World Journal of Pharmaceutical Science and Research
www.wjpsronline.com
Research Article
ISSN: 2583-6579
SJIF Impact Factor: 5.111
Year - 2025
Volume: 4; Issue: 6
Page: 526-529

ADVERSE DRUG REACTION REPORTING IN AYURVEDA: NATIONAL PHARMACOVIGILANCE FRAMEWORK AND REPORTING MECHANISM IN INDIA

Dr. Mohit[1], Dr. Pooja Devi*[2], Dr. Manisha Sharma[3]

[1]Assistant Professor, Department of Kayachikitsa, Guru Nanak Ayurvedic Medical college and Research Institute, Gopalpur, Ludhiana, Punjab, India - 141118.
[2]Assistant Professor, Department of Swasthavritta, Guru Nanak Ayurvedic Medical college and Research Institute, Gopalpur, Ludhiana, Punjab, India - 141118.
[3]Professor, Department of Rog Nidan, Guru Nanak Ayurvedic Medical college and Research Institute, Gopalpur, Ludhiana, Punjab, India - 141118.

Article Received: 6 November 2025 | | ***Article Revised: 27 November 2025*** | | ***Article Accepted: 17 December 2025***

***Corresponding Author: Dr. Pooja Devi**
Assistant Professor, Department of Swasthavritta, Guru Nanak Ayurvedic Medical college and Research Institute, Gopalpur, Ludhiana, Punjab, India - 141118. **DOI:** https://doi.org/10.5281/zenodo.18008697

How to cite this Article: Dr. Mohit, Dr. Pooja Devi, Dr. Manisha Sharma (2025) ADVERSE DRUG REACTION REPORTING IN AYURVEDA: NATIONAL PHARMACOVIGILANCE FRAMEWORK AND REPORTING MECHANISM IN INDIA. World Journal of Pharmaceutical Science and Research, 4(6), 526-529. https://doi.org/10.5281/zenodo.18008697

ABSTRACT

Adverse Drug Reactions (ADRs) represent a significant challenge to patient safety across all systems of medicine, including Ayurveda. Despite the long-standing use of Ayurvedic medicines and their general perception as safe, adverse reactions have been increasingly reported due to factors such as inappropriate drug selection, improper dosage, prolonged use, drug–drug interactions, herbo-mineral formulations, and compromised drug quality. In response to these concerns, the Ministry of AYUSH, Government of India, established the Ayush Pharmacovigilance Program of India (APvPI) to systematically monitor and evaluate ADRs related to AYUSH medicines. This article aims to describe the concept of ADRs in Ayurveda, the importance of ADR reporting, the structured national pharmacovigilance framework, and the standardized reporting process followed in India. Strengthening ADR reporting practices among Ayurvedic practitioners is essential for enhancing drug safety, promoting rational drug use, and integrating Ayurveda into evidence-based healthcare systems.

KEYWORDS: Ayurveda; Adverse drug reaction; Pharmacovigilance; AYUSH; Drug safety.

INTRODUCTION

Pharmacovigilance is defined by the World Health Organization as the science and activities concerned with the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems.[1] With the increasing acceptance and widespread use of Ayurvedic medicines in both national and global healthcare settings,

concerns related to drug safety have gained considerable attention. Although Ayurvedic drugs are derived mainly from natural sources and described extensively in classical texts, adverse drug reactions (ADRs) may occur due to improper administration, individual susceptibility, or inappropriate combinations. Hence, a structured system for monitoring and reporting ADRs is essential to ensure patient safety and promote rational Ayurvedic practice.[2]

MATERIALS AND METHODS

This study is a **narrative review** based on secondary data collected from official publications, guidelines, and reports of the Ministry of AYUSH, Government of India, World Health Organization documents, and peer-reviewed scientific literature. Relevant information regarding ADR definitions, reporting mechanisms, and pharmacovigilance infrastructure for Ayurveda was collected, analyzed, and systematically presented. No experimental animals or human subjects were involved in this study; therefore, ethical committee approval was not required.

RESULTS AND DISCUSSION

Concept of Adverse Drug Reactions in Ayurveda

An adverse drug reaction is defined as any unintended, harmful, or undesirable response occurring at normal therapeutic doses of a medicine.[3] In Ayurveda, ADRs may result from classical formulations, patent or proprietary medicines, rasaushadhis (herbo-mineral preparations), prolonged use, improper anupana, or drug–food and drug–drug interactions as detailed in (Table 1). The occurrence of ADRs does not negate the efficacy of Ayurveda but highlights the need for appropriate drug selection, dosage individualization, and vigilant monitoring.[4]

Table 1: Types of adverse drug reactions reportable under ayush pharmacovigilance program.

Sr. No.	Category	Description	Examples
1	Classical Ayurvedic formulations	Adverse reactions related to formulations described in classical texts	Dashamoola kwatha–induced gastritis
2	Patent / proprietary medicines	Reactions associated with branded Ayurvedic products	Allergic rash due to proprietary syrup
3	Herbo-mineral drugs (rasaushadhis)	ADRs related to formulations containing metals/minerals	GI upset with improper rasaushadhi use
4	Drug–drug interactions	Interaction between Ayurveda and modern medicines	Increased bleeding with herbal anticoagulants
5	Drug–food interactions	Adverse effects due to incompatible ahara	Nausea following viruddha ahara
6	Quality-related issues	ADRs due to adulterated, spurious, or substandard drugs	Hepatotoxicity from contaminated product

Importance of ADR Reporting

ADR reporting plays a pivotal role in identifying rare, serious, or unexpected adverse reactions and ensuring patient safety.[5] Systematic reporting helps in generating safety signals, improving prescribing practices, and strengthening regulatory oversight. In Ayurveda, pharmacovigilance also contributes to validating classical references in the light of contemporary clinical practice and helps identify issues related to drug quality, adulteration, and misuse.[6]

National Pharmacovigilance Framework for AYUSH in India

The Ministry of AYUSH established the **Ayush Pharmacovigilance Program of India (APvPI)** to monitor the safety of Ayurvedic, Siddha, Unani, and Homoeopathic medicines.[7] The program operates through a **three-tier system**.

