to formulation and device design.

3. Pharmacovigilance Tools and Systems Relevant to Pediatric OTC Safety

Several mechanisms allow regulators, healthcare professionals, and pharmaceutical companies to monitor and respond to pediatric OTC safety signals:

Spontaneous reporting systems: Programs such as the FDA Adverse Event Reporting System (FAERS) and the WHO's global ADR database (VigiBase, maintained by the Uppsala Monitoring Centre) collect voluntary reports of suspected ADRs from healthcare professionals, manufacturers, and consumers. Signal detection and disproportionality analysis: Statistical methods are applied to large ADR databases to detect drug–event associations that occur more frequently than expected, helping regulators identify emerging pediatric-specific risks. Poison control centre and emergency department data: Because many pediatric OTC harms result from accidental ingestion or dosing errors rather than "true" ADRs, poison control and ED surveillance data are a critical complementary data source not always captured by standard spontaneous reporting. Pediatric-specific regulatory frameworks: Regulations such as the EU Paediatric Regulation and pediatric labelling initiatives in the U.S. have expanded requirements for pediatric clinical data and mandated pediatric-focused risk management and post-marketing surveillance plans. Community and hospital pharmacist vigilance: Pharmacists play a frontline role by counseling caregivers on correct dosing, screening for duplicate or interacting ingredients across multiple OTC products and reporting suspected ADRs through national PV programs (e.g., the Pharmacovigilance Programme of India, PvPI).

4. Role of Pharmacovigilance Specifically in the OTC-Pediatric Context

Pharmacovigilance contributes to pediatric OTC safety in several concrete ways:

Post-marketing detection of rare and delayed toxicities that were never observed in limited or absent pediatric trials. Identification of medication errors and misuse patterns, such as caregiver confusion between concentration-different formulations (e.g., infant vs. children's acetaminophen drops), which are a leading cause of pediatric OTC harm. Triggering regulatory action, including label changes, dose revisions, formulation changes (e.g., standardized dosing devices), age-restriction warnings, or market withdrawal, as seen with pediatric cough and cold products. Supporting risk communication to caregivers and healthcare professionals through public health advisories, ensuring that safety information reaches the point of use. Generating evidence to close the pediatric data gap, encouraging manufacturers and regulators to conduct dedicated pediatric studies rather than relying on adult extrapolation.

5. Challenges in Pediatric OTC Pharmacovigilance

Despite its importance, pediatric PV for OTC drugs face persistent obstacles:

Underreporting: ADRs in children, particularly from self-administered OTC products, are substantially underreported compared to prescription medicines, partly because caregivers may not

recognize a symptom as drug-related or may not know how to report it. Diagnostic difficulty in young children: Infants and preverbal children cannot describe symptoms, making early recognition of ADRs more difficult for both caregivers and clinicians. Heterogeneity of pediatric subgroups: Neonates, infants, toddlers, and adolescents differ so substantially in physiology that a single pediatric "category" is often too broad for meaningful safety extrapolation. Limited denominator data: Because exact OTC usage volumes in children are hard to quantify, calculating true incidence rates of ADRs remains difficult, weakening some epidemiological analyses. Combination products: Multi-ingredient formulations complicate causality assessment when an ADR occurs, since it may be difficult to attribute the reaction to a specific active ingredient.

6. Future Directions

Strengthening pharmacovigilance for pediatric OTC medicines will likely depend on: expanding caregiver and pharmacist education on accurate dosing and ingredient overlap; encouraging structured pediatric post-marketing surveillance as a regulatory requirement rather than a voluntary activity; leveraging electronic health records and text-mining techniques to identify ADR signals not captured through traditional spontaneous reporting; and harmonizing global pediatric PV standards so that safety signals detected in one region are rapidly communicated worldwide.

7. Conclusion

Children represent a therapeutically distinct and vulnerable population for whom OTC medication safety cannot be assumed simply because a product does not require a prescription. Pharmacovigilance serves as the essential post-marketing safeguard that detects, evaluates, and acts upon the safety signals that inevitably arise once these products are used in real-world pediatric populations — populations that are systematically underrepresented in pre-marketing trials. Continued investment in pediatric-specific PV systems, caregiver education, and regulatory vigilance remains critical to minimizing preventable harm from OTC drug use in children.

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