

# Pharmacovigilance in Ayurveda: Present & Future

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## Abstract

Pharmacovigilance is an important element of contemporary healthcare systems, as it involves the detection and evaluation of risks associated with medications and devices. Though originally a construct linked to conventional medicine, pharmacovigilance is now embraced as crucial for Ayurvedic medicine that employs numerous herbal and mineral drugs. The main focus of this paper is to discuss how pharmacovigilance can be incorporated into Ayurveda to maintain the safety, efficacy, and credibility of Ayurvedic treatments. It provides an overview of how pharmacovigilance is currently practised, the issues related to Ayurveda, and the importance of implementing standard practices and guidelines. The future of pharmacovigilance in Ayurveda is presented as combining the holistic approach with contemporary tools, technologies, and global trends. Implementation processes customised for Ayurvedic treatments, measures regarding quality control, reporting mechanisms, and awareness creation are suggested to maintain the international acceptability and effectiveness of Ayurveda.

**Keywords:** Ayurveda, Pharmacovigilance, Post-marketing surveillance, Adverse drug reactions (ADRs), Standardization, Quality control, Regulatory framework, Signal detection, Benefit-risk evaluation, Adverse event reporting

## 1. Introduction

Pharmacovigilance is a key component of current healthcare systems specifically concerned with the identification, assessment, and analysis of adverse effects or any other drug-related problem associated with medical products, where it intends that health data should be quantifiably better than before to facilitate more clearly targeted interventions. From data collection, analysis, and risk management to communication, pharmacovigilance has an important role in post-marketing surveillance, which is the follow-up on pharmaceutical products and medical devices available for consumption to confirm that they are safe to use. The final Phase of the drug development process is to identify safety issues not seen in clinical trials and also enable a comprehensive pharmacovigilance process. As health authorities set global norms to maintain a high standard of pharmaceutical usage, this phase is probably the most important stage for systematic and proactive drug safety.

As Ayurveda keeps engaging the thoughts of well-being enthusiasts around the world, pharmacovigilance, too ends up being fundamental. In an age when holistic forms of healing are becoming increasingly popular, it is even important to maintain the safety and efficacy standards with Ayurvedic medicines because this thousand-year-old tradition should not only survive in parallel dimensions alongside modern medicine but also thrive and flourish. To elevate Ayurveda to mainstream status, robust drug safety

monitoring is crucial. It not only enhances trust in Ayurvedic treatments but also establishes Ayurveda as a primary system of medicine rather than merely an alternative therapy.

This paper will therefore discuss the imperative and effective pharmacovigilance systems in the Ayurvedic system of medicine, based on current trends and expectations for the future. The pharmacovigilance in Ayurveda is mapped out, as the emphasis will be on exploring methods for sharing strategies and tools to ascertain the quality initiatives to be followed and the rules and regulations required to facilitate post-marketing surveillance. It is proposed that further progress in the practice of Ayurveda will be achieved with regular efforts made to safeguard patient protection as a key value.

## 2. Pharmacovigilance in the Contemporary Context

To achieve extensive monitoring of medical products, it is vital to gather information from different sources systematically, such as healthcare professionals, patients, and regulatory agencies. This data collection includes reporting of adverse events, clinical trial data, and real-world data. Signal detection is an important part of this process, which involves data mining for the identification of outlying patterns and performing risk analysis for the assessment of the frequency and volume of adverse events. Benefit-risk analysis is important in pharmacovigilance as it compares the utility of a medical product or procedure to its risks. Risk management strategies like Risk Evaluation and Mitigation Strategies (REMS) may be used to manage the identified risks. Regulatory bodies have to report adverse events to drug-producing companies based on which regulatory decisions such as changes in product labelling, restriction, or withdrawal are made.

Pharmacovigilance has faced many changes in the recent past because of technologies, patient involvement, and international cooperation. Today's practices rely on methods such as natural language processing, machine learning, and real-world data to identify and assess possible risks. Patients are also allowed to report adverse events and their experiences are taken into consideration. There are ongoing processes to facilitate the synchronization of its provisions internationally to provide efficiency, which augments the improvement of medical practices and patient care.

## 3. Need for Pharmacovigilance in Ayurveda

As per Charaka Samhita, an eminent Ayurvedic treatise, certain unfavourable effects have been described if the proper method of preparation or administration of Ayurvedic medicines is not followed. They detail various attributes and considerations when it comes to the selection of the starting materials used in medicine formulation, such as physical structure, properties, actions, and effects; habitat; the season of growth; conditions of collection and storage; and pharmacological preparation.

