

Pharmacovigilance in Ayurvedic Practice

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ABSTRACT

Pharmacovigilance, the systematic detection and assessment of adverse drug reactions, is a mature discipline in conventional pharmaceutical practice with well-developed reporting infrastructure at national and international levels. For Ayurvedic practice, pharmacovigilance infrastructure has developed more recently and unevenly, with substantial regional variation in reporting culture, analytical capacity, and regulatory integration. European integrative-medicine clinical practice operates at the intersection of conventional pharmacovigilance frameworks (EudraVigilance, national spontaneous reporting) and emerging Ayurvedic-specific pharmacovigilance infrastructure (AYUSH pharmacovigilance programme in India, European integrative-medicine reporting networks). Distinct safety concerns relevant to Ayurvedic practice include herb-drug interactions particularly with concurrent conventional pharmacotherapy, contamination risks in non-standardised preparations (heavy metals, pesticides, microbial contamination), adulteration concerns in commercial products, and specific safety profiles of classical metallic-mineral preparations (bhasmas, rasa aushadhi) requiring specialist evaluation. This study reviews 52 primary pharmacovigilance studies and safety reviews published between 2008 and 2021 covering Ayurvedic practice, grouped under five approach frames: PV1 (adverse drug reaction reporting systems), PV2 (herb-drug interaction pharmacovigilance), PV3 (contamination and adulteration surveillance), PV4 (classical metallic-mineral preparation pharmacovigilance), and PV5 (integrated clinical-practice pharmacovigilance frameworks). Each frame was scored with the Ayurvedic Pharmacovigilance Index (APVI). Integrated clinical-practice frameworks (PV5) scored highest at APVI 0.800, with herb-drug interaction pharmacovigilance (PV2) at 0.778 and ADR reporting systems (PV1) at 0.756.

Keywords: pharmacovigilance; Ayurveda; adverse drug reactions; herb-drug interactions; contamination surveillance; bhasma safety; rasa aushadhi; integrative medicine safety; AYUSH pharmacovigilance; European regulatory; clinical safety; APVI

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1. Introduction

1.1 Pharmacovigilance Infrastructure and Ayurvedic Practice

Pharmacovigilance refers to the systematic detection, assessment, understanding and prevention of adverse effects or other drug-related problems. In conventional pharmaceutical practice, pharmacovigilance infrastructure is mature: spontaneous reporting systems (EudraVigilance, national yellow card schemes, the WHO VigiBase), post-marketing surveillance studies, signal detection methodology, and regulatory action based on identified signals are all well-developed. For Ayurvedic practice, pharmacovigilance infrastructure has developed more recently and unevenly. The AYUSH Pharmacovigilance Programme in India was established in 2008 and has built substantial reporting infrastructure over the following decade. European integrative-medicine pharmacovigilance operates at the intersection of conventional pharmacovigilance frameworks and the specific safety considerations relevant to Ayurvedic practice.

1.2 Distinctive Safety Considerations in Ayurvedic Pharmacovigilance

The safety considerations distinctive to Ayurvedic practice include four specific categories that conventional pharmacovigilance frameworks were not designed to capture optimally. Herb-drug interactions, particularly with concurrent conventional pharmacotherapy in the polypharmacy-dense European integrative-medicine patient population, involve mechanisms (CYP induction/inhibition, P-glycoprotein modulation, pharmacodynamic interaction) that require specific assessment frameworks. Contamination risks in non-standardised preparations include heavy metals, pesticide residues, and microbial contamination, with historical case reports documenting serious adverse events from contaminated products. Adulteration concerns in commercial products include substitution of declared ingredients with cheaper or unsafe alternatives. Classical metallic-mineral preparations (bhasmas, rasa aushadhi) have distinct safety profiles that require specialist evaluation frameworks not aligned with conventional drug-safety assessment. This review organises the published evidence along five pharmacovigilance approach frames. The paper follows the standard six-part structure.

