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REVIEW ARTICLE

Ayurvedic Medicines in Global Markets: Legal Provisions, Pharmacovigilance, and Adverse Reactions

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ABSTRACT

Ayurvedic medicines, though widely marketed across Western countries as food supplements, herbal remedies, or traditional health products, are not recognized as licensed pharmaceuticals requiring premarket efficacy disclosure.[1] Their legal entry is facilitated through frameworks such as the U.S. Dietary Supplement Health and Education Act (DSHEA), the EU Traditional Herbal Medicinal Products Directive (THMPD), Canada's Natural Health Products Regulations, and Australia's complementary medicine listing system.[1,2] Despite bypassing premarket drug approval, these products remain under postmarket pharmacovigilance surveillance.[1,3] Healthcare providers are obliged to document usage and report adverse reactions to national pharmacovigilance agencies, which collate, analyze, and establish causality using World Health Organization–Uppsala Monitoring Centre (WHO-UMC) criteria.[3] Scientific literature has documented major adverse reactions to Ayurvedic supplements, including hepatotoxicity (Tinospora cordifolia, Ashwagandha, Turmeric, Psoralea corylifolia), hypersensitivity reactions, and heavy-metal poisoning (lead, mercury, arsenic).[4-6] Case reports from the United States, United Kingdom, and India substantiate these risks, with outcomes ranging from acute liver failure to Cushing's syndrome due to steroid adulteration.[4,7] Indian statutory bodies—including the Ministry of AYUSH, CDSCO, ICMR, and NCISM—have acknowledged these concerns, establishing the Ayush Pharmacovigilance Program of India (APvPI) and issuing guidelines for adverse drug reaction reporting.[3,8] This deliberation highlights the tension between traditional use and modern regulatory safeguards, underscoring the need for harmonized global vigilance, transparent labeling, and evidence-based integration of Ayurvedic medicines into healthcare systems.[1,8]

KEYWORDS

• Ayurvedic medicines • Herbal supplements • Pharmacovigilance • Adverse drug reactions (ADR) • Hepatotoxicity • Heavy-metal poisoning • Regulatory frameworks • Dietary Supplement Health and Education Act (DSHEA) • Traditional Herbal Medicinal Products Directive (THMPD) • Ayush Pharmacovigilance Program of India (APvPI)

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INTRODUCTION

Ayurveda, an ancient system of traditional medicine originating in India, has seen exponential global expansion over the past three decades.[1] Valued for its holistic approach and botanical preparations, Ayurvedic products are increasingly sought after by consumers worldwide seeking natural preventive or therapeutic health strategies.[1,2] However, the integration of traditional systems into modern global commerce presents complex regulatory and clinical challenges.[1]

In most Western nations, Ayurvedic formulations are not categorized or licensed as pharmaceutical drugs.[1,2] Instead, they enter consumer markets under legal designations such as dietary supplements, traditional herbal remedies, or natural health products.[1,2] This classification scheme allows manufacturers to bypass the rigorous, multi-phase clinical trial requirements—such as demonstrated safety, efficacy, and batch-to-batch standardization—mandated for conventional allopathic pharmaceuticals prior to marketing.[1,2]

While this low barrier to market entry facilitates widespread accessibility, it creates significant regulatory loopholes.[1,2] The common public misconception that "natural" inherently implies "safe" has masked the potential toxicities associated with traditional formulations.[4,5] Pharmacovigilance data and clinical case reports have increasingly linked Ayurvedic products to severe clinical complications, including fulminant hepatic failure, end-stage renal disease, systemic heavy-metal toxicity, and synthetic drug adulteration.[4,6,7]

Consequently, post-market surveillance mechanisms have become the primary defense for consumer safety in international markets.[1,3] This article examines the international legal frameworks governing Ayurvedic medicines, details the operational structures of post-market pharmacovigilance, reviews documented adverse reactions and global case reports, and outlines the regulatory measures initiated by Indian statutory bodies to address these safety concerns.[1-8]

