Received: 24 Apr. 2024	Revised: 09 May 2024	Accepted: 18 June 2024

Review Article

IJRPS
The Power of Wisdom

SCITEKHUB

ISSN: 3048-5606

"PHARMACOVIGILANCE IN AYURVEDIC FORMULATIONS: NEED AND IMPLEMENTATION"

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FUNDING INFORMATION:
Not Applicable

How to cite this article:
Priya Bhaware, "Pharmacovigilance in Ayurvedic Formulations: Need and Implementation" International Journal of Rasa Shastra and Pharmaceutical Sciences. 2024;1(2):34-37.

ABSTRACT

Introduction: Ayurveda, one of the world's oldest medical sciences, has gained global recognition. However, concerns regarding the safety of Ayurvedic formulations, especially in the context of adverse drug reactions (ADRs), contamination, or improper use, have highlighted the importance of pharmacovigilance (PV). Traditionally, Ayurvedic pharmaceutics included safety measures like *Shodhana* (purification) and rational prescribing, but modern large-scale production and global usage necessitate systematic monitoring frameworks. **Methods:** A structured literature review was conducted through PubMed, Scopus, Web of Science, AYUSH Research Portal, and Google Scholar (2000–2025). Classical Ayurvedic texts (*Charaka Samhita, Sushruta Samhita, Rasa Ratna Samucchaya*) were reviewed to explore safety concepts. Research articles, policy reports, case studies, and reviews focusing on PV, ADR monitoring, and regulatory frameworks in Ayurveda were included. **Results:** Traditional texts mention adverse effects, contraindications, and the need for vigilance in prescribing. Modern pharmacovigilance systems in Ayurveda are still evolving. India's Ministry of AYUSH launched the "Pharmacovigilance Program for ASU&H Drugs" in 2008, which has improved awareness but faces challenges like under-reporting, lack of trained manpower, and weak integration with healthcare systems. Studies show ADRs are often linked to poor manufacturing practices, self-medication, or non-adherence to classical guidelines rather than inherent flaws in Ayurveda. Integration of modern PV tools such as digital reporting systems, standard terminology, and data-sharing platforms has shown promise in improving safety monitoring. **Discussion:** Strengthening PV in Ayurveda requires blending classical knowledge with modern systems. Robust reporting networks, mandatory ADR monitoring in clinical trials, global harmonization, and public–practitioner awareness programs are needed for wider credibility. **Conclusion:** Pharmacovigilance in Ayurvedic formulations is essential for ensuring patient safety, sustaining trust, and promoting global acceptance. Proper implementation of PV systems can bridge traditional wisdom with modern pharmacology.

KEYWORDS: Adverse drug reactions, Ayurveda, herbal safety, pharmacovigilance, traditional medicine

INTRODUCTION

Ayurveda has stood the test of time as a holistic medical system emphasizing preventive and therapeutic approaches to health. Its pharmaceutics—*Rasashastra* and *Bhaishajya Kalpana*—provide elaborate guidelines on the preparation, purification, and rational use of medicines[1-2]. The classical emphasis on safety is reflected in the processes of *Shodhana* and *Marana*, rules for dosage, and contraindications for specific conditions. These principles mirror the modern concept of pharmacovigilance (PV), which aims to ensure that medicines are not only effective but also safe[3-4].

In recent decades, Ayurveda has witnessed global growth. However, concerns have emerged regarding adverse drug reactions (ADRs), heavy metal contamination, herb–drug interactions, and misuse of formulations[5-6]. International skepticism toward Ayurvedic safety often arises not from the system itself but from poor-quality manufacturing, lack of regulatory vigilance, and insufficient ADR reporting mechanisms. These factors highlight the urgent need for robust pharmacovigilance in Ayurveda[7-8].

The present review aims to analyze the concept, necessity, and implementation of pharmacovigilance in Ayurvedic formulations. Objectives include: (i) exploring classical Ayurvedic references to ADRs and safety monitoring; (ii) reviewing existing pharmacovigilance frameworks in Ayurveda; (iii) assessing challenges in implementation; and (iv) suggesting future directions for strengthening PV to ensure global credibility of Ayurveda[9-10].

MATERIALS AND METHODS

A systematic review was conducted between February and May 2025.

Databases searched: PubMed, Scopus, Web of Science, AYUSH Research Portal, and Google Scholar[11].

Search strategy: Keywords included "pharmacovigilance Ayurveda," "ADR Ayurvedic formulations," "herbal drug safety," "Ayush pharmacovigilance," and "herbo-mineral safety." Boolean operators (AND/OR) were applied to refine search outputs[12].

Inclusion criteria: [13]

- Studies (2000–2025) addressing ADRs, PV frameworks, or regulatory policies in Ayurveda.
- Case reports, reviews, clinical studies, and policy documents.
- Classical Ayurvedic references describing safety, contraindications, or ADR-like observations.

Exclusion criteria: [14]

- Non-peer-reviewed sources, commercial advertisements, and anecdotal claims.
- Studies unrelated to Ayurveda or pharmacovigilance.

Data extraction and synthesis: Data were analyzed thematically under categories:[15]

1. Classical safety references in Ayurveda.
2. Modern ADR case reports and safety concerns.
3. Existing PV frameworks for Ayurveda.
4. Challenges in PV implementation.
5. Future prospects and strategies.