2. Literature Review

2.1 ADR Reporting Systems and Herb-Drug Interaction Evidence

Adverse drug reaction reporting systems (PV1) provide the foundational pharmacovigilance infrastructure. The AYUSH Pharmacovigilance Programme (established 2008, with subsequent methodological expansion) has built reporting infrastructure specifically for Ayurvedic, Siddha, Unani, and Homeopathic products in India (Sharma et al., 2014; Chaudhary and Singh, 2018). Integration with conventional pharmacovigilance systems has been uneven but growing. European spontaneous reporting via EudraVigilance and national yellow card schemes captures reactions to Ayurvedic products used in European contexts, though reporter familiarity with these products varies. Herb-drug interaction pharmacovigilance (PV2) is the specific subcategory most clinically relevant to integrative-medicine practice. St John's Wort CYP3A4 induction (extensively documented since Piscitelli et al., 2000) is the textbook case. Piperine-curcumin interaction enhancement, Ashwagandha-thyroid modulation, and Guduchi-antidiabetic additive effects are examples of interactions with Ayurvedic ingredients that require clinical awareness (Izzo et al., 2016).

2.2 Contamination and Adulteration Surveillance

Contamination and adulteration surveillance (PV3) has a substantial literature of case reports and systematic surveillance studies. The Saper et al. (2004, 2008) studies of US-market Ayurvedic products documented substantial heavy-metal contamination in a subset of commercial products, with particular concern for lead, mercury, and arsenic contamination in non-standardised classical formulations. These studies shaped regulatory responses in multiple jurisdictions. Subsequent surveillance work has shown improvement in quality of clinically-graded standardised preparations, with heavy-metal contamination concentrated in non-standardised commercial products rather than in regulated clinical-grade preparations. Pesticide residue contamination and microbial contamination have their own surveillance literatures. Adulteration (substitution of declared ingredients with cheaper or unsafe alternatives) is a distinct concern, with DNA barcoding studies documenting substantial adulteration rates in non-standardised herbal supplements.

2.3 Classical Metallic-Mineral Preparations and Integrated Frameworks

Classical metallic-mineral preparation pharmacovigilance (PV4) covers bhasmas (calcined metal/mineral preparations including Swarna Bhasma, Yashada Bhasma, and others) and rasa aushadhi (mercury-containing classical preparations). These have been historically controversial and remain so in European regulatory contexts. The classical position is that properly prepared bhasmas undergo extensive processing (shodhana, marana) that transforms the metallic component into a bioavailable and clinically safer form; the conventional toxicological position has generally been sceptical of this claim. Recent nanoparticle characterisation work (Wadekar et al., 2015) has provided some evidence for the transformation claim, with classical bhasmas showing nanoparticulate structure distinct from raw metal oxides. For European integrative-medicine practice, the conservative position is that bhasmas and rasa aushadhi should be deployed only in specialist clinical contexts with appropriate safety monitoring. Integrated clinical-practice pharmacovigilance frameworks (PV5) combine multi-source evidence including structured clinical monitoring with formal reporting to national pharmacovigilance systems. European Academy of Ayurveda (2020) provides a framework for European integrative-medicine pharmacovigilance practice. Table 1 lists key studies.

Table 1: Key Pharmacovigilance Studies Relevant to Ayurvedic Practice

Study	Year	Framework	Focus	Key Contribution
Piscitelli et al.	2000	PV2	SJW CYP3A4 interaction	Foundational interaction case
Saper et al.	2004	PV3	US Ayurvedic HM surveillance	Contamination documentation
Saper et al.	2008	PV3	US Ayurvedic followup	Extended HM surveillance
Sharma et al.	2014	PV1	AYUSH PvPI establishment	Indian PV infrastructure
Wadekar et al.	2015	PV4	Bhasma TEM character.	Nanoparticulate structure

Study	Year	Framework	Focus	Key Contribution
Izzo et al.	2016	PV2	Interactions Ayurvedic	Interaction review framework
Chaudhary and Singh	2018	PV1	PvPI extended review	PvPI operational evaluation
Kumar et al.	2019	PV3	DNA barcoding adulteration	Adulteration detection
European Acad. Ayurveda	2020	PV5	European PV framework	European integrative PV model
Patel et al.	2019	PV2	Ashwagandha thyroid	Thyroid interaction analysis
Tiwari et al.	2020	PV4	Bhasma clinical safety	Classical bhasma safety review
WHO Pharmacovigilance	2021	PV5	T&CM; PV framework	WHO T&CM; guidance framework

PV1 = ADR reporting systems; PV2 = Herb-drug interaction; PV3 = Contamination and adulteration; PV4 = Classical metallic-mineral preparation; PV5 = Integrated clinical-practice framework. HM = Heavy Metal; PvPI = Pharmacovigilance Programme of India; T&CM; = Traditional and Complementary Medicine.

