# Chapter 8

# Pharmacovigilance in Herbal and Traditional Medicines: Challenges and Future Perspectives

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**Abstract**

In recent years, the use of traditional and herbal medicines has gradually increased worldwide. Many people believe that natural products are safe; however, scientific reports indicate that herbal medicines can also cause harmful effects, side effects, toxicity, and interactions with other drugs. For this reason, pharmacovigilance plays an important role in ensuring and monitoring their safety. Herbal medicines are natural-based medicinal products obtained from plants, including roots, leaves, bark, seeds, or extracts, and are widely used in traditional systems. Most of these products are available without prescription and are frequently used for self-medication. In many cases, patients may use these products without consulting healthcare professionals or combine them with modern medications. Herbal products may produce adverse drug reactions such as liver damage, kidney problems, allergic reactions, and bleeding problems. Major concerns include wrongly identified plants, variation in product quality, contamination, and adulterated drugs.

Improving awareness among healthcare professionals and the public can help strengthen safety monitoring.

*Keywords: Pharmacovigilance; Herbal and traditional medicines; Adverse drug reactions; Drug interactions; Quality control; Safety monitoring.*

## 1. Introduction

Herbal and traditional medicines have been used for many centuries for the control and treatment of various diseases. These medicines are mainly obtained from natural sources such as roots, leaves, and plant extracts. Many people around the world depend on herbal medicines for healthcare, especially in developing countries where modern medical services may be limited [1,3]. Traditional medicine systems such as Ayurveda, Unani, and Chinese medicine play an important role in healthcare by using such medicinal products [3,4].

In the modern era, the use and popularity of herbal medicines have increased worldwide. Many people choose herbal products because they are considered natural and less harmful than synthetic drugs. However, this assumption is not always true, as herbal medicines can also produce side effects, toxicity, and drug–drug interactions [1,2]. The increasing use of herbal medicines without proper medical supervision has raised concerns about their safety, quality, and efficacy [2,4].

Pharmacovigilance refers to the science related to the detection, assessment, understanding, and prevention of adverse drug reactions (ADRs) associated with medicinal products. With the increasing use of herbal and traditional medicines, safety monitoring has become essential for public health [1,2].

This chapter discusses the role of pharmacovigilance in herbal and

ISBN 978-816855389-7

traditional medicines, the challenges in monitoring their safety, and possible ways to improve these practices in the future.

## 2. Overview of Herbal and Traditional Medicines

Traditional medicine systems use plants, including roots, leaves, bark, and seeds, either alone or in combination [3,4,18]. Widely known systems include Ayurveda, Unani, Siddha, and Chinese traditional medicine, each with distinct diagnostic and treatment methods [3,18].

Medicinal plants contain bioactive compounds responsible for therapeutic effects, applied in single or multi-herb preparations. Product quality can vary with geographic origin, cultivation, and preparation techniques [3,4].

*Table 1: Major Traditional Medicine Systems and their Characteristics*

| **Traditional system** | **Origin/Region** | **Key features** | **Examples** |
|---|---|---|---|
| Ayurveda | India | Based on balance of body energies [doshas] | Turmeric, Ashwagandha, Neem |
| Traditional Chinese medicine | China | Uses herbal formulations, acupuncture, and holistic diagnosis | Ginseng, Ginger, Licorice |
| Unani medicine | Middle East and South Asia | Derived from the theory of four humors | Senna, Aloes |
| Siddha medicine | South India | Include herbal, mineral, and spiritual healing | Amla, Pepper |
| Kampo medicine | Japan | Japanese form of Chinese herbal medicine | Licorice, Ginger |

Global demand for herbal products, supplements, and functional foods has steadily increased. Many choose herbal medicines for their natural origin [4,8]. Authorities like WHO emphasize the importance

of standardization, safety monitoring, and integration into national healthcare systems [18].

## 3. Need of Pharmacovigilance in Herbal and Traditional Medicines

The increasing global use of herbal and traditional medicines has raised safety concerns. Though perceived as gentle, they can cause adverse effects, interactions, or toxicity if used improperly [1,2,12]. Pharmacovigilance monitors medicines to identify, evaluate, and prevent harmful effects. Key reasons for applying it to herbal products include:

- Uncontrolled use: Self-medication and combination with prescription drugs may be harmful [1].
- Polyherbal formulations: Complex preparations make it difficult to identify the ingredient causing adverse effects [12].
- Quality variation: Differences in cultivation, processing, and storage can lead to contamination or adulteration [12].
- Safety misconceptions: Belief that “natural = safe” may cause users to ignore risks [2].

