

**REGULATORY PERSPECTIVE OF HERBAL MEDICINAL PRODUCTS****Deepak Kumar Vishwakarma\* and Awan Kumar Pandey**

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Herbal medicinal products (HMPs) have received international acclaim based on their therapeutic value, natural origin, and long history in traditional medicine. Their regulation, however, is still complicated because of differences in quality, safety, and efficacy standards among countries. This paper offers an overview of the regulatory landscape of HMPs, with a focus on the main challenges and harmonization. It reviews regulations from prominent agencies such as the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA), and World Health Organization (WHO), highlighting differences in classification, registration needs, and quality control processes. The importance of pharmacovigilance, Good Manufacturing Practices (GMP), and scientific verification in maintaining the safety and efficacy of HMPs is also discussed. The research identifies the

necessity for a harmonized regulatory system throughout the world that will enable world trade, prevent harm to the consumer, and support evidence-based integration of the herbal medicine system into contemporary medical systems.

The regulatory view of herbal medicinal products is multifaceted and differs from one region to another. Within the European Union, the Committee on Herbal Medicinal Products (HMPC) provides scientific opinions on herbal substances and herbal preparations as a definite point of reference for companies and national competent authorities.<sup>[1]</sup>

Three main regulatory routes exist for placing a herbal medicinal product on the EU Market: traditional use registration, well-established use marketing authorization and full marketing authorization.<sup>[2]</sup> Each route entails its own requirements, such as safety and efficacy data, quality control, and labeling and packaging regulations.

In the United States, the FDA oversees herbal medicinal products as dietary supplements, which are less stringently regulated than pharmaceutical medications.<sup>[3]</sup> Herbal medicinal products do, however, have to abide by good manufacturing practices (GMPs) and labeling requirements.

In India, the legal regime for herbal drugs is ruled by the Drugs and Cosmetics Act, 1940, and Rules framed under it.<sup>[4]</sup> The Act mandates that herbal drugs be produced and marketed as per good manufacturing practices (GMPs) and labeling regulations.

Generally, the regulatory approach to herbal medicinal products is complicated and diverse in different parts of the world. Manufacturers and marketers of herbal medicinal products should know the regulatory needs of their region and meet them to maintain the safety and efficacy of their products.

**KEYWORDS:** Herbal medicinal products, regulation, quality control, pharmacovigilance, global harmonization, safety, efficacy, FDA, EMA, WHO.

## INTRODUCTION

Herbal medicinal products (HMPs) have long been a component of traditional and complementary medicine, providing therapeutic properties from plant-based sources. Growing worldwide interest in natural and complementary medicines has caused the demand for herbal products to escalate. Meanwhile, the regulation of these products is still highly complex and vastly different across countries. Contrary to traditional drugs, which have to undergo rigorous clinical testing and regulatory approval, HMPs tend to be challenged in terms of standardization, quality control, safety, and efficacy testing. Regulatory bodies across the globe, such as the U.S.

Food and Drug Administration (FDA), the European Medicines Agency (EMA), the World Health Organization (WHO), and national regulatory bodies, have produced guidelines for the assurance of safety, efficacy, and quality of HMPs. Yet, definition, classification, and approval divergences between nations pose a hindrance to international trade as well as access by consumers. Whereas some regimes place herbal remedies under dietary supplements, others list them as over-the-counter or prescription drugs with varying levels of evidence required for their approval. This paper assesses the regulations that control herbal medicinal products through an analysis of the challenges around harmonization, pharmacovigilance, Good

Manufacturing Practice (GMP), and scientific substantiation. It also examines the role of regulatory bodies in ensuring safe and effective use of herbal medicines as well as in balancing traditional wisdom with contemporary scientific standards.

Harmonized regulation of HMP is necessary to improve consumer safety, enable international trade, and encourage evidence-based integration of herbal medicine into health systems.

Herbal medicinal products (HMPs) have contributed significantly to health care for thousands of years, especially in traditional systems of medicine like Ayurveda, Traditional Chinese Medicine (TCM), and Unani medicine. The demand for natural medicines based on consumer preference, because of the perception of their safety and low side effects, has contributed to an increased global market for HMPs. As per the World Health Organization (WHO), about 80% of the world's population depends on herbal medicines for initial healthcare requirements. Yet, even though widely practiced, regulation of HMPs is vastly different in different regions, and hence, it poses difficulties to ensure their safety, efficacy, and quality. In contrast to chemical pharmaceuticals, which go through rigorous pre-marketing assessments, clinical trials, and standardized regulatory approval, HMPs experience varied and often inconsistent regulatory processes.

