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PHARMACOVIGILANCE IN AYUSH: ENSURING SAFETY IN TRADITIONAL MEDICINE

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ABSTRACT

Herbal and traditional medicines constitute an important component of healthcare in many regions of the world, being seen as safe alternatives to standard drugs. This has raised concerns in ensuring the safety and efficacy of these products, stressing the utmost need for pharmacovigilance for herbal medicines. The last two decades saw widespread efforts worldwide aimed at developing strong regulatory systems, resulting in the development of phytovigilance systems. The indigenous Indian systems of medicine are Ayurveda, yoga and naturopathy, Unani, Siddha and homoeopathy (AYUSH). The Drugs and Cosmetics Act 1940 and Drugs and Cosmetics Rules 1945 have provision for the regulatory mechanism and for oversight on the quality, safety and efficacy of AYUSH system medicines. For gathering, consolidating and evaluating the safety of AYUSH drugs, in 2007, the Government of India initiated a National Pharmacovigilance Programme for ASU (NPP-ASU) drugs. According to the program, roles and tasks of the National Pharmacovigilance Centre, Intermediary Pharmacovigilance Centres, and Periphery Pharmacovigilance Centres are established. The program has been established with the aid of the Pharmacovigilance Programme of India (PvPI), and the World Health Organization, among others. This review gives a broad overview of the pharmacovigilance systems across different countries, with a focus on recent trends, ongoing challenges, and global views in the area.

KEYWORDS: The indigenous Indian systems of medicine are Ayurveda, yoga and naturopathy, Unani, Siddha and homoeopathy (AYUSH).

1. INTRODUCTION

Pharmacovigilance of AYUSH has emerged as an essential aspect of healthcare in India and overseas, reflecting the need to ensure that traditional drugs are utilized safely, rationally, and efficiently.[1] AYUSH, Ayurveda, Yoga & Naturopathy, Unani, Siddha, and Homoeopathy, represents centuries of gained medicine which has been woven as an integral part of the cultural and social fate of the Indian subcontinent. These systems of medicine have been practiced for centuries mainly on the basis of natural substances such as herbs, minerals, and animal products, and therapeutic modalities such as yoga and naturopathy.[2] Though conventionally associated with holistic treatment with minimal side effects when suitably applied, the changing patterns of production, distribution, and consumption have prompted a critical examination of these systems within the paradigm of modern safety science.[3] The global renaissance in the use of herbal and traditional medicine is driven, in part, by consumer demand for holistic and natural treatments. World Health Organization reports highlight that the majority of the world's population that is 80% in many countries is reliant on traditional medicine for its primary healthcare needs.[5] In India, AYUSH remains a primary and complementary healthcare option, backed by policy, educational systems, and research facilities.[5] However, growing demand, globalizing of AYUSH products, and integration with conventional medicine have introduced new safety issues. The mass advertising and of preparations, variable quality control in a few manufacturing industries, internet advertising, and increasing cases of self-medication raised the spectre of adulteration, contamination, improper dosing, and possible herb–drug interactions. In sharp contrast to the prevailing opinion that natural products are naturally safe, there have been a number of instances that have illustrated that even vegetable or mineral preparations can have adverse effects in specific circumstances.[6] Toxicity can be caused by overdosing, improper preparation, misidentification of ingredients, or contamination with heavy metals and pesticides. Some Ayurvedic formulations have processed metals and minerals such as mercury, lead, or arsenic as a part of their classical pharmacopeia, but unless processed with proper purification protocols, these may be harmful.[6,7] Similarly, like Withania somnifera, which is otherwise well tolerated, in rare cases is linked with thyrotoxicosis, and Piper longum, used for its gastrointestinal and respiratory applications, causes gastric irritation when excessive.[7] These findings underscore the importance of a scientific method of surveillance and documentation of AYUSH therapy adverse effects. Pharmacovigilance, as the scientific and medical endeavor concerned with the detection, assessment, understanding, and prevention of adverse effects or other drug-related issues, plays an important role in the

gap-filling between traditional knowledge and modern healthcare safety requirements. Its function is not limited to detection of adverse effects; it generates evidence-based confidence in the safe use of medicinal drugs.[8] Pharmacovigilance in AYUSH parlance implies the understanding of complex multi-ingredient preparations, evaluation of interactions with allopathic medicines, and comparison of preparation techniques which can affect pharmacological action. This customized approach is required because the majority of AYUSH products are different from single-ingredient new-generation pharmaceuticals in composition as well as manufacturing philosophy.[9] India's organized initiatives in this regard picked up considerable momentum in 2017 with the launch by the Ministry of AYUSH of the Pharmacovigilance Programme for AYUSH (PvP-Ayush). This program aimed at establishing a national system for collecting, documenting, and assessing adverse drug reactions associated with AYUSH products.[10] The All India Institute of Ayurveda (AIIA), New Delhi, is the National Coordinating Centre backed by a network of Peripheral Pharmacovigilance Centres located in AYUSH educational, research, and healthcare institutions. Reporting forms have been suitably modified to identify the unique features of AYUSH therapies, keeping in view the fact that adverse effects can occur differently as opposed to conventional medicine. These reports, collected from practitioners, pharmacists, researchers, and even patients, are reviewed to find patterns and possible safety signals. Though the setting up of a formal network of pharmacovigilance is a big step forward, some practical issues remain.[11] Many AYUSH practitioners and patients still downplay the likelihood of adverse reactions due to natural products and therefore underreport. It is challenging to standardize nomenclature for formulations and symptoms between varied traditional systems, and the polyherbal composition of most preparations makes it challenging to identify the exact component causing an adverse effect.[12] Additionally, differences in raw material source, seasonally varying phytochemical content, and manufacturing processes bring about batch-to-batch variation that influences both efficacy and safety. In rural and informal environments, inadequate record-keeping also restricts the release of credible safety data. Other nations with rich cultures of herbal medicine have incorporated monitoring of safety in their healthcare systems around the world.[13] Pharmacovigilance protocols for Traditional Chinese Medicine, including hospital-based reporting and post-marketing surveillance, have been put in place in China.[14] Japan has a hybrid model of clinical surveillance and regulatory control for Kampo medications, and South Korea has introduced Good Manufacturing Practices to its traditional medicine in addition to systematic ADR reporting systems.[15] These cross-cultural experiences prove that