An effective pharmacovigilance system enables healthcare authorities to detect harmful practices and take action, improving public health [1,12]. The need of pharmacovigilance in herbal and traditional medicines shown in Figure 1.

ISBN 978-816855389-7

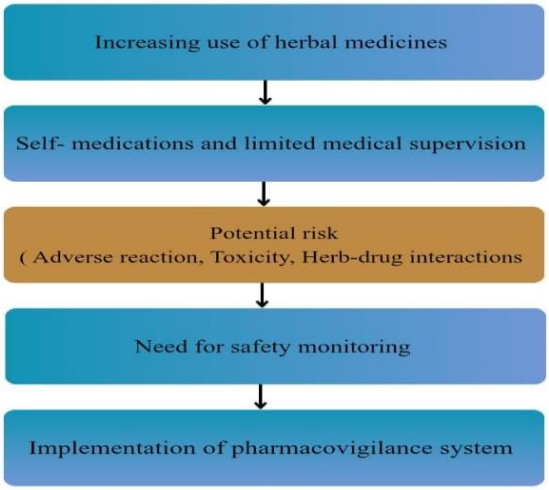


Figure 1: Need for pharmacovigilance in herbal and traditional medicines

## 4. Adverse Drug Reaction and Safety Concerns

People often use herbal and traditional medicines because they are natural and seem safe. But just because something is natural doesn't mean it is completely risk-free. Taking the wrong dose, using them without advice, or mixing them with other medicines can sometimes cause side effects [5,6].

One big problem is drug interactions. Herbs can change the way our body handles other medicines, which might make them less effective or cause extra side effects. For example, St. John's Wort can lower the effect of some prescription drugs [5,8].

Liver problems are another concern. Some herbs, such as kava, can damage the liver if taken in high doses or for a long period [7].

Some people may also experience allergic reactions, ranging from mild skin rashes to more serious immune problems, depending on the person and the herbs used [11,17].

Sometimes the issues aren't the herbs themselves but come from poor quality or contamination. Some products may have heavy metals,

pesticides, microbes, or even synthetic drugs, which can be harmful [11].

In short, while herbal medicines have benefits, they aren't completely safe. Using them carefully, following proper guidance, and monitoring for side effects is very important [5–8,11,17]. To explain the types of adverse reactions reported with herbal medicines, Table 2 outline the common examples, their effect with source reference.

Table 2: Example of ADR associate with herbal medicines

| **Herbal Medicine** | **Adverse Effect** | **Description** |
|---|---|---|
| St. Jhon's wort | Drug interactions | Reduce efficacy of some medicines [5,8] |
| Kava | Hepatoxicity | Liver toxicity reported with prolonged use [7] |
| Ginkgo biloba | Bleeding risk | May rise bleeding with anticoagulants [6] |
| Various herbal products | Allergic reactions | Hypersensitivity reactions occur [11] |

This table shows the different safety concerns related with herbal medicines, highlighting the need for systematic pharmacovigilance. In addition to the examples shown in Table 1, adverse reaction from herbal medicines can generally classified into several categories as illustrate in Figure 2.