Legal Provisions Governing Ayurvedic Medicines in Western Countries

Ayurvedic products are marketed across Western countries under non-pharmaceutical designations, bypassing standard drug approval channels while remaining subject to baseline consumer safety, Good Manufacturing Practices (GMP), and truth-in-advertising laws.[1,2]

United States

- **Legal Basis:** Regulated under the Dietary Supplement Health and Education Act (DSHEA) of 1994.[1,2]
- **Classification & Provisions:** Ayurvedic remedies are classified strictly as dietary supplements rather than pharmaceutical drugs.[1] Manufacturers are not required to provide premarket evidence of therapeutic efficacy to the U.S. Food and Drug Administration (FDA).[1,2]
- **Requirements & Enforcement:** Products must comply with Current Good Manufacturing Practices (cGMP).[1] Labels are legally prohibited from making direct claims to treat, cure, diagnose, or prevent specific diseases, and must feature the mandatory disclaimer: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."[1,2] The FDA possesses authority to intervene, issue public warnings, or remove products from the market post-sale if they present a significant safety risk or feature deceptive health claims.[1,3]

European Union

- **Legal Basis:** Governed by Directive 2004/24/EC, known as the Traditional Herbal Medicinal Products Directive (THMPD).[1,2]
- **Classification & Provisions:** Offers a simplified registration pathway for traditional herbal products.[1,2] To qualify, products must demonstrate a continuous historical use of at least 30 years, including at least 15 years within the EU.[1,2]
- **Requirements & Enforcement:** Manufacturers must satisfy defined quality, purity, and safety standards.[1] Therapeutic indications are restricted strictly to traditional use scenarios, avoiding claims of validated clinical efficacy.[1,2] Products failing to meet THMPD criteria are frequently marketed under general food supplement

regulations, which prohibit medical claims entirely.[1,2]

United Kingdom (Post-Brexit)

- **Legal Basis:** Regulated by the Medicines and Healthcare products Regulatory Agency (MHRA) under national human medicines regulations, preserving frameworks similar to the EU THMPD.[1,2]
- **Classification & Provisions:** Products are registered under the Traditional Herbal Registration (THR) scheme.[1]
- **Requirements & Enforcement:** THR approval requires compliance with rigorous quality standards, GMP, and demonstrated traditional safety.[1,2] Efficacy claims remain restricted to historical traditional usage, and products must display a THR certification mark on consumer packaging.[1,2]

Canada

- **Legal Basis:** Regulated under the Natural Health Products Regulations (NHPR) within Health Canada.[1,2]
- **Classification & Provisions:** Classified as Natural Health Products (NHPs)[1]
- **Requirements & Enforcement:** All products must obtain a Natural Product Number (NPN) prior to commercial sale.[1,2] Health Canada evaluates evidence of safety, quality, and health claims—which may be substantiated using historical traditional references, pharmacopeias, or modern clinical studies.[1,2]

Australia

- **Legal Basis:** Regulated by the Therapeutic Goods Administration (TGA) under the Therapeutic Goods Act.[1,2]
- **Classification & Provisions:** Ayurvedic preparations are typically categorized as "Listed Medicines" (low-risk complementary medicines).[1]
- **Requirements & Enforcement:** Listed medicines are assessed for quality and safety, but not pre-assessed by the TGA for efficacy prior to market entry.[1,2] Manufacturers may only select pre-approved low-level health claims and must hold supporting evidence in their files.[1,2] High-risk formulations requiring premarket efficacy evaluation fall under the "Registered Medicines" pathway.[1]

POST-MARKET SURVEILLANCE AND CAUSALITY ASSESSMENT

Because Ayurvedic preparations enter global markets without formal premarket drug trials, post-market surveillance serves as the primary mechanism for detecting adverse outcomes.[1,3]