traditional medicine can successfully be integrated into modern pharmacovigilance schemes without loss of its cultural and therapeutic identity. For AYUSH, effective pharmacovigilance not only ensures the safety of public health but also enhances the integrity of these systems globally. International trade of herbal goods more and more relies on compliance with top standards of quality and safety by importing countries. Effective pharmacovigilance information can be used to meet such regulatory needs, facilitate evidence-based acceptability, and protect the reputation of Indian traditional medicine abroad. How to move forward involves sensitizing practitioners to the documentation and reporting of adverse events, encouraging manufacturers to conduct rigorous quality control and post-marketing surveillance, and generating public awareness of the rational use of AYUSH products.[16] Computerization, through means like mobile apps to submit ADRs in real-time, can ensure easier reporting, while training modules can acclimatize healthcare providers with causality evaluation and risk communication. Furthermore, collaborative research between AYUSH specialists and contemporary pharmacologists can provide insights into mechanisms of action, possible interactions, and means of lessening the risks without loss of therapeutic gain.[17] Pharmacovigilance in AYUSH is thus an active meeting point of heritage and innovation. It accepts that the sheer tradition of use does not take the place of systematic monitoring of safety in the current setting of industrial production, international trade, and integrative health care. Through promoting a culture of caution, transparency, and evidence-based practice, it is likely to ensure that AYUSH systems remain effective for future generations with the same trust and therapeutic significance they have carried over centuries yet corresponding to the safety expectations of contemporary medicine and regulatory science.

2. Rationale for Pharmacovigilance in AYUSH

AYUSH systems have an age-old tradition of treatment, but the manufacturing, distributional, and consumptional conditions of the times have created new safety challenges that make pharmacovigilance mandatory. The different points of origin, preparation methods, and methods of use of AYUSH products bestow new risks varying from those associated with conventional medicines. Systematic surveillance of these products detects potential harms, builds public trust, and allows safe integration into national as well as international health care systems.[17,18] (Figure 1).

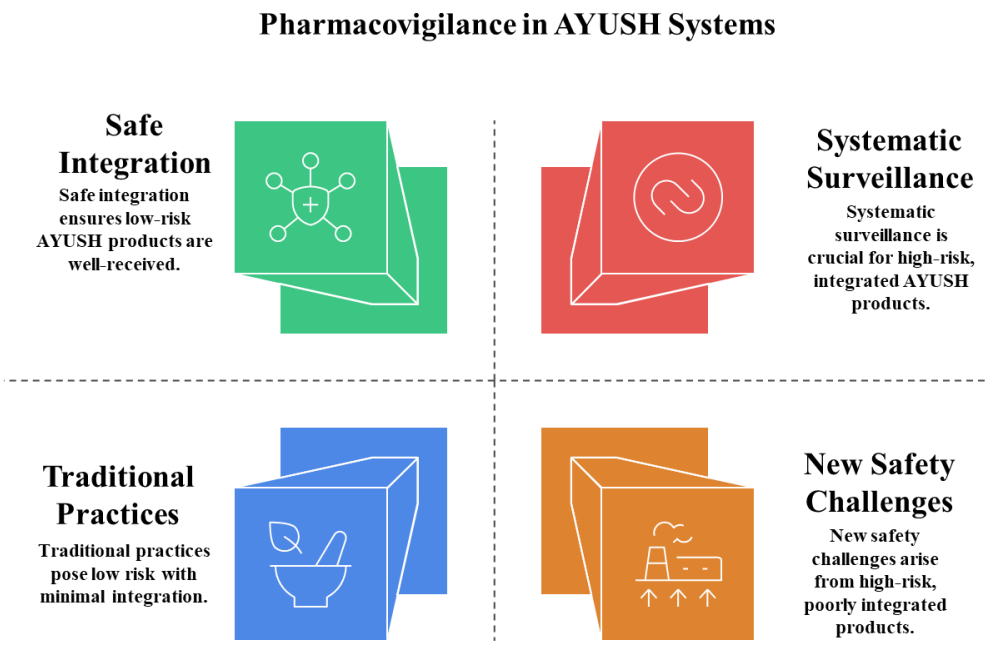

Figure 1 Pharmacovigilance system in AYUSH.

2.1 Complex Composition

Most AYUSH medicines are polyherbal or polyingredient in their composition, having many plant extracts, minerals, and animal materials blended together in fixed proportions as described in traditional literature.[19] This complexity, while being the characteristic of their concept of cure, is hard to track in safety. Side effects may result from a single component, combination of components, or chemical interactions between them. For example, a drug prepared with a blend of Piper longum and Zingiber officinale could enhance bioavailability but also enhance the risk of gastric irritation in vulnerable subjects.[20] Identification of the culprits within the mixture is far more difficult than in single compound drugs and is a special task for qualified pharmacovigilance apparatus and methods for traditional medicine.

2.2 Variable Quality Control

AYUSH product quality can also be fairly variable due to differences in procurement of raw materials, cultivation, variation in phytochemical content based on seasons, and processing. Poor compliance with Good Manufacturing Practices (GMP) can result in heavy metal, pesticide, or microbial contamination. Batch-to-batch variation can also have implications for safety and efficacy even in compliant facilities. This diversity underscores the need for post-marketing safety monitoring to capture adverse effects that may go undetected in controlled clinical trials or common use. Pharmacovigilance offers a platform for detection of quality-

related safety signals and remedial measures, hence protecting consumers as well as the integrity of AYUSH systems.[23,24]

2.3 Global Consumption Boost

AYUSH products no longer confine their indigenous Indian markets. As global trade expands, these preparations are being used by populations having different genetic makeups, diets, and health care systems. In some importing countries, AYUSH products are viewed as dietary supplements rather than drugs, resulting in a varying degree of control. Foreign market reports of adverse events may spread very quickly and affect global AYUSH safety perception and commercial policies. An efficient pharmacovigilance system is capable of detecting and reporting such issues in advance, maintaining pace with international standards and keeping India competitive in the global market for herbal products.[24]

2.4 Misuse & Self-Medication

The belief that "natural equals safe" tends to promote the unmonitored consumption of AYUSH products. Self-medication, inappropriate dosing, extended use, and unverified online purchases can all escalate the risk of side effects. For example, people use high doses of herbal tonics with the expectation that increased quantity will yield quicker outcomes, and this can result in toxicity. In the absence of a surveillance program to identify these misuse-related responses, the actual safety profile of AYUSH products is incomplete. Pharmacovigilance allows such patterns to be identified, directing public health interventions and information campaigns towards ensuring rational use.[1,25]

2.4 Integration with Allopathy

The increased popularity of integrative medicine ensures that AYUSH treatments are combined with allopathic medications by many patients. Although these combinations may be advantageous, they increase the risk of herb–drug interactions, which can change pharmacokinetics or pharmacodynamics. For instance, anticoagulant herbs, when used in combination with prescription blood thinners, could enhance the risk of bleeding. The interactions are not always predictable and may also not be well documented in mainstream drug databases. AYUSH pharmacovigilance, with its specific reporting forms, can systematically capture and analyze such integrative therapy-related events and generate evidence to support clinical decision-making and patient safety guidelines.[26,28] Table 1).

