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Review Article

Pharmacovigilance of Herbal and Traditional Medicine

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ABSTRACT

Herbal and traditional medicines have long been integral to healthcare systems worldwide, offering natural alternatives for the prevention and treatment of various diseases. As interest in alternative medicine rises, these remedies are increasingly used as substitutes or complements to synthetic drugs. While herbal products are often perceived as safe due to their natural origin, growing evidence suggests they are not without risks, including adverse drug reactions (ADRs), toxicity, and herb-drug interactions. Unlike conventional pharmaceuticals, herbal medicines frequently lack proper standardization, scientific validation, and rigorous safety assessment. This presents a major challenge for their integration into existing pharmacovigilance systems, which are largely designed for synthetic drugs. The chemical complexity, variability in herbal formulations, and inadequate regulatory oversight further complicate safety monitoring. This review discusses the importance of pharmacovigilance in monitoring the safety of herbal and traditional medicines, highlights reported adverse effects, and emphasizes the need for standardized practices, scientific evaluation, and global collaboration. Strengthening pharmacovigilance systems tailored to herbal products is essential for ensuring their safe and effective use in modern healthcare.

INTRODUCTION

Herbal and traditional medicines have been used for centuries across cultures to promote health, prevent illness, and treat a wide range of diseases. Derived from whole plants or their parts, these remedies form the basis of several well-established systems of medicine, including Ayurveda, Traditional Chinese Medicine (TCM), Unani, Siddha, and various African and Islamic medicinal traditions. Even today, approximately 80% of the population in developing countries relies on traditional medicine as a primary form of healthcare. Additionally, the popularity of herbal

