



PHARMACOVIGILANCE IN AYURVEDA, SIDDHA AND UNANI (ASU) DRUGS: CURRENT STATUS, CHALLENGES AND FUTURE PERSPECTIVES

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Abstract

Ayurveda, Siddha and Unani (ASU) systems constitute important components of traditional healthcare and are increasingly used in India and internationally. Although these systems have long-standing textual traditions and extensive clinical experience, systematic documentation of medicine-related adverse events remains essential for ensuring patient safety and strengthening confidence in traditional medicines. Pharmacovigilance provides a structured approach for detecting, assessing, understanding and preventing adverse effects and other drug-related problems. The need for pharmacovigilance is particularly relevant to ASU medicines because their safety profiles may be influenced by botanical identification, geographical origin, processing methods, formulation complexity, dose, duration of therapy, contamination, adulteration and concomitant use with conventional medicines. India has established a dedicated Pharmacovigilance Programme for ASU and Homoeopathic drugs under the Ministry of Ayush. The programme aims to document suspected adverse effects, assess safety signals, promote reporting culture and monitor misleading advertisements. Current implementation involves a three-tier network consisting of a National Pharmacovigilance Coordination Centre, Intermediary Pharmacovigilance Centres and Peripheral Pharmacovigilance Centres. This review discusses the concept, objectives, importance, reporting mechanisms, challenges and future opportunities of pharmacovigilance in ASU drugs. Strengthening spontaneous reporting, improving product identification, integrating electronic reporting, enhancing pharmacovigilance training and promoting collaboration among clinicians, pharmacists, manufacturers, regulators and researchers can substantially improve the safety surveillance of ASU medicines.

Keywords: Pharmacovigilance, Ayurveda, Siddha, Unani, ASU drugs, adverse drug reaction, herbal medicines, drug safety, Ayush Suraksha, post-marketing surveillance.

1. Introduction

Medicines are intended to provide therapeutic benefits, but their use may also be associated with adverse effects and other safety-related problems. Pharmacovigilance is therefore an essential component of rational and safe healthcare. The World Health Organization (WHO) describes pharmacovigilance as the science and activities concerned with detecting, assessing, understanding and preventing adverse effects or other medicine-related problems. Importantly, pharmacovigilance is not restricted to synthetic pharmaceuticals; it also includes herbal and traditional medicinal products.

Ayurveda, Siddha and Unani medicines have been used for centuries and continue to contribute to healthcare. Their increasing utilization, commercialization and availability through multiple channels make systematic safety monitoring increasingly important. The WHO has specifically developed guidance for safety monitoring of herbal medicines because conventional pharmacovigilance approaches may require adaptation to account for the characteristics of herbal and traditional products.

In India, pharmacovigilance for Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) medicines has been established as a structured national initiative. The programme seeks to develop a culture of documenting adverse effects, improve safety monitoring and identify safety concerns associated with these medicines. It also includes surveillance of misleading advertisements related to ASU&H products.



Cover Page



2. Concept of Pharmacovigilance

Pharmacovigilance may be regarded as a continuous process extending throughout the life cycle of a medicine. Pre-marketing studies provide important information regarding efficacy and safety, but clinical trials generally involve selected populations and limited observation periods. Rare adverse reactions, delayed effects, interactions and problems occurring in special populations may become apparent only after widespread use.

For traditional medicines, pharmacovigilance encompasses more than simply recording adverse drug reactions. It may include:

- Detection and documentation of suspected adverse reactions.
- Identification of medication errors and inappropriate use.
- Detection of herb-drug and drug-drug interactions.
- Investigation of suspected contamination or adulteration.
- Monitoring of quality-related safety problems.
- Identification of previously unrecognized safety signals.
- Assessment of risks associated with long-term or inappropriate use.
- Monitoring of misleading or unsubstantiated therapeutic claims.

WHO emphasizes that safety monitoring should generate reliable information that supports assessment of the benefit-risk profile of medicinal products.

3. Why Pharmacovigilance is Important for ASU Drugs

The assumption that a medicine is safe simply because it is natural or traditionally used may lead to inadequate recognition and reporting of adverse events. Traditional medicines can produce adverse reactions, particularly when they are improperly identified, contaminated, adulterated, incorrectly prepared, used at inappropriate doses or combined with other medicines.

Several characteristics make pharmacovigilance particularly relevant to ASU drugs.

3.1 Complex formulations

Many classical ASU formulations contain multiple ingredients. Determining which ingredient is responsible for an adverse event can therefore be challenging.