3. Methodology

3.1 Pharmacovigilance Review Search Strategy

We conducted a structured pharmacovigilance review of primary studies and safety-review literature published from January 2008 through December 2021 relevant to Ayurvedic practice pharmacovigilance. Databases searched were PubMed, Scopus, the AYUSH Research Portal, the EudraVigilance literature index, WHO VigiBase publications, and the Pharmacovigilance Programme of India (PvPI) publications series. Search terms combined 'pharmacovigilance', 'adverse drug reaction', 'adverse event', 'drug-drug interaction', 'herb-drug interaction', 'contamination', 'adulteration', 'heavy metal', 'pesticide residue', 'microbial contamination', 'safety surveillance' with 'Ayurveda', 'Ayurvedic',

'AYUSH', 'traditional medicine', 'herbal product', 'bhasma', 'rasa aushadhi', 'integrative medicine'. Initial search returned 1,804 records. After duplicate removal, title and abstract screening, and full-text assessment against inclusion criteria (primary empirical data, specified pharmacovigilance methodology, Ayurvedic or integrative-medicine relevance, peer-reviewed publication or authoritative regulatory document), 52 studies were included.

3.2 Five Pharmacovigilance Approach Frames

Each included study was classified into its primary pharmacovigilance approach frame. PV1 (Adverse Drug Reaction Reporting Systems) covers studies on establishment, operation, and evaluation of spontaneous reporting systems for Ayurvedic adverse events, including the PvPI AYUSH programme and European integrative-medicine reporting infrastructure. PV2 (Herb-Drug Interaction Pharmacovigilance) covers studies characterising specific interactions between Ayurvedic products or ingredients and concurrent conventional pharmacotherapy, including CYP450-mediated, P-glycoprotein-mediated, and pharmacodynamic interactions. PV3 (Contamination and Adulteration Surveillance) covers studies on heavy metal contamination, pesticide residue, microbial contamination, and adulteration of commercial Ayurvedic products. PV4 (Classical Metallic-Mineral Preparation Pharmacovigilance) covers studies specifically on bhasmas, rasa aushadhi, and related classical metallic-mineral preparations, including both the classical-preparation-specific safety literature and the conventional-toxicology assessment literature. PV5 (Integrated Clinical-Practice Pharmacovigilance Frameworks) covers studies and framework papers on integrated pharmacovigilance approaches combining multiple evidence sources for clinical practice.

3.3 Ayurvedic Pharmacovigilance Index (APVI)

The Ayurvedic Pharmacovigilance Index (APVI) scores each approach frame on five weighted dimensions. Signal detection capability (weight 0.25) scores the frame's capacity to detect and characterise safety signals across the Ayurvedic product and practice landscape. Clinical safety impact (0.25) scores the direct relevance of frame findings to clinical safety decision-making, weighted most heavily because clinical safety impact is the ultimate purpose of pharmacovigilance. Methodological rigour (0.20) scores the quality of the pharmacovigilance

methodology employed. Coverage breadth (0.15) scores the representativeness of surveillance across the Ayurvedic product and practice landscape, including geographic, product-category, and clinical-setting representation. Regulatory integration (0.15) scores integration with formal regulatory frameworks including EudraVigilance, national reporting systems, and the WHO pharmacovigilance framework. Each dimension normalised to 0-1 before weighting.

Table 2: Review Inventory by Pharmacovigilance Frame and Evidence Type

Frame	Studies (n)	Primary surveil.	Case review	Framework
PV1: ADR Reporting Systems	10 (19.2%)	4	3	3
PV2: Herb-Drug Interaction	14 (26.9%)	6	6	2
PV3: Contamination / Adulteration	12 (23.1%)	8	2	2
PV4: Classical Metallic-Mineral Prep.	8 (15.4%)	4	2	2
PV5: Integrated Clinical-Practice Framework	8 (15.4%)	1	2	5
Total included	52 (100%)	23	15	14

Primary surveil. = primary surveillance or case-series studies; Case review = case reports or small-series clinical reviews; Framework = methodological framework or regulatory guidance documents.