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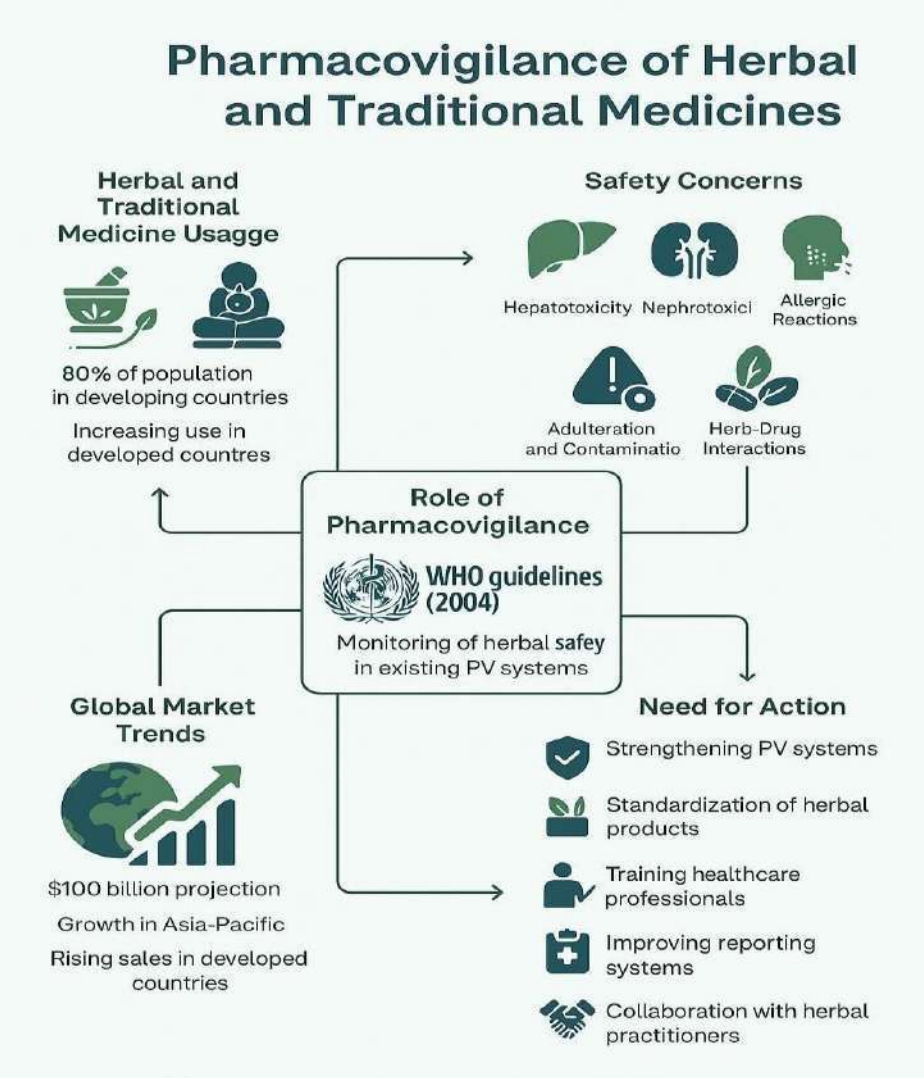
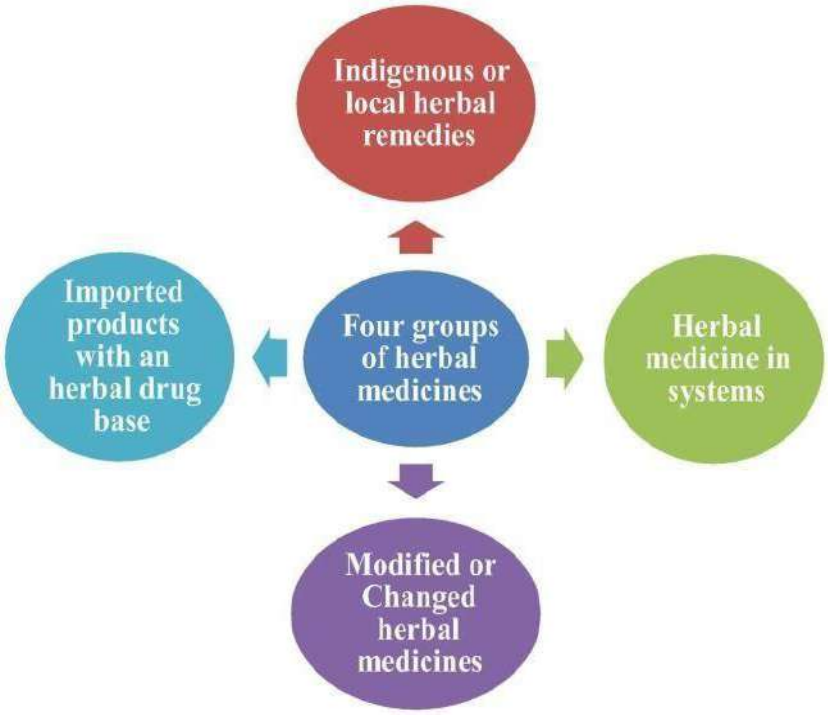
medicines is steadily growing in developed countries due to increasing public interest in natural therapies and dissatisfaction with the side effects and costs of conventional pharmaceuticals. Despite the perception that herbal medicines are inherently safe because they are "natural," studies have shown that they are not free from adverse effects. Herbal products can cause serious health complications such as hepatotoxicity, nephrotoxicity, cardiotoxicity, genotoxicity, and allergic or idiosyncratic reactions. These effects can be due to active constituents, contamination (with heavy metals, pesticides, or microbes), adulteration, improper use, or herb-drug interactions. Many herbal formulations also lack standardization, making dose consistency and safety evaluation challenging.