OBSERVATION AND RESULTS

1. Classical Ayurvedic perspective on safety and vigilance

Ayurvedic texts show remarkable awareness of adverse effects and safety monitoring. *Charaka Samhita* notes that inappropriate combinations (*Viruddha Ahara*) and overdosing may cause harmful outcomes. *Sushruta Samhita* emphasizes contraindications, such as avoiding certain herbs in pregnancy. *Rasa Ratna Samucchaya* and other Rasashastra texts stress purification (*Shodhana*) of metals/minerals to eliminate toxicity. The principle of *Anupana* (vehicle for drug administration) also reflects an early safety measure to reduce side effects. Collectively, these indicate that pharmacovigilance-like practices were embedded in Ayurveda.

2. Modern safety concerns in Ayurvedic formulations

Case reports and analytical studies highlight safety issues, often linked to manufacturing lapses or misuse rather than traditional practices. Examples include:

- **Heavy metal toxicity:** Linked to non-compliance with classical *Shodhana.*
- **Herb–drug interactions:** E.g., *Guggulu* interacting with anticoagulants.
- **Adulteration or substitution:** Poor raw material authentication leading to toxicity.
- **Self-medication:** Patients consuming strong formulations like *Rasaushadhis* without medical supervision.

A systematic review of ADRs in Ayurveda (Mukherjee et al., 2015) revealed that reports were sporadic and often lacked causality assessment, highlighting under-reporting.

3. Evolution of pharmacovigilance in Ayurveda

India's Ministry of AYUSH launched the "Pharmacovigilance Program for ASU&H Drugs" in 2008, later revised in 2017. The All-India Institute of Ayurveda (AIIA) acts as a National Pharmacovigilance Resource Centre, supported by regional and peripheral centers. The program aims to collect, analyze, and report ADRs systematically using structured forms. Internationally, WHO has also advocated PV for traditional medicines, but implementation remains fragmented.

4. Current status and implementation challenges

Despite initiatives, PV in Ayurveda faces several hurdles:

- **Under-reporting:** Practitioners rarely report ADRs due to lack of awareness or fear of discrediting Ayurveda.
- **Training gaps:** Few Ayurvedic colleges systematically train students in PV.
- **Infrastructure limitations:** Inadequate labs and staff for causality assessment.
- **Regulatory enforcement:** Weak monitoring of manufacturers and distributors.
- **Global skepticism:** International agencies remain critical due to insufficient ADR data.

5. Emerging tools and strategies for effective PV

Recent advancements are improving PV implementation:

- **Digital reporting:** AYUSH introduced an online ADR reporting portal and mobile app.
- **Integration with electronic health records:** Linking Ayurveda case sheets with ADR reporting databases.
- **Global harmonization:** WHO's International Drug Monitoring Program expanding to include traditional medicines.
- **Research-driven safety evaluation:** Use of modern toxicology tools (ICP-MS, HPLC, animal models) to validate traditional safety claims.
- **Public awareness campaigns:** Educating patients to report side effects.

6. Evidence of PV outcomes

Studies from PV centers indicate that most reported ADRs are mild to moderate and reversible upon discontinuation. Examples include gastrointestinal irritation with certain herbal decoctions and skin rashes with topical oils. Serious ADRs are rare and usually associated with improper usage. Data collected through PV programs have already led to safety labeling changes in some formulations, indicating tangible impact.

DISCUSSION

Pharmacovigilance in Ayurveda bridges the gap between traditional pharmaceutics and modern patient safety demands. While Ayurveda inherently acknowledges the potential for ADRs, systematic documentation and reporting mechanisms were absent historically. Modern PV provides the missing link by creating structured frameworks for monitoring, causality assessment, and regulatory action[16].

The main challenge lies in perception. Many practitioners hesitate to report ADRs, fearing that acknowledging side effects undermines Ayurveda. However, the reality is that all medicines—modern or traditional—carry risks if misused. Emphasizing this fact can normalize ADR reporting without stigmatizing Ayurveda. Moreover, most ADRs in Ayurveda are linked to poor manufacturing practices or self-medication rather than classical methods, reinforcing the importance of GMP and PV integration[17].

From a scientific standpoint, PV in Ayurveda provides opportunities for global acceptance. Western regulatory authorities demand safety data for herbal products. Active PV networks can generate robust evidence, dispelling myths and increasing confidence. For example, long-term monitoring of *Bhasma* preparations under PV programs can confirm their safety when manufactured traditionally[18].

Gaps remain in manpower training, harmonization of global standards, and incorporation of PV into education curricula. Future strategies should include mandatory ADR reporting in Ayurvedic clinical trials, integration with national PV programs, and cross-disciplinary training of Ayurvedic practitioners in pharmacology and toxicology[19].

In essence, PV represents not just a regulatory formality but an ethical responsibility. By adopting PV, Ayurveda can strengthen its credibility, protect patients, and establish itself as a reliable healthcare system in the global arena[20].

CONCLUSION

Pharmacovigilance is an essential component of

modern healthcare, and its integration into Ayurveda is both timely and necessary. Classical Ayurvedic texts demonstrate awareness of drug safety, contraindications, and the need for vigilance in prescribing. However, large-scale commercialization, international trade, and modern patterns of self-medication demand more robust monitoring systems.

India's Pharmacovigilance Program for ASU&H drugs represents a significant step toward institutionalizing ADR reporting in Ayurveda. Yet, challenges such as under-reporting, lack of trained manpower, and limited global harmonization persist. Addressing these requires a multi-pronged approach—training Ayurvedic practitioners in PV, integrating modern toxicology tools, expanding ADR reporting networks, and raising public awareness.

Pharmacovigilance in Ayurveda is not about questioning its credibility but about strengthening its scientific foundation. By systematically documenting safety, identifying risks, and preventing misuse, PV ensures both patient protection and the sustainable growth of Ayurveda. A strong PV framework will play a crucial role in securing Ayurveda's global acceptance as a safe, effective, and trustworthy healthcare system.

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