Table 1: Common Interactions of Herbal Drugs.

S. No.	Interaction Type	Examples
1	**Herb–Herb Interactions**	Piper betel + Garcinia morella Basella alba + Sesamum indicum Glycyrrhiza roots + Euphorbia pokinensis root Aconite + Bletilla striata rhizome Liquorice + Seaweed
2	**Herb–Food Interactions**	Radish + Milk Madhu + Grutha (equal quantities) Sesame + Black cumin Shilajatu + Kakmachi Asafoetida + Honey Garlic + Milk Kampillaka + Buttermilk Bhallataka + Hot water Kakmachi + Honey Boswellia + various foods
3	**Herb–Animal-Origin Drug Interactions**	Pigeon meat + Brassica alba Pork + Coccus nucifera oil Honey + Ghee
4	**Drug–Disease Interactions**	Terminalia chebula, papaya: contraindicated in pregnancy Aloe vera with blood glucose-lowering drugs Ashwagandha with digoxin or thyroid hormones Ephedrine with steroids
5	**Miscellaneous Factors**	Idiosyncrasy Drug–activity (e.g. exercise) interaction
6	**Herb–Drug (Anticoagulant/Bleeding Risk)**	Ginkgo + NSAIDs/warfarin → ↑ bleeding risk Garlic + warfarin → enhanced bleeding Ginger + anticoagulants → bleeding risk Chamomile potentially interacts with warfarin, aspirin
7	**Herb–Drug (CYP450 & Metabolic Effects)**	St. John's wort: induces CYP3A4/P-gp; reduces efficacy of oral contraceptives, immunosuppressants, digoxin, warfarin, cancer/HIV drugs Ginkgo: ↓ plasma omeprazole, ritonavir; interacts with P450-metabolized drugs
8	**Herb–Drug (Hypoglycemic & Antidiabetic Effects)**	Ginseng + antidiabetics → hypoglycemia Coriander enhances hypoglycemic drug effects
9	**Herb–Drug (Additive CNS or Cardiovascular Effects)**	Kava + sedatives (e.g. benzodiazepines, barbiturates, antipsychotics, alcohol) → CNS depression Ephedra + MAO-inhibitors/cardiac glycosides → hypertension, arrhythmias Yohimbine + tricyclics → hypertension
10	**Herb–Drug (Immune Suppression)**	Astragalus, echinacea, liquorice, milk thistle, neem, sea buckthorn ↓ effectiveness of immunosuppressants (e.g. cyclosporine, methotrexate)
11	**Other Herb–Drug Interactions**	Astragalus: with oral contraceptives, risk of decreased efficacy; ↑ bleeding risk with warfarin Bitter orange: with antihypertensives and MAOIs →

		arrhythmia, hypertension Black cohosh: potential liver toxicity; interactions with statins, acetaminophen, fluconazole Cannabis: ↑ CNS depression with alcohol, sedatives, bleeding risk with warfarin, ↓ phenytoin levels, mania with fluoxetine
12	**Herbs with Antibiotic/Absorption Effects**	Senna, guar gum: reduce absorption of digoxin, antibiotics Piper nigrum/longum: inhibit antibiotic metabolism, ↑ antibiotic toxicity Fenugreek: may retard absorption; spacing oral drugs advised

3. Regulatory Framework in India

India's AYUSH regulatory approach for medicines is unique in the effort to preserve the traditional character of knowledge while integrating modern scientific practices to ensure quality, safety, and efficacy. The legislative framework of AYUSH regulation comprises the Drugs and Cosmetics Act, 1940 and the Rules, 1945, amended from time to time. The Act also empowers the government to make standards relating to identity, purity, and strength of AYUSH medicines by the Ayurvedic Pharmacopoeia of India (API), Siddha Pharmacopoeia of India (SPI), Unani Pharmacopoeia of India (UPI), and Homoeopathic Pharmacopoeia of India (HPI). Despite these measures, prior to 2017, there was no specific, formal system for post-market safety surveillance of AYUSH, and therefore there were loopholes in handling upcoming adverse events in real time.[29] (Figure. 2).

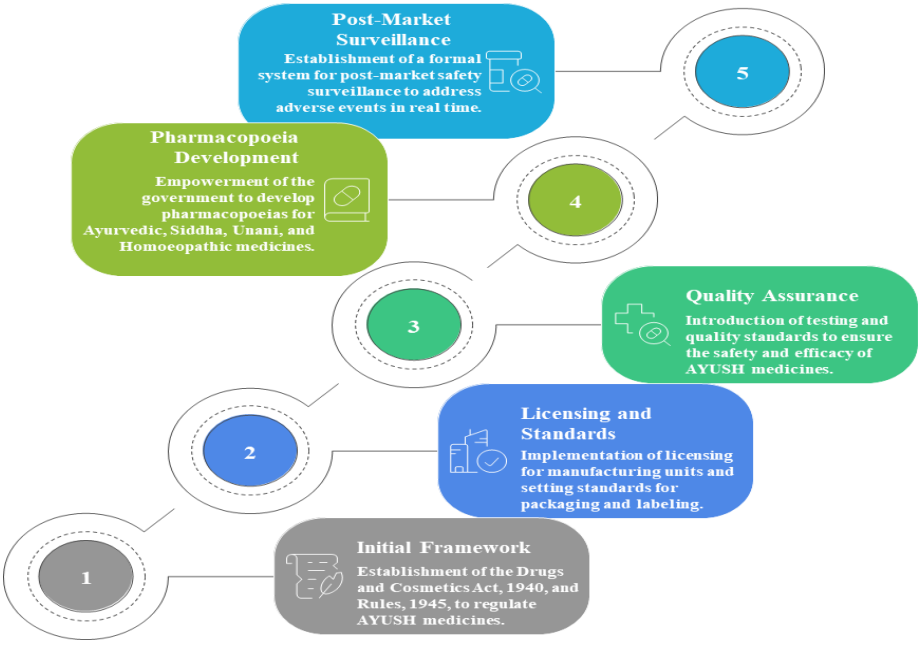

Figure 2 Regulatory Framework in India.