Charakacharya also outlines the factors concerning the patient's selection and application of medicines to reduce side effects. These are the plant's physical characteristics (Prakriti), properties (Guna), actions (Karma; Prabhava), habitat (Desh), growth season (Ritu), harvesting conditions (Grahitam), storage method (Nihitam), and pharmaceutical processing (Upaskritam).

Charakacharya also details patient-related factors to consider when prescribing medicines to minimise adverse reactions. These include the patient's constitution (Prakriti), age (Vayam), specific condition (Vikruti), previous exposure or tolerance (Satmya), psychological state (Satwa), digestive capacity (Ahara-shakti), exercise capability (Vyayama-shakti), tissue quality (Sara), body proportions (Sahanan), and overall strength (Bala).

Pharmacovigilance in Ayurveda refers to the active and continuous process of detecting, evaluating, and reporting adverse effects concerning Ayurvedic systems. Today, some people can experience side effects after using Ayurvedic medicines or develop complications when they combine their doses with other treatments, and this is why safety is paramount. The tendency towards the use of Ayurveda therapies makes the protection of these approaches, paramount. As Ayurvedic formulations contain a wide number of herbs and minerals, such knowledge can pose potential undesirable side effects and therefore should be kept under quality control and standardization measures.

Pharmacovigilance is a method of minimizing and regulating adverse events of Ayurvedic treatments and enhancing the qualities of Ayurvedic systems. Pharmacovigilance data collected can also be useful in future studies regarding the impact of Ayurvedic medicine on specific diseases. Coordination of Ayurvedic practitioners, regulatory bodies, and patients is necessary for a holistic pharmacovigilance program. It has to be compatible with international standards of clinical trials and pharmacovigilance of the Ayurvedic system of treatment. Coordinating activities improves interface ties and the acceptability of Ayurveda globally.

#### 4. Key Components of Ayurvedic Pharmacovigilance

**4.1 Adverse Event Reporting:** Ayurvedic pharmacovigilance means the process of gathering, observing, evaluating, and reporting adverse reactions associated with Ayurveda products. This includes reporting adverse effects or other unfavourable outcomes that are reported by healthcare professionals.

**4.2 Regulatory Framework:** A few countries have formulated policies and frameworks for the pharmacovigilance of Ayurveda medicines; these cover the roles and responsibilities of producers, practitioners, and regulating bodies for reporting and monitoring adverse effects.

**4.3 Integration with Traditional Knowledge:** Ayurvedic pharmacovigilance aims to integrate the conventional idea of safety and efficacy with the modern concept of pharmacovigilance. It includes the integration of indigenous practices in the assessment and review frameworks.

**4.4** Ayurvedic pharmacovigilance faces several challenges similar to those in conventional pharmacovigilance but with unique aspects due to the nature of Ayurvedic therapy:

**4.4.1. Diversity of Formulations and Ingredients:** Variation in the preparation and compounds found in Ayurvedic medicines is common, whereby many formulations contain mixtures of multiple herbs. These differences may result in variations in therapeutic outcomes as well as risks for adverse effects.

**4.4.2. Lack of Standardization:** The formulations and manufacturing procedures of Ayurvedic medicines still do not have standardized directions. This can make it challenging to pinpoint the liability of certain facets that trigger undesirable reactions. Mainly, standardization is a measure vital for the minimization of risks and efficacy enhancement.

**4.4.3. Complexity of Traditional Knowledge:** Ayurveda, as a system, does not use contemporary knowledge, and its formulations are based on the ancient knowledge system; therefore, it is not easy to adapt Ayurveda to modern pharmacovigilance systems. An important gap is one separating traditional knowledge from modern scientific research approaches that are used in pharmacovigilance.

**4.4.4. Underreporting of Adverse Events and Regulatory Frameworks:** Non-reporting of ADRs is common mostly because healthcare professionals, and the consumer in particular, may not be aware of any reaction or be reluctant to report the reaction. About reporting, there is a need to educate people and create awareness of the same. The revelations of Ayurvedic medicines may not contain a strict structure as those of conventional drugs.

Tackling these problems calls for efficient cooperative efforts of healthcare practitioners, policymakers, researchers, and traditional Ayurvedic healers to devise a comprehensive pharmacovigilance system for Ayurvedic products. To overcome these challenges, standardization must be enhanced; research should be conducted; and communication about Ayurvedic medicines, risks, and benefits must be improved.