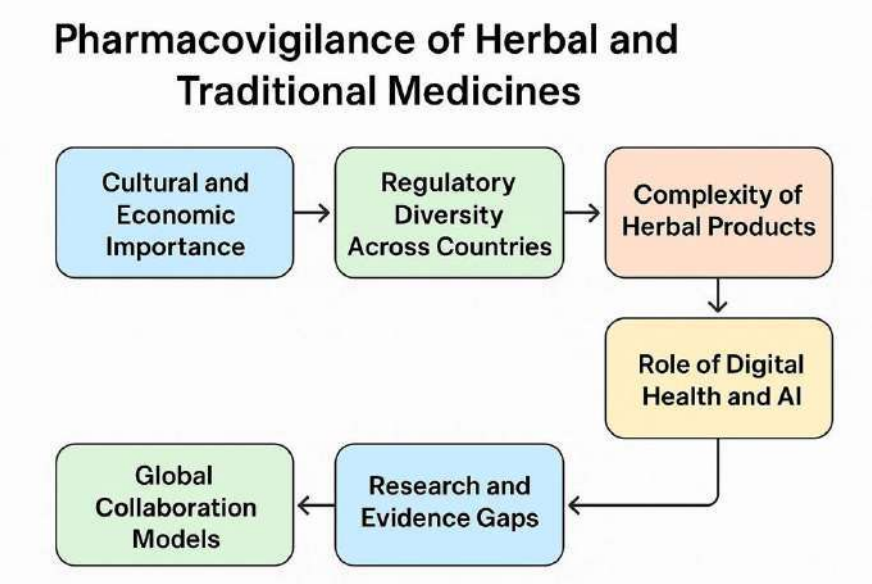
Pharmacovigilance, defined as the science and activities related to the detection, assessment, understanding, and prevention of adverse drug effects, plays a crucial role in ensuring the safety of all medicinal products—including herbal and traditional remedies. However, traditional pharmacovigilance systems were primarily developed for synthetic drugs and are often inadequately equipped to monitor herbal medicines, which present unique challenges such as complex mixtures, inconsistent naming conventions, and variable quality across preparations. Recognizing these issues, the World

Health Organization (WHO) developed specific guidelines in 2004 for the inclusion of herbal medicines in national pharmacovigilance systems. The aim is to extend safety monitoring beyond conventional drugs and ensure the systematic recording and assessment of adverse drug reactions (ADRs) related to herbal use. Recent global market trends also highlight the urgency of pharmacovigilance in this field. The herbal medicine market is expanding rapidly, with forecasts estimating its value to exceed USD 100 billion. Countries like China and Japan have successfully exported their traditional medicines, and in the United States alone, sales of herbal supplements have risen substantially in recent years. However, studies also show that a large percentage of users do not report herbal use to their healthcare providers, which increases the risk of undetected interactions and adverse events.



Given these concerns, there is a critical need for strengthening pharmacovigilance frameworks to include herbal and traditional medicines. This includes raising awareness among healthcare professionals and consumers, training traditional practitioners, improving adverse event reporting systems, and standardizing herbal products to facilitate scientific assessment. A robust pharmacovigilance system for herbal medicines is essential to ensure their safe integration into modern healthcare and to protect public health in both developed and developing regions. Herbal and traditional medicines have been an integral part of healthcare for centuries, serving as the primary source of therapy in many cultures. Today, nearly 80% of the world's population still relies on these remedies for primary health care, particularly in developing regions. Their popularity has also grown in industrialized nations, where natural therapies are increasingly viewed as safer alternatives to synthetic drugs. However, the perception that herbal medicines are entirely harmless is misleading. Reports of hepatotoxicity, nephrotoxicity, allergic reactions, and herb–drug interactions highlight the urgent need for systematic safety evaluation. Pharmacovigilance, defined as the science and activities related to the detection, assessment,

understanding, and prevention of adverse effects of medicines, plays a crucial role in ensuring the safe use of traditional and herbal therapies. Unlike synthetic drugs, herbal medicines pose unique challenges due to variability in plant composition, lack of standardization, contamination, and differences in preparation methods across regions. Furthermore, the underreporting of adverse drug reactions (ADRs) by both healthcare professionals and traditional practitioners limits the generation of reliable safety data. The World Health Organization (WHO) has emphasized the importance of integrating herbal and traditional medicines into existing pharmacovigilance systems through specific guidelines and global collaborations. Strengthening monitoring mechanisms is essential not only to detect and prevent risks but also to support evidence-based integration of traditional medicine into modern healthcare. This review discusses the safety concerns, pharmacovigilance systems, challenges, strategies, and future perspectives for enhancing the safe use of herbal and traditional medicines worldwide.



Cultural and Economic Importance: Herbal and traditional medicines are not only medical resources but also carry cultural heritage and economic value. In many countries, the herbal industry contributes significantly to local economies through cultivation, trade, and export. However, the economic pressure for mass production often leads to adulteration and poor-quality control, raising safety concerns.

Regulatory Diversity Across Countries: Unlike conventional pharmaceuticals, herbal medicines face highly variable regulations worldwide. For example, in the European Union they are often registered under "Traditional Herbal Medicinal Products," whereas in many Asian and African countries they may be sold as dietary supplements without stringent safety requirements. This diversity complicates pharmacovigilance efforts at the global level.