3.1 Initiative for Pharmacovigilance Programme for AYUSH (2017)

The Pharmacovigilance Programme for AYUSH (PvP-Ayush) was initiated in October 2017 by the Ministry of AYUSH to collate, review, and respond to safety information systematically for traditional medicine. The program was patterned on the WHO Programme for International Drug Monitoring principles but modified to suit the nature of AYUSH systems that are commonly multi-herbal, herbo-mineral, and containing animal-derived products. The launch of the programme was motivated by the growing international pressure on herbal products following heavy metal contamination, adulteration with pharmaceuticals, and herb–drug interactions.[30] Prior to PvP-Ayush, ADR reports for AYUSH drugs were largely anecdotal, appearing as single case reports in medical journals or hidden in hospital records. The new program sought to institutionalize reporting, enhance methods of causality assessment of complex mixtures, and harmonize India's herbal pharmacovigilance with international standards. The formal launch involved training modules for more than 200 institutions, with the aim of establishing a countrywide network that could be integrated with the larger pharmacovigilance system.[31,32]

3.2 Function of National Coordinating Centre (NCC)

The All India Institute of Ayurveda (AIIA) in New Delhi was opened as the National Coordinating Centre (NCC) for PvP-Ayush. This was a strategic decision, as AIIA is the apex academic and research institution under the Ministry of AYUSH having state-of-the-art laboratories, multidisciplinary faculty, and strong clinical infrastructure. The roles of the NCC are to develop reporting tools tailored to AYUSH needs, offer national-level training to government and private practice practitioners, and render ADR reports scientifically and legally acceptable.[11] The NCC is the central repository of all ADR data received from the network and performs quality control drills before forwarding validated reports to the Indian Pharmacopoeia Commission (IPC). It also broadcasts quarterly pharmacovigilance newsletters, issues safety notices, and apprises the Ministry of upcoming regulatory action. Between 2017 and 2022, the NCC guided the setting up of more than 50 Peripheral and 8 Regional Pharmacovigilance Centres, covering almost all union territories and states, thereby extending reach from urban academic centres to rural health centres.[33,34]

3.3 Peripheral Pharmacovigilance Centres (PPvCs)

Peripheral Pharmacovigilance Centres (PPvCs) constitute the cornerstone of PvP-Ayush's surveillance architecture. Situated within AYUSH teaching hospitals, research centers,

district-government-level hospitals, and selected private practice centers, PPvCs are the key points of ADR data collection.[35] Their role goes beyond reporting; they do community outreach, raise awareness among local practitioners regarding the significance of ADR monitoring, and assist patients in filling out the report. Every PPvC is manned by trained coordinators, frequently assisted by postgraduate students, who undergo frequent capacity-building training to ensure reporting consistency. The PPvCs send their validated reports to RPvCs, which offer a further check before passing on to the NCC. As of 2023, the PvP-Ayush network had set up more than 80 PPvCs, greatly expanding geographic coverage and providing a means for safety monitoring to reach AYUSH's vast rural consumer base, where traditional medicine is most heavily used.[36]

3.4 Monitoring and Reporting Adverse Drug Reactions

ADR monitoring under PvP-Ayush occurs according to a systematic process that highlights the distinctive aspects of traditional formulations. Practitioners, pharmacists, or patients may submit a report through AYUSH-specific ADR forms in English and Hindi, with electronic submission facilities via email and internet portals. The forms obtain the essential information of exact formulation name, dosage form, manufacturer, batch number, route of administration, concomitant therapies, and extensive description of the adverse event, including onset, duration, and outcome.[37] The process of causality assessment employs a revised WHO-UMC system that considers the multi-ingredient and polyherbal composition of AYUSH drugs in which direct causality attribution to one component can be difficult. The report, once it comes to the NCC via the PPvC–RPvC pathway, is finally validated and retained in the IPC's national database.[37] Genuine, unforeseen, or cluster ADRs initiate a fast-track review procedure that may lead to product recalls, relabeled products, or practitioner alerts. During its introduction up to 2022, PvP-Ayush received more than 2,500 ADR reports, of which most involved herbal-metallic preparations in Ayurveda, followed by some high-potency homoeopathic preparations and powerful Siddha drugs (Table 2).[38,39]

Table 2: Various Herb or Toxic Agents with their Health Risks and Clinical Symptoms.

Herb	Toxic Agents	Health Risks / Clinical Symptoms
Tripterygium wilfordii Hook F. (TWHF)	Triptolide, Celastrol	Hepato- and nephrotoxicity, gastrointestinal, cardiovascular, reproductive toxicity, bone marrow suppression; fatal renal and hematopoietic outcomes reported in ESRD patients.
Aristolochia sp. (e.g., A. fangchi,	Aristolochic acid	Rapidly progressive nephropathy evolving to renal failure, increased risk of urothelial cancer; ~100+

A. longa)		cases of nephropathy, IARC Group 1 carcinogen
Radix Bupleuri (Bupleurum species)	Saikosaponins (SSb2, SSd)	Mitochondrial dysfunction and hepatocellular injury via mitochondrial membrane disruption and caspase activation; combined toxicity is additive.
Herbs in a broad nephrotoxicity context	Various botanical compounds	A diverse array of renal dysfunction—including acute interstitial nephritis, oxalate nephropathy, acute kidney injury, chronic renal disease, papillary necrosis, urothelial malignancy; 27 case reports globally; nephrotoxic herbs include Dioscorea quinqueloba, Lawsonia inermis, Cassia senna, Artemisia herba-alba, Chenopodium polyspermum, Euphorbia paralias, Crataegus orientalis, Colchicum autumnale, Tribulus terrestris
Oleander (Nerium oleander)	Oleandrin (cardiac glycoside)	Life-threatening poisoning. Symptoms may include GI distress (nausea, vomiting, abdominal pain), arrhythmias (tachy-, bradyarrhythmias, AV block), CNS effects (seizures, coma), yellow vision, respiratory paralysis, potentially fatal
Atractylis gummifera	Atractylate	Hepatotoxic effects producing nausea, vomiting, epigastric pain, anxiety, headache, convulsions, potentially leading to coma

4. Methods of Safety Monitoring

Maintaining the safety of AYUSH medicines involves a multidimensional monitoring system that combines conventional pharmacovigilance systems with modifications for polyherbal and herbo-mineral preparations. As compared to single-molecule drugs, AYUSH medicines tend to be comprised of several active moieties, complex excipients, and traditional processing systems, hence making safety monitoring challenging and atypical. The Ministry of AYUSH, under PvP-Ayush, has embraced an integrated system of spontaneous reporting, active surveillance, epidemiological research, signal detection, and laboratory tests. Collectively, these processes are designed to capture rare and frequent adverse events, determine possible risk factors, and inform regulatory and clinical decision-making.