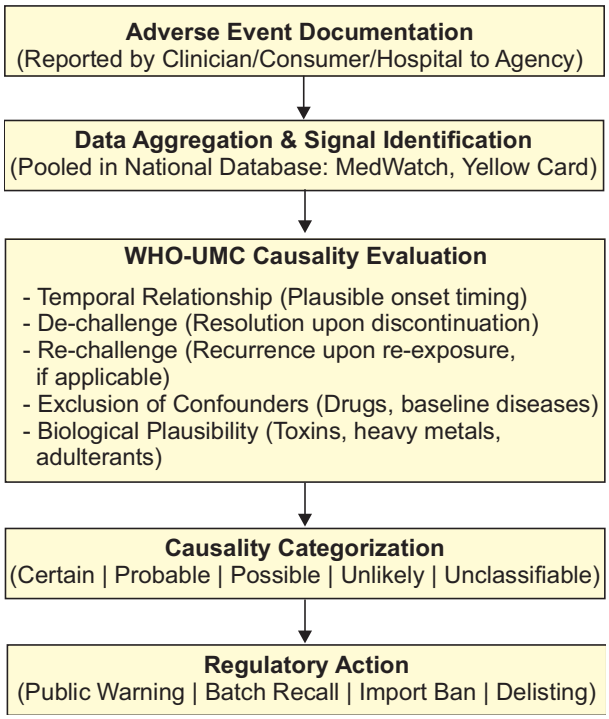
International Pharmacovigilance Systems

National regulatory bodies rely on structured reporting networks to monitor herbal safety:[3]

- **United States:** The FDA operates the MedWatch program alongside the Center for Food Safety and Applied Nutrition (CFSAN) Adverse Event Reporting System (CAERS).[3] While voluntary for healthcare providers, manufacturers are legally mandated under the Dietary Supplement and Nonprescription Drug Consumer Protection Act to submit reports of serious adverse events within 15 business days.[1,3]
- **European Union:** The European Medicines Agency (EMA) utilizes EudraVigilance to aggregate adverse event data reported by healthcare professionals, consumers, and national competent authorities.[3]
- **United Kingdom:** The MHRA utilizes the Yellow Card Scheme, which explicitly collects consumer and clinical reports of adverse drug reactions (ADRs) associated with herbal and traditional remedies.[3]
- **Canada:** The Canada Vigilance Program collects adverse reaction reports concerning NHPs, enabling Health Canada to issue public advisories or revoke NPN licenses.[3]
- **Australia:** The TGA manages the Adverse Event Management System (AEMS), evaluating reported reactions to delist unsafe complementary products.[3]

Establishing Causality in Adverse Reactions

When an adverse event is reported, national pharmacovigilance centers apply standardized algorithms—most notably the **WHO-UMC Causality Assessment System**—to determine whether the product directly caused the observed clinical harm.[3]



Documented Major Adverse Reactions and Clinical Toxicity

Peer-reviewed literature systematically details severe organ toxicities and adverse outcomes associated with Ayurvedic supplements.[4-7]

Summary of Key Scientific Reviews

Review / Study	*Domain*	*Key Findings*
Drug Safety (2025)[4]	Global Pharmacovigilance Scoping Analysis	Identified international signals of liver injury, renal toxicity, hypersensitivity, and heavy-metal poisoning linked to herbal and Ayurvedic supplements.[4]
Curr Opin Allergy Clin Immunol (2026)[5]	Hypersensitivity and Allergic Reactions	Documented IgE-mediated and non-IgE-mediated immediate hypersensitivity reactions to herbal products, manifesting clinically as urticaria, acute asthma, and systemic anaphylaxis.[5]
Medicine (2024)[6]	Hepatotoxicity in Indian Systems of Medicine	Characterized herb-induced liver injury (HILI) linked to Tinospora cordifolia, Ashwagandha, Turmeric, and Psoralea corylifolia, detailing cases of acute liver failure.[6]