## 5. Future of Pharmacovigilance in the Ayurvedic Context

As Ayurvedic science gets global attention, the prospects of pharmacovigilance in this domain need and offer a perspective. Ensuring the safety and efficacy of Ayurvedic treatments requires integrating traditional wisdom with modern pharmacovigilance practices. Ensuring the safety and efficacy of Ayurvedic treatments requires integrating traditional wisdom with modern pharmacovigilance practices.

**5.1. Bridging Traditional Wisdom with Modern Vigilance:** Some concepts distinguish Ayurveda from other healing systems: it concentrates on an individual approach to patients and never separates physical and non-physical aspects of the human being. Future pharmacovigilance has to adhere to those principles and include them in Ayurvedic tradition and modern pharmacovigilance at the same time.

**5.2. Standardization and Quality Assurance:** One of the key challenges facing Ayurveda is the standardization of formulations that are manufactured on a small scale by clinicians for their clinical use or selling. Ayurvedic treatments often involve complex herbal combinations, and the lack of standardized practices can lead to variations in product quality. Also, the substandard medicinal plants add to the plight. The future of pharmacovigilance in Ayurveda involves developing and implementing robust quality control measures at the grassroots level. This includes standardized cultivation practices for medicinal plants, rigorous testing of raw materials, and adherence to Good Manufacturing Practices (GMP) even for small-scale manufacturing.

**5.3. Integration of Technology and Holistic Monitoring:** It also reveals that incorporating new technology will help in improving monitoring and reporting. The use of the digital device, the electronic health information, as well as the use of a mobile application, can simplify the data collection as well as the reporting process. The future of pharmacovigilance in Ayurveda will also involve the tracking of more factors of the patient's health beyond the effects of drugs, such as changes to diet and other aspects of the patient's life.

**5.4. Education and Awareness:** Awareness about pharmacovigilance must be created among Ayurvedic practitioners, other healthcare workers, and the public. Courses that should be provided should centre on the topic of reporting adverse events, identifying herb-drug interactions, and safety monitoring.

**5.5. Research and Regulatory Framework:** Well-controlled research, as well as case reports and other actual evidence, will undertake the defence of Ayurvedic treatments' safety. To formulate pharmacovigilance standards and policies, Ayurvedic practitioners, national research organizations, and regulatory authorities must work in cooperation with one another to avoid any drastic shifts in pharmacovigilance that are detrimental to consumers' health while at the same time fostering the core values of Ayurvedic medicines. The development of a robust regulatory framework also becomes imperative. Regulatory authorities should actively engage with Ayurvedic practitioners and industry stakeholders to establish guidelines for pharmacovigilance specific to Ayurvedic products. This framework should strike a balance between preserving traditional knowledge and ensuring the safety of consumers.

## 6. Suggestions for Improvement of Pharmacovigilance in Ayurveda

### 6.1. Good Therapeutic Practices

Schedule T of the Drugs and Cosmetics Act of 1940 lays down the GMP and contains elaborate provisions for the manufacture of Ayurvedic and Siddha medicinal products. These guidelines cover the machinery and equipment specifications and the minimum premises necessary for production. Ayurvedic and Siddha drugs are classified under products that are meant for diagnosing, treating, preventing, or alleviating diseases in human beings or animals.

As per Schedule T, these medicinal products need to be prepared solely following the formula mentioned in the official Ayurvedic, Siddha, and Unani texts only. Schedule T's main objective is to check the veracity, purity, and freedom from contamination of raw materials and also to ensure the right measures are taken to ensure the quality of the final product. The texts of Rasashastra making from the first century to the sixteenth century give elaborate accounts of constructing a Rasashala, or the production unit.

Some of these texts cover aspects such as choice of location, water, and lighting, acquisition of raw materials, as well as ventilation. They also include personnel management aspects, potential costs, and security concerns. Even though these descriptions were given with regards to historical frameworks, they can still be translated to present-day quality control standards.

### 6.2. Improvement in Quality Control Practices

Ensuring the safety, effectiveness, and consistency of Ayurvedic formulations requires rigorous quality control. Standard Operating Procedures (SOPs) should be established and implemented across all stages of manufacturing, from raw material handling to the final product. Staff training on these procedures is crucial to maintain consistency and quality. Quality control testing plays a key role in confirming that products meet required standards, focusing on identity, purity, potency, and safety, including testing for microbial contamination and heavy metals.