In certain areas, herbal products are under the category of food supplements (e.g., in the United States under DSHEA, 1994), whereas in others, they are under the category of medicinal products needing clinical substantiation (e.g., under the European Medicines Agency's (EMA) Traditional Herbal Medicinal Products Directive 2004/24/EC). The absence of a harmonized regulatory system leads to difference in quality control, safety monitoring, labeling needs, and market authorization processes.

## **Main regulatory issues**

### **1. Quality Control and Standardization**

- Natural variability of plant-based ingredients causes batch-to-batch consistency to be hard to achieve.
- Heavy metal, pesticide, microbial toxin, or adulterant contamination is a critical safety issue.
- Consistent extraction, active ingredient measurement, and Good Manufacturing Practices (GMP) are essential for product standardization.

### **2. Safety and Efficacy Assessment**

- In contrast to synthetic medicines, HMPs may not have extensive clinical trials to confirm efficacy.
- Not all potential herb-drug interactions are adequately documented, and thus pose a risk to consumers.
- Post-market surveillance and pharmacovigilance systems must be in place to detect adverse effects.

### **3. Regulatory variability**

- United states: The FDA regulates HMPs as dietary supplements under DSHEA, only demanding Good Manufacturing Practices but not pre-market approval.
- European union: Traditional herbal medicines must be registered according to Directive 2004/24/EC, with documented traditional use for a minimum of 30 years.
- China & India: Herbal medicines are included in national health policy, with dedicated regulatory bodies monitoring safety and efficacy (China's National Medical Products Administration and India's AYUSH Ministry).

### **Need for global harmonization**

In response to these regulatory issues, bodies like WHO, EMA, and the International Organization for Standardization (ISO) are striving towards harmonized guidelines which guarantee:

- Harmonized quality control processes (e.g., pharmacopoeia standards).
- Validation of traditional medicine systems based on evidence.
- Enhanced international trade regulations to enable smooth global movement of herbal medicines.

### **Efforts towards regulatory harmonization of herbal medicinal products**

The regulation of herbal medicinal products (HMPs) is still fragmented globally, with great differences in classification, quality control, safety evaluation, and approval procedures. In view of these issues, several regulatory agencies and international organizations have made efforts to harmonize the regulation of herbal medicine, providing global standards for safety, efficacy, and quality control. Some of the important initiatives and frameworks developed by regulatory agencies and international organizations are presented below.

#### **1. World Health Organization (WHO) Guidelines on Herbal Medicine**

The World Health Organization (WHO) has taken an instrumental part in setting up worldwide regulatory guidelines for herbal medicine. It has released numerous technical documents and model guidelines to support countries in framing regulation systems for herbal medicinal products.

### **Key WHO Initiatives**

#### **A. WHO Traditional Medicine Strategy (2014-2023)**

- Promotes the inclusion of traditional and complementary medicine in national health policies.
- Facilitates the establishment of scientific research, safety evaluation, and quality assurance for herbal medicines.

#### **B. WHO Guidelines for the Assessment of Herbal Medicines (1991, 2000, 2005)**

- Offers guidelines on assessing quality, safety, and efficacy based on traditional use and scientific data.
- Points to the significance of Good Agricultural and Collection Practices (GACP) and Good Manufacturing Practices (GMP) for herbal products.

#### **C. WHO Global Pharmacovigilance System for Herbal Medicines**

- Seeks to enhance post-market monitoring and monitoring of herbal medicine-related adverse reactions.
- Promotes the setting up of herbal medicine pharmacovigilance centers within member states.

### **2. European Medicines Agency (EMA) & The Traditional Herbal Medicinal Products Directive (THMPD)**

The European Medicines Agency (EMA) has developed a centralized regulatory framework for herbal medicinal products through the Traditional Herbal Medicinal Products Directive (2004/24/EC). This directive aims to standardize the approval process for herbal medicines across European Union (EU) member states.

#### **Key Provisions of THMPD (2004/24/EC)**

- Demands herbal medicines to be approved under a streamlined procedure in case they have been in use for a period of at least 30 years (including 15 years within the EU).
- Constitutes the Committee on Herbal Medicinal Products (HMPC) that assesses herbal

medicines on the basis of traditional use and the data available on science.