4.1 Spontaneous Reporting System (SRS)

Spontaneous Reporting System (SRS) is the cornerstone of PvP-Ayush's safety monitoring. It relies on spontaneous, voluntary reporting of suspected ADRs by clinicians, pharmacists, and patients themselves. SRS has been put in place at AYUSH through developing AYUSH-specific ADR reporting forms in different languages and formats, i.e., physical forms distributed among PPvCs and web portals linked to the Indian Pharmacopoeia Commission database. This system captures critical information such as formulation name, ingredients, dose, duration of therapy, and clinical description of occurrence. SRS is particularly useful in

capturing rare, unexpected, or not previously reported adverse reactions but also has limitations such as underreporting and incompleteness.[12] PvP-Ayush SRS recorded over 2,500 ADR reports between 2017-2022, with Ayurveda contributing almost 60%, Unani 20%, Siddha 15%, and Homoeopathy the remaining fraction. Of particular interest is that the majority of the severe ADRs reported were seen in formulations containing heavy metals like lead, mercury, and arsenic, which typically arose due to poor quality manufacturing or storing practices.[40]

4.2 Active Surveillance

Whereas SRS relies upon voluntary reports, active surveillance actively seeks out safety information through systematic monitoring of selected populations. For AYUSH, active surveillance has been applied in teaching hospitals, governmental wellness centres, and some rural outreach schemes. In this setting, field investigators or clinical personnel trained and specially assigned actively screen patients on AYUSH medicines for signs of adverse events and have regular follow-up visits or telephone calls. This strategy works best for detection of ADRs associated with chronic usage, high doses, or seasonal therapy like Panchakarma detoxification therapy or Rasayana rejuvenation therapy. For instance, a 2019-2021 multi-centre active surveillance study followed more than 5,000 patients on classical Ayurvedic formulations and reported the most frequent events to be gastrointestinal disturbances and mild allergic reactions, with rare but occurring severe toxicity happening in the case of herbo-mineral preparations.[1]

4.3 Case Series and Case–Control Studies

Case series and case–control studies are intermediate-level study tools to investigate associations between a given AYUSH medicine and adverse outcomes. In a case series, clinicians report multiple patients developing similar ADRs following exposure to a specific formulation, generating a descriptive dataset for pattern recognition. In case–control studies, individuals with a particular unwanted effect (cases) are compared to individuals who lack it (controls) in order to determine possible risk factors, including specific ingredients, dosages, or co-administered allopathic drugs. Such investigations have helped pin down risks such as herb–drug interaction between Ayurveda's Ashwagandha and sleep-promoting drugs, or hepatotoxicity due to long-term consumption of certain Siddha herbo-mineral preparations. Although smaller in scope, these studies offer essential evidence that can inform practitioners and regulators alike.[31,41] Table 3).

Table 3: Case Reports of Herbal Supplements and Associated Health Risks.

Herbal Supplement	Case Details	Health Risks
Garcinia cambogia	A 52-year-old female required a liver transplant after taking 1,000 mg daily of pure Garcinia cambogia for 15 days for weight loss. Another 42-year-old female developed extreme transaminase elevations (ALT ~70x ULN, AST ~45x ULN) and coagulopathy after just one week of use; both recovered upon cessation.	Acute liver failure; hepatocellular injury
Hydroxycut (pre-2009 formulation)	Two male patients (aged 27 and 30) developed jaundice after 2–5 weeks of use (elevated bilirubin and ALT), which resolved in ~5 weeks. Also linked to cases requiring transplant and at least one death; FDA issued a public warning in 2009.	Acute liver injury, liver failure
Aloe vera (extracts, tablets)	A 57-year-old German woman developed acute hepatitis after taking 500 mg/day for 4 weeks; liver biochemistry normalized over a year.	
Garcinia-containing multi-ingredient supplement	A 39-year-old overweight woman developed acute drug-induced liver injury after ~12 days of a powder containing hydroxycitric acid (Garcinia cambogia), green tea, aloe, kelp, etc. Lab work and biopsy indicated injury, and symptoms resolved with supportive care over four months.	Acute liver injury with biopsy-confirmed cholestasis and necrosis
Turmeric (curcumin supplements)	A 57-year-old woman nearly required a liver transplant after taking 2,250 mg/day of turmeric—well over safe limits. She experienced jaundice, dark urine, and extreme enzyme elevation; recovered with intensive care. Broader data show ~70 cases of supplement-linked liver injury, including hepatitis and, in at least one, death. DILI Network identified 10 cases (2004–2022), typically presenting after ~86 days of use.	Severe hepatotoxicity, acute liver injury, at least one fatality
Green tea extract (GTE)	GTE (rich in EGCG) is linked to mitochondrial liver damage and reactive oxygen species. Several cases involve liver injury from weight-loss supplements, with recurrence on re-exposure documented.	Hepatocellular injury, especially in high doses or fasting states
Kava kava	In one series of 36 patients, 9 developed fulminant liver failure and 8 required liver transplants; likely immune-mediated.	Fulminant hepatic failure
Usnic acid products	Weight-loss supplements containing usnic acid (e.g., LipoKinetix®, UCP-1®): at least 21 cases of liver injury including one transplant and one death.	Acute liver injury, liver failure, death
Noni juice	Acute liver failure reported in users of noni juice, including at least one case requiring transplant.	Acute liver failure
(Germander, Chaparral, Ephedra)	Germander (Teucrium chamaedrys) and Chaparral (Larrea tridentata) have well-documented hepatotoxicity. Ephedra (Ma huang) linked to several DILI cases, including about 10 with acute liver injury and some requiring transplant.	Hepatocellular and cholestatic injury, liver failure

4.4 Pharmacoepidemiological Studies

Large-scale pharmacoepidemiology studies are needed to measure the risk of ADRs in real-world practice and identify patterns of use among various populations. These studies combine prescription records, hospital data, and patient interviews to provide population-level estimates of risk. Pharmacoepidemiology is in its nascent stages in AYUSH pharmacovigilance but picking up, particularly with the digital health efforts of the Ministry of AYUSH. For instance, a recent epidemiological survey conducted in five Indian states followed more than 50,000 AYUSH prescriptions over two years and found that polyherbal mixtures were prescribed in more than 80% of cases, while co-therapy with allopathic medication was present in close to 30% of patients, a factor that enhanced the probability of herb–drug interactions and ADRs. Such studies are critical in guiding public health policies and framing practitioner training courses.[25,42]