SPECIFIC MANIFESTATIONS OF TOXICITY

1. Herb-Induced Liver Injury (HILI)

- **Giloy *(Tinospora cordifolia):*** Implicated in presenting clinical patterns resembling autoimmune-like hepatitis and acute liver failure, particularly during periods of unmonitored self-administration.[6,9]
- **Ashwagandha (Withania somnifera):** Linked to cholestatic jaundice and hepatocellular liver injury, resolving upon product withdrawal.[6]
- **Turmeric (Curcuma longa):** While widely consumed, concentrated extracts have been reported to induce idiosyncratic acute hepatocellular injury.[6]
- **Bakuchi (Psoralea corylifolia):** Contains active furocoumarins; clinical reports associate its use with fulminant hepatic failure.[6]

2. Hypersensitivity and Allergic Reactions

Immediate hypersensitivity reactions (IHRs) stem from bioactive botanical proteins, contaminants, or preservatives.[5] Clinical presentations include:

- **Dermatological:** Acute urticaria, angioedema, and maculopapular eruptions.[5]
- **Respiratory:** Bronchospasm, rhinitis, and severe asthmatic exacerbations.[5]
- **Systemic:** IgE-mediated anaphylactic shock requiring emergency intervention.[5]

3. Heavy-Metal Toxicity

In traditional Rasa Shastra practices, metals such as lead (Naga), mercury (Parada), and arsenic (Somala) are intentionally processed into therapeutic formulations (Bhasmas).[1,7] Inadequate detoxification, improper manufacturing, or unintentional environmental contamination leads to clinical toxicity:[1,7]

- **Lead (Pb):** Microcytic anemia with basophilic stippling, peripheral neuropathy (e.g., wrist drop), abdominal colic, encephalopathy, and developmental delays in pediatric populations.[7]
- **Mercury (Hg):** Tubulointerstitial nephritis, nephrotic syndrome, intention tremors, and cognitive dysfunction.[7]
- **Arsenic (As):** Hyperkeratosis, Mees' lines, peripheral neuropathy, and gastrointestinal toxicity.[7]

4. Synthetic Adulteration & Undeclared Additives

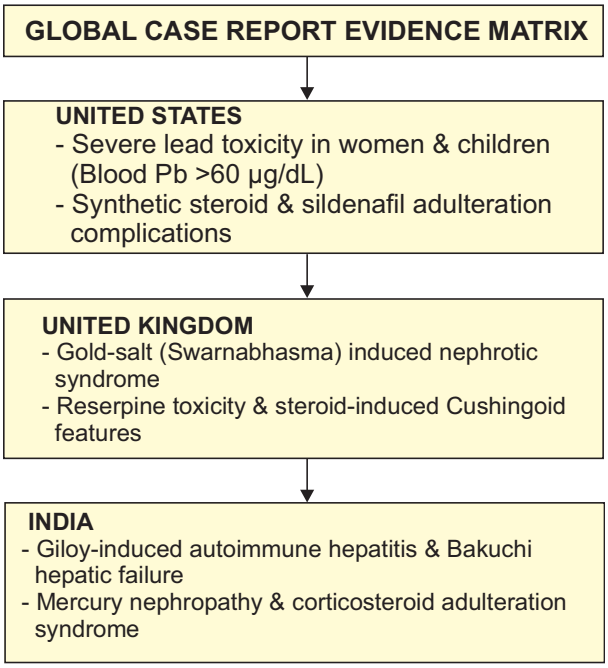
To achieve immediate therapeutic results,

unscrupulous manufacturers sometimes illegally adulterate remedies with synthetic pharmaceuticals:[1,7]

- **Corticosteroids:** Leads to iatrogenic Cushing's syndrome, adrenal suppression, acute hyperglycemia, and secondary osteoporosis.[7]
- **NSAIDs & Analgesics:** Causes gastrointestinal ulceration, upper GI hemorrhage, and acute kidney injury.[7]
- **Sildenafil Analogs:** Causes unexpected hypotension and adverse cardiovascular events.[7]