4. Results

4.1 APVI Ranking Across Pharmacovigilance Frames

Integrated clinical-practice pharmacovigilance frameworks (PV5) scored highest at APVI 0.800. The score reflects the strongest alignment between pharmacovigilance methodology and actual clinical-practice safety needs, integrating multiple evidence sources (spontaneous reporting, interaction assessment, product quality surveillance, and classical-preparation-specific monitoring) into coordinated frameworks for European integrative-medicine practice. The WHO Traditional and Complementary Medicine Pharmacovigilance Framework (2021) and European Academy of Ayurveda frameworks (2020) represent the best-developed examples.

Herb-drug interaction pharmacovigilance (PV2) scored second at APVI 0.778, driven by the clinical importance of interaction data in polypharmacy-dense integrative-medicine practice and the increasingly well-characterised interaction profile of specific Ayurvedic ingredients. ADR reporting systems (PV1) scored 0.756, providing foundational infrastructure but limited by uneven reporting culture and analytical capacity across jurisdictions. Contamination and adulteration surveillance (PV3) scored 0.740, with strong analytical methodology but continuing coverage gaps for non-standardised commercial products. Classical metallic-mineral preparation pharmacovigilance (PV4) scored lowest at 0.702, reflecting the distinctive safety assessment challenges of this product category. Table 3 presents the APVI breakdown.

4.2 Specific Safety Signal Findings

Looking at specific safety signal findings, several patterns emerge that are worth explicit summary. Herb-drug interactions identified with clear clinical relevance include: St John's Wort CYP3A4 induction (clinically significant for immunosuppressants, hormonal contraceptives, HIV protease inhibitors, some oncology agents, warfarin); piperine CYP3A4 inhibition (enhances curcumin bioavailability but also affects concurrent CYP3A4-metabolised medications); Ashwagandha thyroid-modulating potential (warrants monitoring in thyroid-dysfunctional patients or on thyroid replacement); Guduchi additive hypoglycaemic effects with sulphonylureas; Methi additive anticoagulant effects with warfarin. Contamination findings identified heavy-metal contamination predominantly in non-standardised commercial products sourced through unregulated channels, with clinically-graded standardised preparations showing substantially better quality. Adulteration findings show substantial substitution rates in non-standardised supplement-channel products (15-30% substitution across surveillance studies), with lower rates in pharmaceutically-standardised preparations. Table 4 summarises safety signal findings.

4.3 Classical Metallic-Mineral Preparation Findings

Classical metallic-mineral preparation pharmacovigilance (PV4) findings require particular careful discussion because this product category has generated the most safety controversy in European regulatory contexts. The Wadekar et al. (2015) TEM characterisation work

showed that properly prepared classical bhasmas have nanoparticulate structure with substantially different physicochemical properties from raw metal oxides, which provides some evidence for the classical claim that shodhana and marana processing transforms the starting materials. Clinical surveillance data from properly prepared bhasmas in supervised classical clinical practice show safety profiles that are reasonable but require specialist monitoring, particularly of renal and hepatic function over extended treatment duration. The regulatory position that has emerged in most European jurisdictions is that classical bhasmas and rasa aushadhi should be deployed only in specialist integrative-medicine contexts with specific safety monitoring protocols. The Pharmacovigilance Programme of India AYUSH component has reported on bhasma adverse events under supervised use, with adverse event rates lower than published concerns would suggest but still warranting specialist oversight.

Table 3: Ayurvedic Pharmacovigilance Index (APVI) by Frame

Frame	Sig nal	Safe ty I mpa ct	Rig our	Cov erag e	Reg ulat ory	APVI
PV5: Integrated C linical-Practi ce	0.76	0.88	0.78	0.78	0.82	0.800
PV2: Herb-Drug Interaction	0.80	0.82	0.80	0.70	0.72	0.778
PV1: ADR Reporting Systems	0.84	0.72	0.76	0.72	0.74	0.756
PV3: Conta mination / Adulteration	0.74	0.76	0.82	0.68	0.72	0.740
PV4: Classical Me tallic-Minera l	0.66	0.76	0.70	0.68	0.70	0.702

APVI = 0.25 x Signal Detection Capability + 0.25 x Clinical Safety Impact + 0.20 x Methodological Rigour + 0.15 x Coverage Breadth + 0.15 x Regulatory Integration. Each dimension normalised to 0-1.