4.5 Detection of Signal and Assessment of Causality

Detection of signal in AYUSH pharmacovigilance refers to the detection of new or unusual safety problems by analyzing cumulative ADR information from spontaneous reporting, surveillance, and epidemiologic research. A potential signal discovered — e.g., frequent reports of nephrotoxicity with a specific preparation — is then checked for causality to determine the likelihood of an actual association. For traditional herbal remedies, causality evaluation is harder to do than for chemical drugs because of the variety of active ingredients and variability between batches. PvP-Ayush employs a revised WHO-UMC causality system that takes into account factors such as traditional indications, method of preparation, and published toxicologic profiles of ingredients. Established signals can prompt regulatory response in the form of updating product labels, sending out safety alerts, limiting use, or banning particular formulations.[25,43]

4.6 Laboratory and Analytical Testing

Apart from clinical and observation data, laboratory and analytical testing is critical in determining causes of ADR. Suspected products are tested for quality control tests including pharmacognostic analysis, chromatography (HPTLC, GC-MS), heavy metal estimation assay, microbial contamination check, and pesticide residue test. These tests are necessary to detect substandard, spurious, or counterfeit AYUSH drugs that could be dangerous. For instance, certain ADR clusters in 2018 were traced back to contaminated herbal powders that were not up to microbial quality standards. The Central Council for Research in Ayurvedic Sciences

(CCRAS) and national laboratories collaborate with PvP-Ayush to the extent that analytical information goes straight into the regulatory decision-making process.[44,45] (Figure 3).

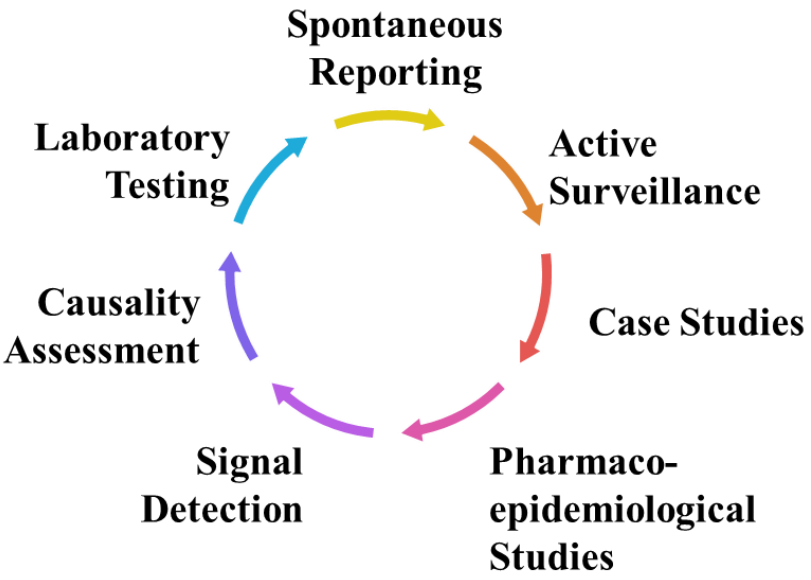

Figure 3: Cycle of Drug Safety Monitoring.

5. Challenges in AYUSH Pharmacovigilance

AYUSH pharmacovigilance presents a unique set of challenges that arise due to the traditional, culturally rooted nature of the practices, formulations diversity, and the dynamic interface with contemporary regulatory systems. The challenges are not just logistic; they entail socio-cultural orientations, scientific sophistication, and gaps in global harmonization.[46]

5.1 Underreporting of ADRs

Underreporting remains the single largest bottleneck in building a robust safety profile for AYUSH medicines. A study showed that even in well-established pharmacovigilance systems, underreporting can be as high as 90%, but in AYUSH, the figure is estimated to exceed 95% for non-serious reactions and around 70–80% for serious cases. An investigation in 15 Peripheral Pharmacovigilance Centres in India (2018–2021) revealed that a mere 426 ADR reports were reported for herbal medicines, even though they were used commonly by millions.[47,48] The reason is that AYUSH professionals frequently give more emphasis to clinical outcomes than documentation, particularly in resource-scarce environments. Another is the absence of explicit incentive to report; in allopathic pharmacovigilance, hospital

accrediting agencies at times tie reporting compliance to quality grades, but no such associations exist in AYUSH practice.

5.2 Cultural Beliefs and Safety Assumptions

Infactuated cultural narratives are responsible for the belief that "time-proven" medicines are safe. For instance a typical case is the long-term use of Guggulu formulations for lipid control, which has caused skin rashes and gastrointestinal upset in individual patients; yet, since these effects are mild and insidious, they are rarely ascribed to the drug. The cultural obstacle also affects practitioners, who might believe that the admission of ADRs could damage patient trust or question their therapeutic competence.[49]

5.3 Standardization and Documentation Issues

AYUSH formulation manufacturing variability is a multifaceted problem beyond the lack of consistent raw material quality. Climate, soil type, and timing of harvesting may vary phytochemical content by 20–30% in some medicinal herbs, causing differences in strength. Moreover, variations in preparation method, e.g., duration of boiling for Kashaya preparations or calcination duration for bhasma preparation can change bioavailability and risk of toxicity. Documentation is compromised due to the fact that small-scale producers, which constitute almost 65% of the AYUSH production industry, tend to have poor batch-level quality control or traceable supply chain documents. For pharmacovigilance, this implies that even when an ADR is identified, proving its cause to be so can be almost impossible in the absence of accurate ingredient profiling.[50,51]

5.4 Complexity of Multi-Ingredient Formulations

Polyherbal and herbo-mineral preparations are a signature feature of AYUSH systems, but they result in gargantuan analytical challenges. For instance, one Chyawanprash formula can consist of more than 40 spices, herbs, and minerals, with each having its own pharmacology, ability to interact, and uncertain safety level. Some have the potential to interact with one another and with allopathic drugs as well as Triphala has been found to modify cytochrome P450 enzyme function with the potential to change the drug metabolism of warfarin or statins.[52] When ADRs do happen, identifying whether it is an individual herb, a synergistic interaction, or a manufacturing impurity (e.g., heavy metals) involves sophisticated chemical analysis and toxicology knowledge not readily available in PPvCs.