Country-Wise Summary of Published Case Reports

Peer-reviewed medical journals detail specific clinical cases linking Ayurvedic products to adverse outcomes across international jurisdictions.[4,7]



United States

- **Lead Poisoning Clusters:** Multiple CDC and medical journal reports document severe lead poisoning in patients consuming imported Ayurvedic powders and pills.[7] Clinical investigations identified blood lead levels exceeding 60 µg/dL (normal <3.5 µg/dL) in pregnant women and children, presenting with severe microcytic anemia, neurocognitive decline, and abdominal pain.[7]
- **Adulteration Incidents:** FDA MedWatch reports document cases of severe metabolic derailment and acute hypotension traced to Ayurvedic supplements adulterated with undeclared dexamethasone and sildenafil analogs.[1,7]

United Kingdom

- Oxford Case Series & Hospital Reports:
  - ◊ A 35-year-old female presented with worsening acute hepatitis and nephrotic syndrome following the consumption of traditional Ayurvedic remedies containing Swarnabhasma (gold ash).[7]
  - ◊ A 57-year-old male experienced severe bradycardia and extrapyramidal symptoms traced to an Ayurvedic preparation containing Rauwolfia serpentina (reserpine), an alkaloid restricted in conventional medicine due to toxicity.[7]
  - ◊ A 47-year-old female developed full-blown Cushingoid features, weight gain, and proximal muscle weakness after taking steroid-adulterated Ayurvedic tablets for two years.[7]

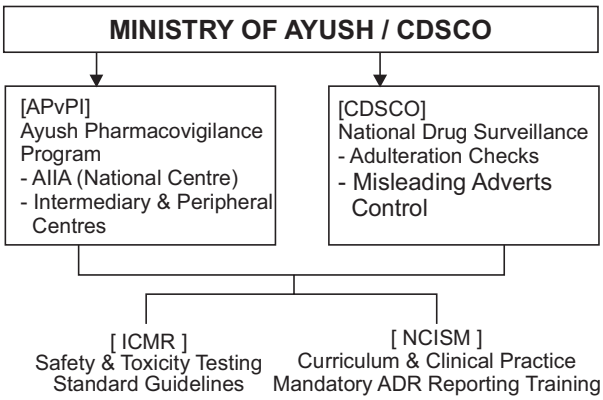
India

- **Herb-Induced Liver Injury Series:** Clinical studies published in hepatology journals document cohorts of patients presenting with acute liver failure after self-medicating with Psoralea corylifolia (Bakuchi) or Tinospora cordifolia (Giloy).[6,7]
- **Heavy Metal Toxicity & Adulteration:** Tertiary care hospitals report cases of mercury-induced nephrotic syndrome and chronic arsenicosis linked to long-term consumption of unstandardized Rasa Shastra formulations purchased from unregulated local vendors.[7,8]

REGULATORY FRAMEWORKS AND STATUTORY INITIATIVES IN INDIA

Indian regulatory authorities and statutory health bodies have acknowledged these safety challenges, establishing formal surveillance networks and issuing guidelines to enforce product safety.[3,8]

Indian Statutory Bodies and Oversight Initiatives



1. Ministry of AYUSH

- **Ayush Pharmacovigilance Program of India (APvPI):** Established a structured, multi-tier national pharmacovigilance network with the All India Institute of Ayurveda (AIIA), New Delhi, acting as the National Pharmacovigilance Centre.[3,8]
- **Reporting Infrastructure:** Coordinates Intermediary and Peripheral Pharmacovigilance Centres across India to monitor and log Adverse Drug Reactions (ADRs) associated with Ayurveda, Siddha, Unani, and Homeopathy (ASU&H) drugs.[3,8]
- **Standardized Tools:** Mandates the use of standardized ADR reporting formats and WHO-UMC causality assessment protocols for traditional medicines.[3,8]