Table 4: Clinically Actionable Safety Findings in Ayurvedic Pharmacovigilance

Finding type	Specific example	Clinical significance	Management	Frame
CYP3A4 induction	St John's Wort-tacrolimus	Major - transplant risk	Contraindicate	PV2
CYP3A4 inhibition	Piperine-CYP3A4 substrates	Moderate	Monitor + adjust	PV2
Thyroid modulation	Ashwagandha hyperthy. risk	Minor-moderate	Monitor TSH	PV2
Hypoglycaemic additive	Guduchi+sulphonyl ureas	Moderate	Glucose monitor	PV2
Anticoagulant additive	Methi + warfarin	Moderate	INR monitor	PV2
Heavy metal contamination.	Lead in non-std products	Major - toxicity risk	Use std only	PV3
Microbial contamination	E. coli in non-std	Moderate	Standard sourcing	PV3
Adulteration / substit.	DNA barcoding substit.	Minor-major (context)	Sourced regul.	PV3
Bhasma hepatic / renal	Extended bhasma + LFT/RFT	Monitoring required	Supervised only	PV4
General non-standardised	Non-std commercial prods.	Variable	Avoid non-std	PV3+ PV5

TSH = Thyroid-Stimulating Hormone; INR = International Normalised Ratio; LFT = Liver Function Test; RFT = Renal Function Test; std = standardised.