5.5 Integration with National and Global Databases

Global integration is needed for detecting patterns of ADRs, particularly since AYUSH products are increasing in popularity in global markets. However, PvP-Ayush's sharing of its data with WHO's VigiBase is not consistent, owing in part to the lack of Herbal Anatomical Therapeutic Chemical (H-ATC) coding for most indigenous ingredients.[53] This implies that when an ADR related to a generic herb such as Tinospora cordifolia (Giloy) happens in India and Europe, it can't necessarily be identified as part of the same safety signal.[54,55] In addition, local integration within PvP-Ayush with the PvPI mainstream Pharmacovigilance Programme of India remains incomplete; ADR reports related to herb–drug interactions are occasionally kept in parallel systems, which creates data silos. Without coordinated reporting, safety warnings will be delayed at the early stages, particularly in the case of patients consuming AYUSH in combination with modern medicine.[56]

6. Strategies to Strengthen AYUSH Pharmacovigilance

If pharmacovigilance in AYUSH is to grow into a strong and well-regarded worldwide system, it has to combine ancient wisdom and contemporary regulatory science, buttressed by improved institutional capacity and public involvement. Targeted action is needed at practitioner, technological, community, and policy levels.[1]

6.1 Practitioner Training and Sensitization

In India, more than 7.8 lakh registered AYUSH practitioners are the first point of contact for millions, but very few have been trained in structured pharmacovigilance training. Scaling up the existing outreach needs integrating ADR detection and reporting modules into Bachelor of Ayurvedic Medicine and Surgery (BAMS), Bachelor of Unani Medicine and Surgery (BUMS), Bachelor of Siddha Medicine and Surgery (BSMS), and Homoeopathy courses. Simulation workshops can simulate actual ADR situations, allowing practitioners to distinguish between disease progression, drug reaction, and herb–drug interaction. In Gujarat and Tamil Nadu states, where ADR reporting through such focused workshops was tested for the first time, ADR reporting by AYUSH practitioners increased by almost 60% in 18 months.[57]

6.2 Public Awareness Campaigns

Public awareness campaigns are important because much of ADRs become apparent only when patients provide information voluntarily. Campaigns may bring to the limelight such high-risk practices as the use of AYUSH formulations in combination with NSAIDs or statins

without taking medical counsel, or taking high-dose herbal tonics for extended durations. Evidence from Maharashtra's awareness drives indicated that just the placement of ADR information posters at rural dispensaries doubled patient-spontaneous reports within six months.[58]

6.3 International Collaborations

India can further extend its influence by actively providing AYUSH safety information to WHO-Uppsala Monitoring Centre and helping develop the WHO Global Traditional Medicine Database. Partnerships with organizations such as the European Medicines Agency's Herbal Medicinal Products Committee (HMPC) may enable harmonization of monographs for herbs like Tinospora cordifolia and Boswellia serrata, traded internationally. Harmonized pharmacovigilance guidelines with ASEAN nations may be particularly applicable to plants such as Centella asiatica (Gotu kola) that are consumed throughout South and Southeast Asia. Harmonization across national borders would facilitate the detection of geographic differences in ADR occurrence due to plant chemotype variation (Figure 4).[26]

Figure 4 AYUSH Pharmacovigilance Strategies.

7. Global Perspective

Ensuring safety in traditional medicine is not an Indian problem alone. Many nations with long herbal medicine histories already have organized pharmacovigilance models that

incorporate ancient healing systems into contemporary regulatory systems. A look at these experiences provides useful lessons for the further development of AYUSH safety systems.

7.1 China's Pharmacovigilance for Traditional Chinese Medicine

China boasts one of the most developed pharmacovigilance systems for herbal medicines, regulated under the National Medical Products Administration (NMPA). Surveillance of Traditional Chinese Medicine (TCM) follows the same centralized system as traditional drugs, promoting equality in regulatory management. Since 2011, China has had an electronic reporting system linking hospitals, community health centers, and pharmacies across the country for real-time reporting of Adverse Drug Reaction (ADR) reports.

TCM pharmacovigilance also pays particular attention to herb–drug interaction research, particularly for blends including chemotherapy agents, anticoagulants, or immunosuppressants. For instance, intensive post-marketing surveillance of Artemisia annua-derived artemisinin products has enabled refinement of safety criteria for malaria treatment worldwide. In 2020, China's ADR database logged more than 260,000 reports of TCM-related ADRs, the majority of which were of injectable herbal preparations, a class subject to strict labelling and use controls because of increased risk of ADRs. In addition, the Chinese system incorporates toxicological profiling of herbal raw materials, such as geo-authentication to prevent adulteration with toxic lookalike species.[60]

7.2 Japan's Approach to Kampo Medicines

Japan governs Kampo medicines (traditional Japanese herbal remedies) as the Pharmaceuticals and Medical Devices Act places them in the same category as prescription and over-the-counter drugs. In contrast to most traditional systems, Kampo prescriptions are routinely reimbursed under national health insurance, which encourages practitioners to prescribe to standardized product quality and dosing.[61]

Pharmacovigilance in Kampo is aided by the Pharmaceuticals and Medical Devices Agency (PMDA), which actively follows up on adverse events through the Japanese Adverse Drug Event Report (JADER) database. The database retains structured ADR information submitted by healthcare professionals, manufacturers, and patients. A significant success of Japan's system is its capability to identify rare but serious ADRs. To illustrate, the Kampo formula Sho-saiko-to was associated with interstitial pneumonia in a small number of patients, prompting nationwide warnings and updated usage recommendations. Japan also invests in

public education regarding safe Kampo use, with pharmacists trained to advise patients on potential interactions with widely used drugs such as antihypertensives and anticoagulants.[15]

7.3 Lessons for India's AYUSH Programme

India's AYUSH pharmacovigilance efforts can gain a lot from the Chinese and Japanese experiences. The most important of these lessons are:

Unified Regulatory Supervision: China and Japan both incorporate traditional medicine ADR monitoring into their mainstream national pharmacovigilance systems without creating silos. India could do the same with incorporating AYUSH ADR data into the Central Drugs Standard Control Organization (CDSCO) master database for cross-system evaluation.

Mandatory Manufacturer Reporting: In both countries, manufacturers are legally mandated to report ADRs detected during PMS, so there is accountability up the supply chain. This could be applied to India's AYUSH sector, especially for high volume proprietary products.