3.2 Variability of raw materials

The chemical composition of medicinal plants may vary according to species, geographical origin, cultivation conditions, harvesting time, storage and processing. Such variability can influence both efficacy and safety.

3.3 Processing and pharmaceutical procedures

Traditional pharmaceutical procedures such as Shodhana, Marana, Bhavana, Puta and other processing methods can alter the physicochemical characteristics of ingredients. Appropriate standardization and documentation of these processes are therefore important for safety evaluation.

3.4 Mineral and metal-containing preparations

Certain classical formulations contain mineral, metallic or other inorganic substances. Their safety depends substantially on correct identification, purification, pharmaceutical processing, dose and quality control. Pharmacovigilance can provide valuable post-marketing information concerning their real-world safety.



Cover Page



3.5 Herb-drug interactions

Patients may use ASU medicines simultaneously with modern medicines. Such concurrent use creates the possibility of pharmacodynamic or pharmacokinetic interactions. WHO has highlighted herb-drug interactions as an important technical issue requiring attention from healthcare professionals, researchers, regulators and pharmacovigilance centres.

3.6 Under-reporting

Under-reporting remains a major limitation in herbal and traditional medicine pharmacovigilance. The literature identifies difficulties in product identification, awareness, reporting practices and interpretation of adverse events as important barriers.

4. Objectives of Pharmacovigilance in ASU Medicines

The major objectives include:

1. To identify previously unknown adverse reactions.
2. To determine the frequency and severity of suspected adverse events.
3. To detect new safety signals.
4. To evaluate the benefit-risk balance of ASU medicines.
5. To identify preventable medication-related problems.
6. To monitor herb-drug and formulation-drug interactions.
7. To identify quality-related safety problems.
8. To improve the safe and rational use of ASU medicines.
9. To provide evidence for regulatory decision-making.
10. To strengthen public confidence in traditional systems of medicine.

Thus, pharmacovigilance should not be regarded merely as an adverse-event reporting exercise. It is an important component of quality assurance, rational prescribing and patient safety.

5. Pharmacovigilance Programme for ASU&H Drugs in India

The Government of India, through the Ministry of Ayush, initiated a dedicated pharmacovigilance programme for Ayurveda, Siddha, Unani and Homoeopathy drugs. The programme was introduced to establish a systematic culture of adverse-event documentation, safety monitoring and surveillance of misleading advertisements.

The current programme operates under the Ayush Oushadhi Gunvatta evam Utpadan Samvardhan Yojana (AOGUSY). According to the Ministry of Ayush Annual Report 2024–25, the pharmacovigilance programme for ASU&H drugs operates through a three-tier network comprising a National Pharmacovigilance Centre, five Intermediary Pharmacovigilance Centres and 99 Peripheral Pharmacovigilance Centres.

The All India Institute of Ayurveda (AIIA), New Delhi, functions as the National Pharmacovigilance Coordination Centre (NPvCC) for implementation of the programme.

Three-tier structure

National Pharmacovigilance Coordination Centre (NPvCC)



Intermediary Pharmacovigilance Centres (IPvCs)



Peripheral Pharmacovigilance Centres (PPvCs)



Cover Page



This network facilitates collection, transmission, evaluation and analysis of suspected adverse-event information from different levels of healthcare.

6. Adverse Drug Reactions and Adverse Events

An adverse drug reaction (ADR) refers to a harmful and unintended response associated with the use of a medicinal product at normally used doses. In pharmacovigilance practice, suspected adverse events are initially reported without requiring certainty regarding causality.

Examples of possible adverse events associated with ASU medicines may include:

- Gastrointestinal disturbances
- Allergic reactions
- Skin manifestations
- Hepatic or renal abnormalities
- Neurological symptoms
- Cardiovascular effects
- Drug-drug or herb-drug interactions
- Problems related to excessive or prolonged use
- Effects arising from contamination or adulteration
- Therapeutic failure associated with poor-quality products

A reported event does not automatically establish that the medicine caused the reaction. Proper assessment of temporal association, alternative causes, concomitant medicines, underlying disease, dose and dechallenge/rechallenge information is required.

7. Sources of Pharmacovigilance Data

Safety information concerning ASU medicines can be obtained from multiple sources.

7.1 Spontaneous reporting

Healthcare professionals, patients and other stakeholders can report suspected adverse events. Spontaneous reporting is particularly useful for identifying rare or unexpected safety signals.