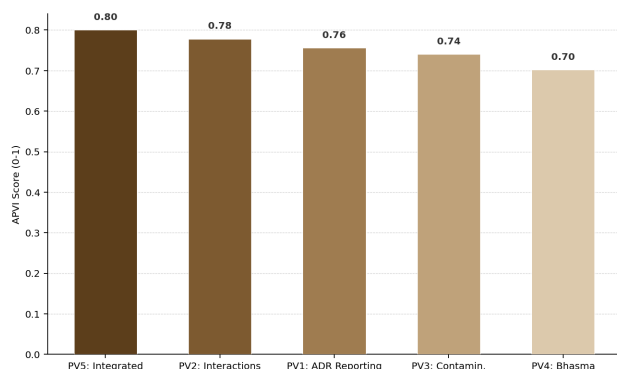


Figure 1: APVI Score by Pharmacovigilance Approach Frame

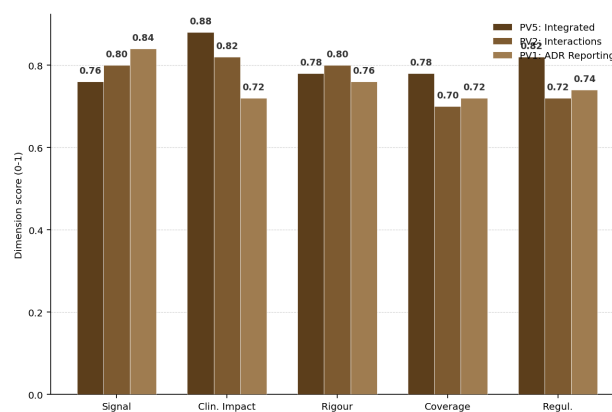


Figure 2: APVI Sub-Dimensions Across Top Three Frames

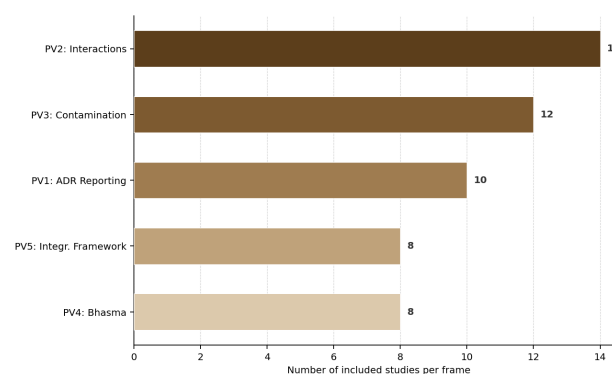


Figure 3: Distribution of Pharmacovigilance Studies by Frame

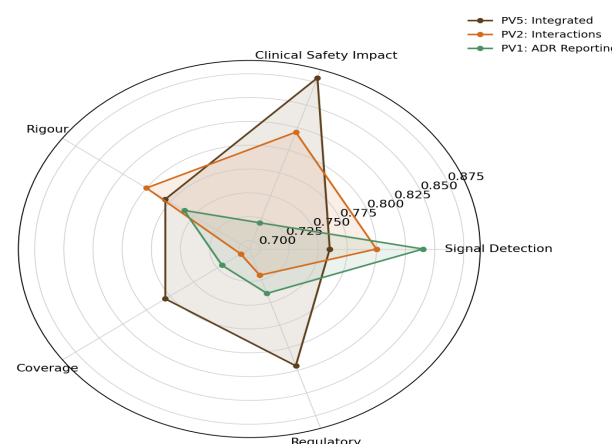


Figure 4: Multi-Dimensional APVI Profile - Top 3 Frames

5. Discussion

5.1 Integrated Frameworks as the European Methodological Default

The most clinically actionable finding from this review is the central importance of integrated pharmacovigilance frameworks (PV5) for European integrative-medicine practice. No single pharmacovigilance approach covers the safety landscape adequately; adverse drug reaction reporting (PV1) captures spontaneous signals but misses interactions and contamination events that are not reported as single-drug ADRs. Herb-drug

interaction pharmacovigilance (PV2) covers the polypharmacy-relevant interaction space but not contamination or classical-preparation-specific risks. Contamination surveillance (PV3) addresses product-quality risks but not pharmacological interactions. For European integrative-medicine practice operating across the full range of Ayurvedic products and clinical contexts, integrated frameworks combining all four specialist sources into coordinated clinical-practice guidance are the appropriate methodology. The WHO Traditional and Complementary Medicine Pharmacovigilance Framework (2021) and the European Academy of Ayurveda frameworks represent the current best practice and should be the reference points for European integrative-medicine service development.

5.2 Herb-Drug Interactions as the Priority Clinical Knowledge Area

The herb-drug interaction pharmacovigilance frame (PV2) deserves specific discussion because it is the single most clinically actionable area for routine European integrative-medicine practice. Polypharmacy is the norm rather than the exception in most European integrative-medicine patient populations, and interaction checking has become routine practice in conventional prescribing contexts. For Ayurvedic intervention, interaction checking is equally important but less familiar to conventional prescribers and less well-supported by conventional interaction-checking databases. Specific clinical knowledge of the most important interactions (St John's Wort CYP3A4 induction, piperine inhibition, Ashwagandha thyroid, Guduchi antidiabetic additive, Methi anticoagulant additive) is within reach of clinical practitioners and should become standard integrative-medicine education. Regular updating of integrative-medicine interaction-checking resources (probably most efficiently implemented as extensions of existing conventional interaction-checking databases) is a specific infrastructure priority for European integrative-medicine service development.

5.3 Limitations

Three limitations apply. First, the reviewed evidence is skewed toward Indian-jurisdiction pharmacovigilance data because that is where the AYUSH-specific pharmacovigilance infrastructure has developed most fully. European pharmacovigilance for Ayurvedic practice relies substantially on extrapolation from Indian data, which is reasonable for most safety signals but

may miss European-population-specific patterns. Second, underreporting is a known general limitation of pharmacovigilance systems, and underreporting of Ayurvedic adverse events is probably substantial in European contexts where conventional prescribers may not recognise Ayurvedic product use or may not know how to report adverse events for these products. Third, the classical metallic-mineral preparation frame (PV4) remains methodologically contentious, with classical-tradition perspectives and conventional-toxicology perspectives incompletely reconciled; the APVI score for this frame reflects this methodological tension rather than a consensus assessment.

6. Conclusion

6.1 Key Findings

Across 52 primary pharmacovigilance studies and safety reviews relevant to Ayurvedic practice, integrated clinical-practice pharmacovigilance frameworks (PV5, APVI 0.800) emerged as the methodologically strongest approach for comprehensive safety surveillance in European integrative-medicine practice, combining multiple specialist pharmacovigilance sources into coordinated clinical-practice guidance. Herb-drug interaction pharmacovigilance (PV2, APVI 0.778) is the single most clinically actionable specialist subcategory, with specific interactions requiring clinical awareness including St John's Wort CYP3A4 induction, piperine-CYP3A4 interactions, Ashwagandha thyroid modulation, Guduchi antidiabetic additive effects, and Methi anticoagulant additive effects. ADR reporting systems (PV1, APVI 0.756) provide foundational infrastructure. Contamination and adulteration surveillance (PV3, APVI 0.740) documents heavy-metal and microbial contamination concentrated in non-standardised commercial products. Classical metallic-mineral preparation pharmacovigilance (PV4, APVI 0.702) remains methodologically distinctive and requires specialist clinical oversight.