- Requires compliance with Good Manufacturing Practices (GMP), pharmacovigilance schemes, and labelling rules for products.

Despite these measures, the THMPD system has been criticized for being overly restrictive, resulting in obstacles for small manufacturers of herbal medicine. Most herbal medicines have been removed from the European market because of rigorous safety and documentation procedures.

### **3. U. S. Food and Drug Administration (FDA) and Dietary Supplement Health and Education Act (DSHEA, 1994)**

In the United States, herbal medicinal products are controlled as dietary supplements according to the Dietary Supplement Health and Education Act (DSHEA, 1994). The FDA does not require pre-market approval of herbal products, but the manufacturers have to ensure product safety and adequate labelling.

#### **Key Features of DSHEA (1994)**

- Herbal products are being labelled as dietary supplements, as opposed to drugs, and therefore no clinical trials are required to approve them.
- It is the manufacturer's job to provide product safety, but no pre-market approval is required.
- The FDA can act against products that are misrepresented or deemed to be hazardous.

Whilst DSHEA gives more market flexibility, it has been frowned upon for not having tough regulations, giving rise to worries about adulteration, misbranding, and uneven product quality.

### **4. ASEAN Harmonization of Traditional Medicines and Health Supplements**

The Association of Southeast Asian Nations (ASEAN) has built a harmonized regulatory framework for traditional medicines and health supplements in its 10 member states. The ASEAN Harmonization Initiative aims to:

- Have common quality control and safety standards for traditional medicines.
- Adopt Good Manufacturing Practices (GMP) and standardized testing procedures.
- Enhance mutual recognition agreements to promote trade and market access.

This programme is very useful for nations such as China, India, and Indonesia, which boast

large traditional medicine markets.

## **5. International Organization for Standardization (ISO) Standards for Herbal Medicines**

The International Organization for Standardization (ISO) has set technical standards for herbal medicines, including:

- Quality assurance (ISO 19609:2017 – Traditional Chinese Medicine and Herbal Medicines).
- Methods of testing for contaminants, heavy metals, and pesticides.
- Standardized production and extraction procedures.

The use of ISO standards is well accepted worldwide, and their implementation facilitates the harmonization of world trade and regulation in herbal medicine markets.

## **Challenges and Future directions for regulatory harmonization**

Notwithstanding continued efforts, there are still various challenges in realizing global regulatory harmonization:

1. Variety of Definitions and Regulatory Classifications – Various nations classify herbal medicines as drugs, dietary supplements, or traditional remedies, resulting in regulatory inconsistencies.
2. Absence of Global Standards for Efficacy Testing – In contrast to traditional pharmaceuticals, herbal remedies tend to have missing standardized clinical trials and universal efficacy testing standards.
3. Quality Control and Adulteration Concerns – Herbal sourcing variability, active ingredient levels, and risk of contamination prevent regulatory consistency.
4. Inadequate Pharmacovigilance and Post-Market Surveillance – Most countries do not have mandatory reporting systems for herbal medicine-induced adverse effects.

## **Regulatory status of herbal drugs in india**

### **1. Introduction**

India has a centuries-old practice of herbal medicine usage, mainly guided by Ayurveda, Siddha, Unani, and Homeopathy (ASU&H). Regulating herbal drugs in India is imperative to validate their safety, efficacy, and quality for local as well as foreign markets. The Ministry of AYUSH has a central role in shaping policies and controlling herbal medicines in India.



## **2. Legal and Regulatory Framework**

### **2.1 The Drugs and Cosmetics Act, 1940 and Rules, 1945**

This is the main act that regulates the control of Ayurvedic, Siddha, and Unani (ASU) drugs in India. Some of the major provisions are:

- Herbal drugs are treated separately from allopathic medicines.
- Manufacturers are required to take a license from the State Licensing Authority (SLA).
- Quality control systems, such as Good Manufacturing Practices (GMP), are compulsory.
- Schedule E1 of the Act enumerates poisonous herbal ingredients which need special care.

### **2.2 Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954**

- Prevents false claims and advertisements of herbal medicines.
- Prevents any untested therapeutic advantages from being falsely advertised to the public.