2. Central Drugs Standard Control Organization (CDSCO)

- **Integrated Safety Monitoring:** Integrates ASU&H products into national drug safety surveillance mechanisms.[8]
- **Regulatory Enforcement:** Acts against illegal adulteration (e.g., synthetic steroids, NSAIDs) and enforces prohibition of objectionable or misleading therapeutic advertisements under the Drugs and Magic Remedies (Objectionable Advertisements) Act.[8]

3. Indian Council of Medical Research (ICMR)

- **Toxicity Evaluation:** Formulates standardized protocols and ethical guidelines for evaluating the safety, acute/sub-acute toxicity, and clinical efficacy of herbal preparations.[8]
- Research Support: Generates systematic safety data to distinguish intrinsic botanical toxicity from extrinsic contamination.[6,8]

4. National Commission for Indian System of Medicine (NCISM)

- **Educational Integration:** Mandates training in pharmacovigilance and ADR documentation within undergraduate and postgraduate Ayurvedic medical curricula.[8]
- **Clinical Documentation:** Requires teaching hospitals to log and submit observed adverse reactions to national databases.[3,8]

DISCUSSION

The global expansion of Ayurvedic medicine highlights a persistent tension between historical traditional use and modern pharmacovigilance standards.[1,3] In Western countries, classifying Ayurvedic formulations as dietary supplements or natural health products creates an open marketplace, but leaves consumer safety heavily reliant on post-market surveillance.[1,2] Under this regulatory framework, products enter the market without mandatory premarket testing for batch consistency, heavy-metal content, or potential toxicities.[1,7] Consequently, regulatory enforcement occurs reactively—often only after patient harm has already been documented.[1,3]

A major clinical challenge is the widespread public assumption that natural therapies are inherently free of risk.[4,5] Botanical remedies contain complex mixtures of bioactive chemical compounds that can cause intrinsic toxicities, trigger IgE-mediated or non-IgE-mediated hypersensitivity reactions, or interact with allopathic medications.[5,6] Furthermore, preparations within the Rasa Shastra tradition intentionally incorporate heavy metals.[1,7] Without strict standardization, controlled detoxifying procedures (Shodhana), and rigorous batch testing, these formulations present significant risks of lead, mercury, or arsenic toxicity.[1,7] These issues are further compounded by instances of illegal adulteration with synthetic

corticosteroids or NSAIDs, which can lead to severe systemic side effects.[7,8]

Addressing these risks requires a multi-pronged international response.[1,3] Western regulatory bodies should consider strengthening oversight for dietary supplements by introducing mandatory post-market batch testing for heavy metals and synthetic adulterants.[1,2] At the same time, international pharmacovigilance networks must improve cross-border communication and adopt standardized reporting protocols for traditional medicines.[3,4] Regulatory agencies, medical organizations, and traditional health bodies must collaborate to establish clear safety standards, transparent consumer labeling, and robust reporting systems.[3,8] Only through systematic oversight and evidence-based safety evaluation can Ayurvedic medicine be responsibly integrated into modern global healthcare systems.[1,8]

CONCLUSION

Transparency in the marketing and monitoring of Ayurvedic medicines is not merely a regulatory obligation but a moral imperative.[1,8] When products are sold as food supplements or traditional remedies, the public must be clearly informed of their limitations, potential risks, and the absence of formal drug approval.[1,2] Equally, adverse reactions must be openly documented and shared across pharmacovigilance networks to build trust and safeguard health.[3,4] By fostering public awareness campaigns, transparent labeling, and accessible reporting systems, regulators and healthcare institutions can bridge the gap between traditional use and modern safety standards.[1,8] Only through openness and vigilance can Ayurvedic medicines retain their cultural value while ensuring patient safety in a globalized marketplace.[1,8]

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