Complexity of Herbal Products: Most herbal formulations are polyherbal (containing multiple plant components), making it difficult to attribute adverse reactions to a single ingredient. This complexity complicates causality assessment in pharmacovigilance systems, especially when used alongside modern drugs.

Role of Digital Health and AI: Emerging technologies such as mobile health apps, electronic medical records, and artificial intelligence are being explored to strengthen herbal pharmacovigilance. AI-based text mining can detect herb–drug interaction signals from published literature, while mobile-based ADR reporting platforms can encourage wider participation by consumers and traditional practitioners.

Research and Evidence Gaps: Despite their widespread use, herbal medicines often lack robust preclinical and clinical trial data. Limited toxicological studies, absence of dose standardization, and inadequate long-term safety evaluation hinder the development of evidence-based guidelines. Expanding clinical research on herbal products is a crucial step toward effective pharmacovigilance.

Global Collaboration Models:

Several countries have initiated dedicated herbal pharmacovigilance centers—for example, China, India, and South Korea have specialized monitoring programs for traditional medicine. The WHO's global network for monitoring herbal medicines is also evolving, promoting shared databases and regional collaborations to improve ADR reporting.

Objectives of Pharmacovigilance of Herbal and Traditional Medicines:

1. Detect and assess adverse effects associated with herbal and traditional medicine use.
2. Monitor herb-drug interactions when used alongside conventional medicines.
3. Ensure patient safety by identifying toxic or contaminated herbal products.
4. Improve the quality and standardization of herbal preparations.
5. Educate healthcare professionals and traditional practitioners about safe use and adverse event reporting.
6. Enhance public awareness about the risks and proper use of herbal products.
7. Strengthen global and national pharmacovigilance systems to include traditional medicines.

Scope of Pharmacovigilance of Herbal and Traditional Medicines:

1. Monitoring adverse drug reactions (ADRs) from herbal and traditional remedies.
2. Evaluating herb-drug interactions with allopathic medicines.
3. Detecting contamination and adulteration in herbal products (e.g., heavy metals, pesticides).
4. Assessing the safety of polyherbal formulations and multi-ingredient preparations.
5. Standardizing plant identification and product labeling across systems and regions.
6. Recording and investigating product misidentification or substitution errors.
7. Monitoring traditional medicine use in vulnerable populations (pregnant women, elderly, children).
8. Integrating herbal and traditional products into national pharmacovigilance reporting systems.

9. Tracking long-term toxicity and cumulative side effects of chronic herbal use.

10. Supporting regulatory policies and safety guidelines for herbal medicine practice.

Functions of Pharmacovigilance of Herbal and Traditional Medicines:

1. Collect and monitor adverse event reports related to herbal and traditional medicine use.

2. Identify and evaluate safety signals from herbal product usage.

3. Assess causality between herbal remedies and observed adverse reactions.

4. Detect herb-drug interactions and unexpected toxicities.

5. Support regulatory decisions on banning, restricting, or labeling unsafe herbal products.

6. Promote safe and rational use of traditional and herbal medicines.

7. Educate healthcare professionals and traditional practitioners on adverse effect reporting.

Safety Concerns with Herbal and Traditional Medicines

- **Adverse Drug Reactions (ADRs):** Can include hepatotoxicity, nephrotoxicity, cardiotoxicity, neurotoxicity, genotoxicity, and hypersensitivity reactions.

- **Herb-Drug Interactions:** For example, St. John's Wort can reduce the effectiveness of oral contraceptives or antidepressants.

- **Contamination:** Herbal products may contain heavy metals (e.g., arsenic, lead), pesticides, microbial contaminants, or other harmful substances.

- **Adulteration:** Some traditional medicines are illegally mixed with steroids, NSAIDs, or other pharmaceuticals without declaration.

- **Misidentification:** Use of incorrect plant species or parts can result in poisoning.

- **Lack of Dosage Standardization:** Variability in preparation and administration leads to inconsistent potency and risk of overdose.

- **Self-medication and Lack of Professional Guidance:** Patients may misuse herbal medicines without understanding their risks.