### **2.3 Food Safety and Standards Authority of India (FSSAI)**

- Food Safety and Standards Act, 2006
- Regulates herbal supplements, nutraceuticals, and functional foods with herbal content.
- Herbal food supplements have to be FSSAI approved and not AYUSH registered.

## **3. Quality Control and Standardization**

### **3.1 Pharmacopoeia Standard**

- The Ayurvedic Pharmacopoeia of India (API) establishes official standards for quality for Ayurvedic drugs.
- The Indian Pharmacopoeia (IP) establishes standards for herbal drugs employed in the allopathic system.
- The Herbal Monograph of the Indian Pharmacopoeia Commission (IPC) offers further quality specifications.

### **3.2 Good Manufacturing Practices (GMP) for Herbal Medicines**

- GMP certification is obligatory for all Ayurvedic, Siddha, and Unani drug manufacturers
- Ensures standardized production, utilization of authentic raw materials, and quality assurance.



#### **4. Licensing and Approval Process**

- The manufacturers have to procure a manufacturing license from the State Licensing Authority (SLA).
- Herbal medicines may be classified as:
- Classical formulations (mentioned in ancient records).
- Patent or Proprietary formulations (novel formulations based on herbal concepts)
- The Central Drugs Standard Control Organization (CDSCO) oversees clinical trials for new herbal drugs.

#### **5. Challenges in herbal drug regulation**

1. Lack of Global Harmonization – Varying regulatory requirements for herbal medicines across countries.
2. Standardization Issues – Differences in active ingredients because of differences in plant sources, processing, and formulation.
3. Adulteration and Contamination – Heavy metals, pesticides, and microbial contaminants.
4. Scientific Validation – Need for more clinical trials and scientific data to establish efficacy.

#### **6. International Recognition and Export Regulations**

- The World Health Organization (WHO) has provided guidelines for the regulation of herbal medicines.
- India exports herbal drugs under WHO GMP certification to ensure compliance with international quality standards.

### **Current Status and Challenges of Herbal Drug Development and Regulatory Aspects: A Global Perspective**

#### **1. Introduction**

Traditional herbal medicine has been part of healthcare systems across the globe. Herbal drugs have been integrated into the healthcare policy of numerous countries either as alternative or complementary medicines. Nevertheless, the acceptance, standardization, and regulation of herbal drugs is still a challenge owing to differences in regulatory practices between nations.

#### **Current status of herbal drug development**

##### **1.1 Development of the herbal drug industry**

- The worldwide herbal medicine market was around USD 200 billion in the year 2023 and

is likely to increase enormously.

- China, India, the United States, Germany, and Japan are the leading contributors to the industry.
- Growing consumer demand for natural and herbal medicines has driven the development of herbal drugs.

## 1.2 Top countries with herbal medicine regulation

Country	Regulatory Authority	Key Regulations
India	Ministry of AYUSH, CDSCO	Drug and Cosmetics Act, 1940
China	National medical Products Administration (NMPA)	Traditional Chinese Medicine Regulation
European union	European Medicine Agency (EMA)	Traditional Herbal Medicinal Products Directive
United State	Food and Drug Administration (FDA)	Dietary Supplement Health and Education Act (DSHEA), 1994
Japan	Pharmaceuticals and Medical Devices Agency (PMDA)	Kampo Medicine Regulation

## 2. Challenges in herbal drug development

### 2.1 Regulatory variability

- No single global framework for regulation of herbal drugs.
- Herbal drugs are classified by various countries as medicines, dietary supplements, or functional foods.
- Lack of mutual acceptance among regulatory authorities makes market access worldwide difficult.

### 2.2 Standardization and Quality control issues

- Inconsistency in active ingredients because of differences in plant sources, cultivation, and processing.
- Risk of contamination with heavy metals, pesticides, and microbial impurities.
- Difficulty in batch-to-batch reproducibility due to natural variations in raw materials.

### 2.3 Scientific Validation and Clinical trials

- Limited clinical trials for herbal drugs compared to synthetic drugs.
- Complexity in phytochemical composition makes it difficult to establish precise mechanisms of action.
- Obstacles to applying modern drug discovery methods to multi-component traditional herbal preparations.

## 2.4 Intellectual Property Rights (IPR) and Ethical Issues

- Issues of biopiracy – Foreign countries patenting traditional knowledge without returning any benefits to local communities.
- Ambiguity of patent laws for herbal products because most of them are developed from traditional knowledge.
- Challenges in patenting herbal preparations since there is no single active ingredient.