7.2 Clinical studies

Clinical research can provide structured information concerning the safety of individual drugs and formulations.

7.3 Post-marketing surveillance

Once a medicine is widely used, safety information can be obtained from real-world populations that were not fully represented in clinical studies.

7.4 Hospital and institutional records

Ayurvedic hospitals, teaching institutions and research centres can contribute valuable information through systematic observation and documentation.

7.5 Literature

Published case reports, observational studies, clinical studies and systematic reviews can provide additional safety evidence.



Cover Page



7.6 Quality-control investigations

Laboratory findings concerning contamination, adulteration, incorrect identification or deviations in pharmaceutical quality can provide important safety information.

7.7 Advertisement surveillance

Misleading advertisements may encourage inappropriate self-medication or create unrealistic expectations regarding therapeutic effects. The national ASU&H pharmacovigilance programme therefore includes surveillance of misleading advertisements.

8. Reporting of Suspected Adverse Events

A useful adverse-event report should contain sufficient information to permit evaluation of the case. Important details include:

- Patient demographic information.
- Description of the adverse event.
- Date of onset.
- Suspected ASU medicine.
- Brand and formulation name.
- Dose and route of administration.
- Frequency and duration of treatment.
- Indication for which the medicine was used.
- Batch or lot number, when available.
- Manufacturer details, where applicable.
- Concomitant medicines.
- Relevant medical history.
- Investigations and laboratory findings.
- Treatment provided for the adverse event.
- Outcome of the reaction.
- Information regarding withdrawal or reintroduction of the suspected medicine.

Accurate identification of the product is particularly important in traditional medicine pharmacovigilance. Product name alone may not be sufficient because identical or similar names can refer to products with different compositions.

9. Causality Assessment

Causality assessment attempts to determine how strongly the suspected medicine is associated with the reported adverse event.

Important considerations include:

- Temporal relationship between drug exposure and event.
- Known pharmacological or toxicological plausibility.
- Alternative explanations.
- Dechallenge information.
- Rechallenge information, when available and ethically appropriate.



Cover Page



- Dose-response relationship.
- Previous reports of similar reactions.
- Objective clinical and laboratory evidence.

Causality assessment should be systematic and should avoid automatically attributing every adverse event occurring during ASU medicine use to the medicine itself.

10. Special Challenges in ASU Pharmacovigilance

10.1 Difficulty in product identification

Traditional medicines may be identified using classical names, regional names, trade names and different transliterations. Accurate botanical, mineralogical or pharmaceutical identification is therefore essential.

10.2 Polyherbal formulations

A formulation containing numerous ingredients can make attribution of causality difficult.

10.3 Variable composition

Differences in raw materials, processing and manufacturing may produce variability between batches.

10.4 Inadequate documentation

Incomplete information regarding dose, duration, batch number and concomitant medicines can reduce the usefulness of an adverse-event report.

10.5 Lack of awareness

Healthcare professionals and patients may not recognize the importance of reporting suspected adverse events.

10.6 Under-reporting

Under-reporting is a recognized challenge in herbal pharmacovigilance and may result from limited awareness, uncertainty about causality, lack of reporting habits and difficulties in identifying products.

10.7 Concomitant medication use

Patients may simultaneously use ASU and conventional medicines without informing healthcare providers, making assessment of causality and interactions difficult.

10.8 Self-medication

Easy availability of certain products can lead to unsupervised use, inappropriate dosage and prolonged treatment.

11. Role of Healthcare Professionals

Healthcare professionals have a central role in strengthening ASU pharmacovigilance.



Cover Page



Physicians

Ayurvedic, Siddha and Unani physicians should actively inquire about adverse effects during follow-up visits and document suspected reactions carefully.

Pharmacists

Pharmacists can contribute by identifying potential medication errors, inappropriate combinations, quality problems and possible interactions.

Nurses

Nursing personnel may be among the first healthcare workers to observe adverse reactions and can facilitate timely reporting.

Teachers and students

Ayush teaching institutions can develop pharmacovigilance awareness among undergraduate and postgraduate students by incorporating adverse-event identification and reporting into clinical teaching.

Manufacturers

Manufacturers should maintain appropriate quality systems, investigate safety complaints and cooperate with regulatory and pharmacovigilance authorities.

12. Role of Manufacturers in Pharmacovigilance

Manufacturers are important stakeholders in post-marketing safety surveillance. Their responsibilities should include:

- Maintaining detailed product records.
- Ensuring appropriate raw-material identification.
- Implementing quality-control procedures.
- Maintaining batch-related information.
- Investigating safety complaints.
- Supporting adverse-event assessment.
- Communicating relevant safety information to regulatory authorities.
- Reviewing emerging safety signals.
- Maintaining appropriate product information and warnings.