Emphasize High-Risk Formulations: China's focused surveillance of injectable TCMs and Japan's early-warning systems against unusual ADRs indicate the need to allocate pharmacovigilance resources towards higher-risk formulations in AYUSH, e.g., metallic bhasmas or concentrated extracts.

Insurance-Linked Compliance: Japan's inclusion of Kampo in national health insurance promotes standardization and traceability. While India's public insurance programs such as Ayushman Bharat have initiated coverage of certain AYUSH treatments, making reimbursement dependent upon ADR reporting compliance could reinforce safety culture.

Patient-Centric Reporting: Both systems engage patients actively in ADR detection through helplines and online portals. India can extend its digital reporting infrastructure to include easier access for rural and low-literacy populations.

By applying these best practices on a global level, India can fast-track the growth of its AYUSH pharmacovigilance network so that traditional healing is both scientifically accountable as well as culturally relevant.

Future Outlook

The future of AYUSH pharmacovigilance is balancing traditional medicine heritage retention and compliance with modern standards of safety. As global healthcare trends shift towards

integrative and personalized medicine, AYUSH systems are likely to gain international recognition, contingent on safety monitoring adapting to support this goal. In the next decade, AYUSH pharmacovigilance will likely move towards predictive safety analytics using artificial intelligence, where machine learning algorithms will examine large volumes of data from clinical histories, laboratory tests, and ADR reports to give early warning signals for impending adverse effects. Not only would response time be improved, but proactive risk handling could also be done in susceptible patient groups. Real-world evidence (RWE) generation will also change how safety is assessed. Wearable health devices and mobile health applications may monitor physiological changes in AYUSH medicine-consumption patients, streaming data into centralized databases. Such technology-supported continuous surveillance may become the alternative to the present culture of delayed voluntary reporting, particularly in remote regions where traditional medicine finds its peak usage. Globally, there is increasing interest in setting up a Global Herbal Pharmacovigilance Network, coordinated by the WHO, which would standardize safety coding systems for herbal drugs so that AYUSH data can be compared with such systems as TCM or Kampo. This cross-border integration may facilitate early detection of rare but severe ADRs and enhance mapping of herb–drug interactions for polytherapy patients. On the production side, the future will probably find blockchain-based tracking of raw materials in AYUSH drugs for authenticity, purity, and traceability from the farm to the pharmacy. This would eliminate risks of contamination, adulteration, and variation in quality, all of which are currently impeding causality determination in ADRs. Educationally, pharmacovigilance principles should be ingrained into AYUSH courses to a deep extent, with training units on adverse reaction detection, documentation, and communication competencies to shatter the cultural reluctance of reporting. A future where each AYUSH graduate is not just a healer but a safety sentinel, trained, is desirable as well as attainable. From a public health perspective, the aim is that community-level safety ambassadors, ASHA workers and trained laypersons would enable ADR reporting and patient counseling in rural settings. This grass-roots participation would increase reporting rates by leaps and bounds and help communities to make informed health decisions. Ultimately, the future prospective for AYUSH pharmacovigilance is one of integration, digitization, and globalization. By embracing new-generation monitoring technologies, encouraging global cooperation, and integrating safety culture into every aspect of practice, AYUSH can cement its position as a trusted, safe, and science-proven pillar of global healthcare. Success of this dream will rely on the collective work of regulators,

practitioners, researchers, producers, and patients, all concurring to make sure that science and tradition walk side by side in strides toward a safer future.

CONCLUSION

AYUSH pharmacovigilance is slowly emerging as a necessary bridge for India's ancient systems of medicine with a rich past to the high safety standards of present-day healthcare. Though Ayurveda, Yoga, Unani, Siddha, and Homeopathy have been working among communities for ages, their contemporary emergence in urban, international, and integrative healthcare settings has put more responsibility on verifying safety through scientific, transparent, and worldwide accepted surveillance systems. The diversity of AYUSH preparations, which typically combine various herbal, mineral, and animal-derived materials, presents both therapeutic potential and difficult issues regarding safety. Unlike single-molecule medicines, these preparations are at risk for herb–herb and herb–drug interaction, heavy metal or pesticide pollution, and sourcing and processing dependence on pharmacological activity variation. Without adequate safety monitoring, these issues can create public mistrust and impede mainstream integration of AYUSH into healthcare systems. The Pharmacovigilance Programme for AYUSH (PPvAYUSH) launched in 2017 is a policy landmark, proclaiming the importance of monitoring ADR in traditional medicine as the government acknowledges. The setting up of a tiered system of National Coordinating Centres, Regional and Peripheral Centres, and the usage of standard ADR reporting forms have laid a platform for a safety culture in the country. Still, operational issues such as poor reporting rates, lack of adequate feedback mechanisms, minimal utilization of live digital tools, and practitioner training gaps remain major obstacles to achieving best-case scenarios. Experiences elsewhere are a fertile source of lessons. China's Traditional Chinese Medicine pharmacovigilance network integrates hospital, manufacturer, and regulatory agency information to enable early signal detection and risk communication. Japan's Kampo medicine monitoring relies heavily on clinician voluntarism, mandatory reporting, and integration into electronic health records. Replication of similar models for AYUSH requires culture sensitivity, legal frameworks to balance freedom of traditional practice with accountability, and investment in long-term human resources and infrastructure. In the coming years, the success of AYUSH pharmacovigilance will depend on its evolution from a reactive to a proactive model. This would mean the adoption of artificial intelligence for predictive risk assessment, wearable tech for tracking patients, and blockchain for supply chain traceability.[62] Equally important will be the proactive role assumed by community

health workers, NGOs, and civil society in promoting public awareness, destigmatizing reporting of side effects, and incorporating safety into an enabler, not a deterrent, to AYUSH practice. Ultimately, the greatest challenge for AYUSH pharmacovigilance will be its ability to protect patients without compromising the ethos of these traditional systems. The vision is not to replace traditional wisdom with biomedical domination, but to supplement it with evidence-based safety assurance. When pharmacovigilance becomes an integral part of AYUSH culture embraced by practitioners, demanded by patients, and mandated by regulators. India's traditional medicine can be a global model for showing how legacy and cutting-edge science can collaborate. The way ahead demands collective efforts. There should be policy sharpening by regulators, open reporting compliance by practitioners, quality and traceability by manufacturers, sound safety evidence generated by researchers, and activation of patients to take part actively in their own healthcare safety. It is only through such joint initiatives that AYUSH can guarantee the twin goals of maintaining its ancient tradition and conformity to the highest international standards of safety, so that its contribution to global health continues to be both ageless and credible.

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