Pharmacovigilance Systems for Herbal and Traditional Medicines :

Pharmacovigilance systems for herbal medicines aim to integrate traditional medicine safety into national health monitoring programs.

- **WHO Initiatives:** In 2004, WHO released guidelines titled *"Safety Monitoring of Herbal Medicines in Pharmacovigilance Systems."*

- **National Programs:**

o **India:** Ministry of AYUSH, in collaboration with IPC, has a national pharmacovigilance program for Ayurveda, Siddha, Unani & Homeopathy (ASU&H). o **China:** Includes Traditional Chinese Medicine (TCM) in its regulatory framework. o **USA & Europe:** FDA and EMA regulate herbal products, but oversight is often less stringent than for conventional drugs.

- **Pharmacovigilance Centers:** Many countries have designated centres to report and monitor herbal ADRs.

Challenges in Pharmacovigilance of Herbal and Traditional Medicines:

Pharmacovigilance systems face unique challenges when applied to herbal and traditional medicines:

- **Complex Formulations:** Polyherbal mixtures make it difficult to identify the causative agent of ADRs.
- **Inconsistent Nomenclature:** Same plant may have different names across cultures and languages.
- **Limited Scientific Data:** Few herbal medicines undergo rigorous clinical trials.
- **Underreporting:** Patients and traditional practitioners often do not report adverse effects.
- **Regulatory Gaps:** Inadequate regulation, especially in developing countries.
- **Lack of Trained Personnel:** Many practitioners lack pharmacovigilance training.
- **Cultural Beliefs:** Traditional healers and users may not believe ADRs are due to herbal products.

Strategies for Strengthening Herbal Pharmacovigilance (PV):

To improve the safety monitoring of herbal and traditional medicines, the following strategies are essential:

- **Standardization of Herbal Products:** Include identity, purity, strength, and quality control measures.
- **Training and Capacity Building:** Educate traditional medicine practitioners and healthcare providers on ADR reporting.
- **Integration with National PV Systems:** Use a single platform for synthetic and herbal drug safety monitoring.
- **Public Awareness Campaigns:** Encourage users to report side effects and avoid self-medication.
- **Use of Technology:** Digital tools, AI, and mobile apps can support adverse event data collection and analysis.
- **Collaboration with Herbal Industry:** Encourage good manufacturing practices and transparent labeling.
- **International Cooperation:** Global data-sharing platforms like WHO's VigiBase can include herbal ADRs.

Case Studies and Global Reports:

- **India:** Cases of liver damage from *Giloy (Tinospora cordifolia)* misuse during COVID-19 prompted regulatory warnings.
- **China:** Adverse reactions from Aristolochia-containing TCMs led to bans in several countries due to their carcinogenic risk.
- **Europe:** EMA monitors herbal medicines through its Committee on Herbal Medicinal Products (HMPC).
- **Nigeria:** Reports show lack of ADR monitoring among traditional practitioners; efforts underway to educate them.
- **USA:** Cases of contamination and interaction of herbal supplements (e.g., kava, ephedra) led to FDA interventions.

Lack of Standardization in Herbal Medicines:

One of the key challenges in ensuring the safety and efficacy of herbal and traditional medicines is the lack of standardization. Unlike allopathic medicines, where the active ingredient is well defined and measured, herbal products often vary due to:

- Differences in plant species or parts used: The same herbal name may refer to multiple species or use different plant parts (roots, leaves, bark), leading to variability in chemical composition.
- Geographical and seasonal variations: The phytochemical content of herbs can change depending on soil, climate, and harvesting time.
- Preparation and extraction methods: Decoctions, tinctures, dried powders, and extracts may all yield different concentrations of active compounds.
- Unstandardized dosage: Herbal products often lack precise dosage guidelines, increasing the risk of overdose or underdose.
- Lack of quality control during manufacturing: Many herbal products are prepared without adherence to Good Manufacturing Practices (GMP), resulting in batch-to-batch variability.