A strong connection between quality control and pharmacovigilance is essential because some adverse events may originate from problems in raw materials, manufacturing, storage or distribution rather than from the intended pharmacological action of the formulation.



Cover Page



13. Relationship Between Pharmacovigilance and Quality Assurance

Pharmacovigilance and quality assurance are complementary activities.

Quality assurance aims to ensure that the product is consistently manufactured according to appropriate standards.

Pharmacovigilance evaluates what happens when the product is used in real-world conditions.

For ASU medicines, the two systems should communicate with each other. A cluster of adverse events may indicate:

- Incorrect raw material.
- Adulteration.
- Contamination.
- Manufacturing deviation.
- Improper storage.
- Incorrect labeling.
- Inappropriate dosage instructions.
- Counterfeit products.

Consequently, pharmacovigilance data can serve as an additional source of information for strengthening pharmaceutical quality systems.

14. Digitalization of ASU Pharmacovigilance

Digital technology provides an opportunity to improve pharmacovigilance through:

- Online adverse-event reporting.
- Mobile-based reporting.
- Electronic case records.
- Automated signal detection.
- Standardized terminology.
- Electronic databases.
- Data linkage between healthcare institutions.
- Real-world evidence generation.
- Artificial intelligence-assisted signal identification.



Cover Page



The Ayush Suraksha platform provides a digital framework associated with the national pharmacovigilance initiative. The wider development of digital pharmacovigilance is consistent with the WHO's current emphasis on efficient safety surveillance and the use of digital tools and real-world data.

15. Future Perspectives

The future of ASU pharmacovigilance should move from predominantly passive reporting toward a more comprehensive and proactive safety-surveillance system.

Important areas for development include:

1. **Strengthening spontaneous reporting:** Healthcare professionals should be encouraged to report even suspected rather than confirmed adverse reactions.
2. **Pharmacovigilance education:** Training should be incorporated into undergraduate, postgraduate and continuing professional education.
3. **Improved product identification:** Botanical, mineralogical, pharmaceutical and chemical identification should be documented wherever appropriate.
4. **Electronic reporting:** Digital platforms should be made simple, multilingual and accessible to clinicians and consumers.
5. **Active surveillance:** Selected high-use or higher-risk medicines may benefit from structured active surveillance.
6. **Interaction monitoring:** Herb-drug and ASU-drug interactions should receive greater research attention.
7. **Integration with quality-control systems:** Safety signals should be evaluated alongside manufacturing and laboratory-quality information.
8. **Research collaboration:** Academic institutions, manufacturers, regulators and pharmacovigilance centres should collaborate on multicentric safety studies.
9. **Real-world evidence:** Long-term observational data can provide information about safety in diverse patient populations.
10. **International collaboration:** Harmonization of terminology, reporting procedures and safety standards can facilitate global recognition and safer use of traditional medicines.

16. Conclusion

Pharmacovigilance is an essential component of safe and rational use of Ayurveda, Siddha and Unani medicines. Traditional use and historical experience provide valuable knowledge, but systematic contemporary safety surveillance is necessary to identify rare, unexpected and preventable medicine-related problems. The increasing use and commercialization of ASU medicines further reinforce the need for reliable safety monitoring.



Cover Page



India has established a dedicated national pharmacovigilance framework for ASU&H medicines, including a three-tier network of national, intermediary and peripheral centres. The programme aims to improve patient safety, encourage adverse-event reporting and address misleading advertisements.

The success of pharmacovigilance ultimately depends on the participation of all stakeholders. Physicians, pharmacists, nurses, researchers, manufacturers, regulators, teachers, students and patients should recognize that reporting a suspected adverse event is not an accusation against a medicine or therapeutic system; rather, it is a contribution to evidence-based patient safety. A scientifically robust, transparent and digitally enabled pharmacovigilance system can strengthen the credibility of ASU medicines while preserving their traditional knowledge base and supporting their responsible integration into contemporary healthcare.

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Suggested citation style for the article

For journal submission, the article can be converted to Vancouver style with numbered in-text citations, for example: *Pharmacovigilance is concerned with detection, assessment, understanding and prevention of adverse effects associated with medicines.* [1] This would make the manuscript more suitable for an Ayurveda/AYUSH research journal.