National Pharmacovigilance Centre

The **National Pharmacovigilance Centre (NPvCC)** is located at the **All India Institute of Ayurveda (AIIA), New Delhi**. It functions as the apex body responsible for coordination, data analysis, signal detection, training, and communication with regulatory authorities.[8]

Intermediary Pharmacovigilance Centres

There are **five Intermediary Pharmacovigilance Centres (IPvCs)** located at national institutes across India, namely

1. Institute of Teaching and Research in Ayurveda, Jamnagar
2. National Institute of Ayurveda, Jaipur
3. National Institute of Unani Medicine, Bengaluru
4. National Institute of Siddha, Chennai
5. National Institute of Homoeopathy, Kolkata

These centres act as regional hubs for training, validation, and forwarding of ADR reports.[9]

Peripheral Pharmacovigilance Centres

At the field level, ADRs are collected through **Peripheral Pharmacovigilance Centres (PPvCs)** situated in Ayurvedic colleges, hospitals, and research institutions across the country. Currently, **approximately 97–100 PPvCs** are functional nationwide, ensuring extensive geographical coverage.[10]

ADR Reporting Process

ADR reporting is performed using the **Suspected Adverse Drug Reaction Reporting Form for AYUSH medicines**. The form captures patient demographics, details of the suspected drug, nature and chronology of the adverse reaction, concomitant medications, management, and outcome. Reports can be submitted to the nearest PPvC or forwarded to IPvCs or the NPvCC. Causality assessment is carried out using standardized tools such as the WHO–UMC scale as shown in *(Fig. 1)*.[11]

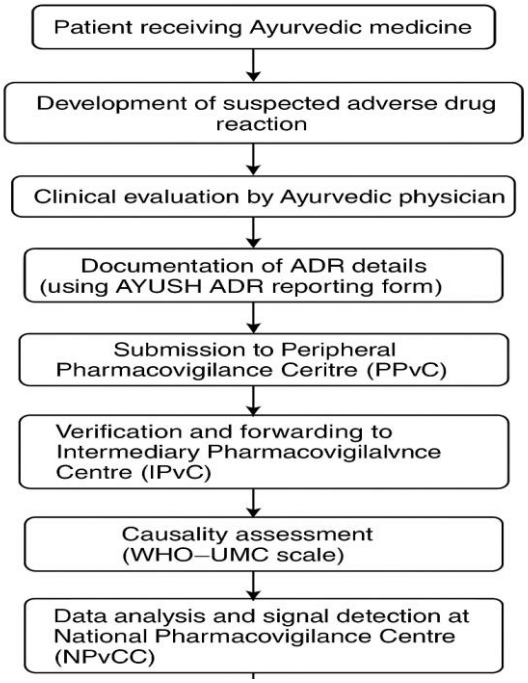

Fig. 1: Flowchart depicting adverse drug reaction reporting process in ayurveda.

CONCLUSION

ADR reporting in Ayurveda is an essential component of patient safety and quality assurance. The structured pharmacovigilance framework established by the Ministry of AYUSH provides an effective mechanism for monitoring adverse reactions associated with Ayurvedic medicines. Active participation of Ayurvedic practitioners in ADR reporting will strengthen evidence-based practice, improve regulatory decision-making, and promote the safe and rational use of Ayurveda in modern healthcare.

ACKNOWLEDGEMENTS

The author acknowledges the Ministry of AYUSH, Government of India, for providing accessible guidelines and resources on pharmacovigilance of AYUSH medicines.

REFERENCES

1. The Importance of Pharmacovigilance, Compilation prepared by World Health Organization (WHO), Geneva, http://apps.who.int/medicinedocs/en/d/Js4893e/
2. Thatte U, Bhalerao S. Pharmacovigilance of Ayurvedic medicines. *Indian J Pharmacol*, 2008; 40(Suppl 1): S10–S12.
3. Edwards IR, Aronson JK. Adverse drug reactions: definitions, diagnosis, and management. *Lancet*, 2000; 356: 1255–1259.
4. Patgiri BJ, et al. Safety evaluation and pharmacovigilance of Ayurvedic drugs. *AYU*, 2011; 32(3): 364–370.
5. WHO-UMC. *The use of the WHO-UMC system for standardized case causality assessment*.
6. Kumar A, et al. Challenges in pharmacovigilance of traditional medicines. *J Ayurveda Integr Med*, 2017; 8(2): 82–86.
7. Ayush Pharmacovigilance Program of India (APvPI), Compilation prepared by Ministry of AYUSH, Government of India, https://www.ayushsuraksha.com/
8. National Pharmacovigilance Centre for AYUSH medicines, All India Institute of Ayurveda (AIIA), New Delhi, https://www.aiia.gov.in/
9. Pharmacovigilance Network for AYUSH medicines, Central Council for Research in Ayurvedic Sciences (CCRAS), Ministry of AYUSH, Government of India, https://ccras.nic.in/
10. List of Peripheral Pharmacovigilance Centres in India, Ministry of AYUSH, Government of India, https://www.ayushsuraksha.com/
11. Causality Assessment of Suspected Adverse Drug Reactions, WHO–Uppsala Monitoring Centre (WHO-UMC), https://who-umc.org/