WHO Guidelines on Safety Monitoring of Herbal Medicines in

Pharmacovigilance Systems (2004):

The World Health Organization (WHO) recognized the increasing global use of herbal medicines and their potential risks. In 2004, it published specific guidelines to integrate herbal medicine into national pharmacovigilance systems. The goals of these guidelines are to:

- Ensure safety monitoring of herbal medicines similar to conventional drugs.
- Improve ADR reporting systems to include herbal and traditional medicine reactions.
- Promote collaboration between modern healthcare professionals and traditional practitioners.
- Provide training to stakeholders on ADR recognition and reporting.
- Encourage national regulatory authorities to assess the safety, efficacy, and quality of herbal products.
- Include herbal medicines in international PV databases, such as WHO's Vigi Base.

Adverse Drug Reactions (ADRs) from Herbal and Traditional Medicines:

Herbal medicines are often assumed to be safe because they are natural, but they can cause a wide range of adverse drug reactions (ADRs). These may be due to:

- Toxic phytochemicals naturally present in the plant.
- Interactions with conventional drugs (pharmacodynamic or pharmacokinetic).
- Contamination or adulteration with harmful substances (e.g., heavy metals, steroids).
- Inappropriate use or dosing, especially in self-medication.

Examples of Herbal ADRs:

- Hepatotoxicity: From kava (Piper methysticum), green tea extract, or Tinospora cordifolia (Giloy).
- Nephrotoxicity: From Aristolochia species (linked to Balkan nephropathy).
- Cardiotoxicity: From ephedra (Ma Huang), associated with hypertension and stroke.
- Neurotoxicity: From nutmeg (Myristica fragrans) in high doses.
- Allergic reactions: From echinacea and chamomile in sensitive individuals.
- Bleeding risks: With ginkgo, garlic, and ginseng when combined with anticoagulants.

Stability Testing of Herbal Medicines

Stability testing evaluates the shelf-life and consistent efficacy of herbal products over time. This is crucial for determining:

- Storage conditions (temperature, humidity, light sensitivity).
- Packaging material suitability (e.g., glass vs. plastic).
- Changes in active compound levels over time.
- Microbial contamination risk during storage.
- Physical stability (e.g., color, odor, solubility).

Regulatory guidelines recommend real-time and accelerated stability testing using scientifically validated methods. However, many herbal manufacturers skip these processes, leading to the sale of expired, degraded, or unsafe products. Standardized stability protocols are needed to ensure herbal medicines maintain quality throughout their shelf life.

Standardization of Herbal Medicines:

Standardization refers to the process of ensuring consistent quality, safety, and efficacy of herbal products. It includes:

1. **Botanical Identification:** Correct plant species and parts must be verified using botanical taxonomy, microscopy, and DNA fingerprinting.
2. **Chemical Standardization:** Quantification of active ingredients or marker compounds using analytical techniques (e.g., HPLC, GC-MS, TLC).
3. **Quality Control:** Screening for adulterant Here is a well-structured conclusion for your review paper on Pharmacovigilance of Herbal and Traditional Medicines:

Future Perspectives

The future of pharmacovigilance in herbal and traditional medicines depends on:

- **Regulatory Harmonization:** Unified international standards for safety evaluation.
- **Enhanced Surveillance Systems:** More robust PV systems tailored to the needs of herbal products.
- **Scientific Research:** More clinical studies on efficacy, safety, and pharmacokinetics of herbal medicines.
- **Digital Pharmacovigilance:** Use of e-health tools, AI, and real-time ADR reporting.
- **Pharmacogenomics:** Personalized monitoring of herbal drug responses based on genetic profiles.

- **Public–Private Partnerships:** Collaboration between government, industry, academia, and traditional medicine practitioners.

- **Bridging Traditional and Modern Medicine:** Integration to develop evidence-based complementary healthcare systems.

CONCLUSION:

The global rise in the use of herbal and traditional medicines underscores the urgent need for robust pharmacovigilance systems to ensure their safe and effective use. While these medicines offer therapeutic benefits and cultural significance, they also pose significant safety concerns due to lack of standardization, quality control, and scientific validation. Adverse drug reactions, herb-drug interactions, contamination, and mislabeling remain persistent challenges. The World Health Organization's guidelines have laid a foundation for integrating herbal medicines into existing pharmacovigilance frameworks. However, effective implementation requires collaborative efforts among regulatory authorities, healthcare professionals, traditional practitioners, and manufacturers. Strengthening reporting systems, promoting education and awareness, ensuring quality assurance through standardization, and conducting scientific research are essential strategies.

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