ISBN 978-816855389-7

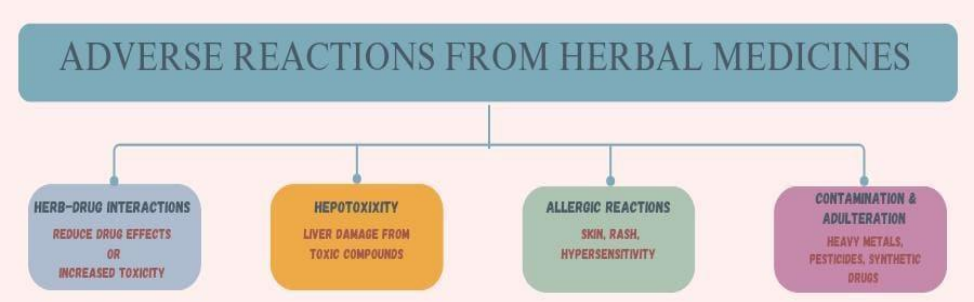


Figure 2: Types of ADRs from herbal medicines

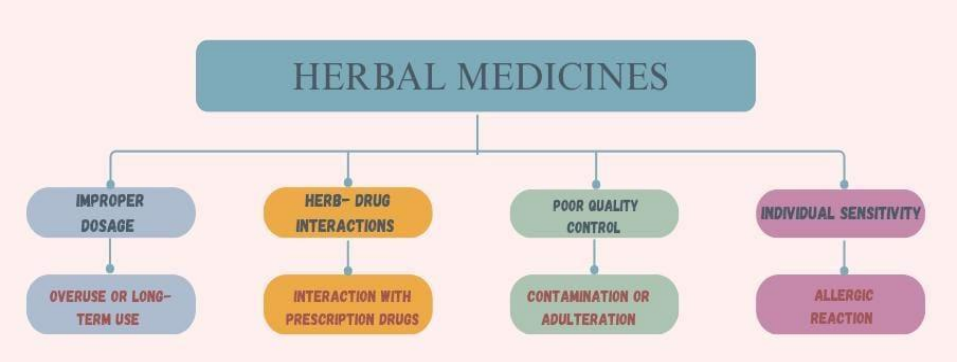


Figure 3: Factors Leading to Herbal Medicine ADRs

## 5. Challenges in Herbal and Traditional Medicine Pharmacovigilance

Monitoring the safety of herbal medicines is not easy. Many people don't report side effects, and healthcare professionals sometimes overlook them [9].

Herbal products can vary a lot in quality because of differences in plant types, origin, or preparation methods. Multi-herb mixtures make it even harder to know which ingredient caused a problem [10,13].

Lack of research and weak regulations in some countries make safety monitoring even more difficult [9,13].

In short, better reporting systems, clear standards, and more awareness among healthcare professionals and users are needed to make herbal medicine use safer.

Table 3: Major Challenges in Pharmacovigilance of Herbal and Traditional Medicines

| Challenge | Description |
|---|---|
| Underreporting of ADRs | Many side effects from herbal and traditional medicines are not reported |
| Lack of standardization | The ingredients maybe different in each product |
| Poly-ingredient products | Traditional medicines often contain many herbs, so it is hard to know which one caused the side effects |

## 6. Current Pharmacovigilance Programs and Startegies

Keeping herbal and traditional medicines safe needs strong monitoring systems. Many programs around the world track side effects (ADRs) to help protect people who use these medicines.

### 6.1 WHO Guidelines for Herbal Medicine and Safety Monitoring

WHO guidelines recommend adding herbal medicines to national monitoring systems, using standard forms to report side effects, training healthcare workers to spot problems, and keeping track of interactions and quality issues [20].

### 6.2 National Pharmacovigilance Systems

Many countries monitor herbal medicines alongside conventional drugs:

- India: Pharmacovigilance Program covers Ayurveda, Siddha, and Unani medicines.
- China: ADR Monitoring System includes Traditional Chinese Medicine.
- European Union: Herbal products are monitored with conventional medicines [15,16,20].

ISBN 978-816855389-7

### 6.3 Modern Strategies for Monitoring

Modern methods use technology to detect safety issues. Data mining identifies unusual ADR patterns [15,16], electronic reporting allows online submission of ADRs, and integration with digital health records helps with active monitoring and early detection [16].

Figure 4 shows the pharmacovigilance reporting process used in modern monitoring systems. It explains how adverse drug reactions are reported, analyzed, and evaluated for medicine safety.

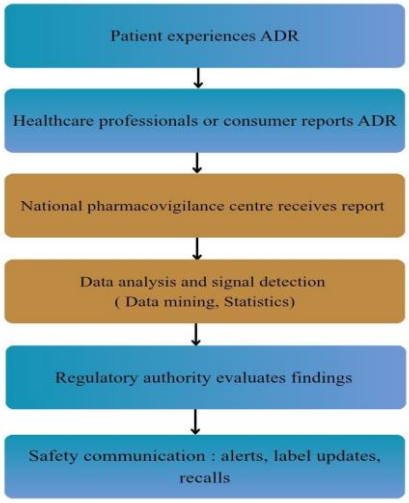


Figure 4: harmacovigilance Reporting Process

## 7. Future Perspectives and Conclusion

Herbal and traditional medicines are really helpful, but they aren't completely risk-free. People often think natural means safe, but side effects, interactions, or contamination can still happen [5,6]. Because of this, it's really important for healthcare workers and users to be aware and report any problems quickly [8].

One big challenge is that herbal products can be very different in quality, and not all countries have strong rules to check them. Better reporting systems, clearer regulations, and proper quality standards can make these medicines much safer [9,10,13].

In the future, more research is needed to standardize herbal products and understand possible side effects. Using digital tools, like online reporting or linking with health records, can help catch problems early [15,16,20]. It's also important for people to use herbs carefully and talk to doctors if they are taking other medicines [11,17].

In short, herbal medicines can give a lot of benefits, but we need to be careful. Using them properly, keeping track of side effects, and improving safety systems will help people enjoy their benefits without risking harm [5–8,11,17,20].

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