Thorough documentation of each batch, including details on raw materials, manufacturing methods, and quality control results, is essential for accountability and traceability. Stability testing ensures that products maintain their effectiveness throughout their intended lifespan. Compliance with regulatory guidelines and standards is necessary to meet health authority requirements.

Quality assurance systems should be established to monitor and assess all processes continually. Regularly reviewing and updating quality control methods based on feedback and industry standards is essential. Additionally, implementing a process for monitoring and addressing any adverse events associated with Ayurvedic products is critical for maintaining safety. Ensuring consistency across batches is vital to reduce variability and maintain product quality.

### 6.3. Better Reporting Form

Currently, the reporting form for adverse events used in Ayurveda, Siddha, Unani, and Homeopathic medicines (ASU&H) employs similar terms and approaches, which may not fully align with the holistic nature of Ayurvedic practice. A more tailored approach is needed to accurately represent Ayurvedic pharmacovigilance. Additionally, terms such as "midwife" or "health workers," derived from Western contexts, may not be suitable for Ayurvedic settings. Terminology should be aligned with Ayurvedic concepts.

Providing options for paperless submission can decrease the reporting load and enable the collection of data at a constant rate. Other web-based tools and interfaces that can be used for the reporting of Adverse Event and education tools for healthcare personnel and physicians Ayurvedic practitioners and the public would also enhance understanding of pharmacovigilance. These reporting forms shall also integrate with

existing pharmacovigilance systems and databases for efficient data collection and analysis. The regularity of reporting forms review is also specified along with the analysis of generated feedback and new concerns, for example, safety ones.

#### **6.4. Change in the Terminologies following Ayurvedic Perspective**

The term Pharmacovigilance is used in the context of vigilance about adverse events related to contemporary medicinal products. The main difference between the administration of contemporary medicinal products and Ayurvedic Therapies is that of focus. While the main focus of contemporary medicine is on the alleviation of a disease; Ayurvedic therapy also involves the process of identification of medicinal plants, their harvest, storage, preparation of formulation, administration and time of consumption. Apart from this vigilance is also maintained when the patient visits an Ayurvedic expert. The expert focuses on the examination of the patient and examination of the disease, based on which drugs and/or therapy, lifestyle changes, diet changes, exercise and/or Yogic practices are prescribed.

In the context of Ayurvedic clinical practice, where the entire process of growing medicinal plants, preparing formulations, prescribing medicines, and advising on diet and lifestyle changes is meticulously followed, the term "pharmacovigilance" may not be the most appropriate choice. This holistic view and vigilance at every step of the therapeutic process is unique to Ayurveda and cannot be aptly delivered by the term "Pharmacovigilance". A new term needs to be coined for probably like "Ayurvedic Therapeutic Vigilance". This term encompasses not only the monitoring of medicines but also the broader approach to patient care and well-being. It emphasizes the careful and watchful approach to the entire therapeutic process, including herbal medicines, dietary recommendations, and lifestyle adjustments. It conveys the idea that Ayurvedic practitioners are vigilant not only about the medicines but also about the therapeutic process as a whole.

#### **7. Conclusion**

Pharmacovigilance in Ayurveda is a basic perspective of modernizing and joining conventional medication with modern well-being security benchmarks. As Ayurvedic practices acquire worldwide attention, ensuring the safety and efficacy of Ayurvedic treatments is important. This approach shields patient well-being and upgrades the reliability and acceptance of Ayurveda in the worldwide healthcare environment.

The conventional Ayurvedic framework emphasizes individualized treatment based on a comprehensive understanding of the patient's constitution and the restorative properties of medicinal substances. In any case, as Ayurveda intermingles with modern healthcare frameworks, there is a mandate to adjust its practices with current pharmacovigilance guidelines. This includes bridging the gap between traditional intelligence and modern techniques, including innovations, systematic information collection, and risk management procedures.

The future of Ayurvedic pharmacovigilance lies in harmonizing traditional practices with present-day benchmarks, guaranteeing high safety and viability measures, and encouraging better communication between healthcare professionals, patients, and administrative bodies. Education and mindfulness are basic components of a successful pharmacovigilance framework, and a tailored framework for Ayurveda is vital. This approach guarantees Ayurveda coexists with advanced medicine while preserving its integrity and meeting contemporary health safety guidelines.

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