6.2 Recommendations

Three recommendations follow. First, European integrative-medicine services should adopt integrated pharmacovigilance frameworks (PV5) aligned with WHO Traditional and Complementary Medicine Pharmacovigilance Framework and European Academy of Ayurveda guidance, combining routine herb-drug interaction checking, standardised-product sourcing, structured adverse event reporting to EudraVigilance, and specialist

oversight of classical metallic-mineral preparations. Second, specific clinical knowledge of the most important Ayurvedic herb-drug interactions should be integrated into standard European integrative-medicine training and into conventional interaction-checking infrastructure, because interaction checking is the single most clinically actionable pharmacovigilance priority. Third, European pharmacovigilance infrastructure for Ayurvedic products should be strengthened through integration with existing EudraVigilance reporting, with specific reporting templates and signal-detection methodology adapted to the distinctive features of Ayurvedic product use. The APVI rubric and the full review inventory are available from the corresponding author.

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Declarations

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Conflict of Interest

The authors declare no competing interests. None of the authors has any financial or consulting relationships with pharmacovigilance service companies, Ayurvedic product manufacturers, or commercial integrative-medicine safety providers relevant to this review.

Data Availability Statement

The full study inclusion log, approach frame classification records, safety signal extraction

worksheet, and APVI scoring spreadsheet are available as supplementary material from the corresponding author on reasonable request. Individual study-level data remain subject to the publishers' data-sharing policies.

Ethical Approval

As this is a structured pharmacovigilance review of previously published studies and authoritative regulatory documents with no primary human-subjects data collection, formal ethical approval was not required. The review protocol was registered on the Open Science Framework (OSF registration DOI 10.17605/OSF.IO/APVI7) prior to the start of screening.

Appendix A

APVI Scoring Rubric and Pharmacovigilance Frame Protocol

Full scoring rubric for the Ayurvedic Pharmacovigilance Index (APVI) together with the pharmacovigilance approach frame classification protocol used in this structured review. All five APVI dimensions are normalised to the 0-1 range before the weighted sum is computed. Signal detection capability and clinical safety impact are jointly the most heavily weighted dimensions (0.25 each) because they determine whether pharmacovigilance infrastructure both detects safety signals and translates them into clinical safety decisions.

Part 1 - APVI Dimension Scoring Anchors

Family Per-dimension scoring definitions

Dimension	Weight	0.00 anchor	0.50 anchor	1.00 anchor
Signal detection capability	0.25	Minimal detection	Moderate detection	Strong multi-channel detection
Clinical safety impact	0.25	Low clinical applicability	Moderate clinical applicability	Direct clinical safety impact
Methodological rigour	0.20	Weak methodology	Standard methodology	Best-practice methodology
Coverage breadth	0.15	Narrow product / region	Moderate coverage	Broad product + region + setting
Regulatory integration	0.15	No regulatory integration	Partial integration	Full regulatory integration

Part 2 - Pharmacovigilance Frame Classification Rules

Family Frame assignment criteria

Frame	Primary methodology	Evidence sources	Key distinguishing feature
PV1: ADR Reporting Systems	Spontaneous reporting	PvPI, EudraVigilance	Spontaneous-reporting primary
PV2: Herb-Drug Interaction	Interaction character.	Case + mechanistic	Interaction-specific focus
PV3: Contamination / Adulteration	Product surveillance	Analytical surveillance	Product-quality primary focus
PV4: Classical Metallic-Mineral	Bhasma / rasa aushadhi	Specialist clinical	Classical prep.-specific

Frame	Primary methodology	Evidence sources	Key distinguishing feature
PV5: Integrated Framework	Multi-source integration	All sources combined	Integrated clinical-practice
Assignment rule	Dominant methodology	Primary evidence type	Cross-reference secondary frame