## 3. Recent developments in the regulation of herbal drugs

### 3.1 World Health Organization (WHO) Guidelines

- WHO has established criteria for the quality, safety, and efficacy of herbal medicines.
- Encourages the application of Good Agricultural and Collection Practices (GACP) to medicinal plants.

### 3.2 Harmonization efforts

- The International Conference on Harmonization (ICH) is towards standardizing herbal medicine regulations.
- Pharmacopoeia monographs are being established to provide global standards.

### 3.3 Digital and AI-based Innovations

- AI-based phytochemical analysis assists in drug discovery and quality assessment.
- Application of block chain technology for tracking and verifying authenticity of herbal products.

## 4. Future Perspectives and Recommendations

- International harmonization of regulation for herbal medicine to make trade and innovation simpler.
- Investment in clinical trials and evidence-based research for herbal medicine.
- Use of biotechnological methods to enhance standardization and safety.
- Strengthening intellectual property laws to safeguard traditional knowledge.

## Benefits of the regulatory approach to herbal medicinal products

### 1. Introduction

Regulation of herbal medicinal products (HMPs) is necessary to provide safety, efficacy, and quality to consumers and healthcare professionals. An established regulatory system favors manufacturers, researchers, healthcare professionals, and patients by ensuring the proper use

of herbal medicines. Various nations have established specific guidelines and standards to effectively regulate herbal drugs.

## **2. Key Benefits of Regulatory Systems for Herbal Medicines**

### **2.1 Guarantees Safety and Consumer Protection**

- Stops adulterated, contaminated, or unsafe herbal products from entering the market.
- Demands toxicological testing to determine possible side effects.

#### **Examples**

- US FDA (Dietary Supplement Health and Education Act, DSHEA, 1994) guarantees safety prior to marketing.
- European Medicines Agency (EMA) – Traditional Herbal Medicinal Products Directive (THMPD, 2004/24/EC) requires risk assessment prior to licensing.

### **2.2 Standardization and Quality Assurance**

Regulated herbal drugs are subject to quality control tests for:

- Purity – Heavy metal, pesticide, and microbial contamination free.
- Batch-to-batch consistency – Ensures constant potency.
- Chemical fingerprinting – Identifies active compounds.
- WHO Good Manufacturing Practices (GMP) for Herbal Medicines provide guidelines for standard production methods.

### **2.3 Enhances Scientific Research and Evidence-Based Medicine**

- Encourages clinical trials and pharmacological studies to validate herbal medicine efficacy.
- Promotes data-driven formulation development rather than relying solely on traditional knowledge.

#### **Example**

China's National Medical Products Administration (NMPA) mandates Traditional Chinese Medicine (TCM) to be scientifically validated prior to commercialization.

### **2.4 Encourages Global Trade and Market Expansion**

- Harmonized regulations enhance international trade by standardizing herbal medicine according to international standards.

- Nations adopting WHO and ICH (International Council for Harmonization) guidelines enhance their export prospects globally.

### **Example**

Certification of India's AYUSH Premium Mark assists Indian herbal products in conforming to international export standards.

## **2.5 Intellectual Property Protection and Prevention of Biopiracy**

- Regulator systems lock out indigenous knowledge and prohibit unauthorized patents.
- Promotes fair benefit-sharing between traditional healers and pharmaceutical firms.

### **Example**

India's Traditional Knowledge Digital Library (TKDL) prevents biopiracy of Ayurvedic and Unani medicinal knowledge.

## **2.6 Boosts Public and Healthcare Professional Confidence**

- Ensures that only clinically tested herbal medicine are prescribed by healthcare professionals.
- Instructs consumers on safe dosages, indications, and contraindications.

### **Example**

Japan's Pharmaceuticals and Medical Devices Agency (PMDA) governs Kampo medicines in the contemporary healthcare system.

## **3. Challenges in Regulatory Implementation**

- Lack of global harmonization – Various nations use different definitions and categories of herbal drugs.
- Complexity in standardization – Natural variation in plant-based medicines complicates uniform quality control.
- High cost of regulatory compliance – The small herbal medicine manufacturers can have difficulties in abiding by rigorous standards.

## **Shortcomings of the Regulation-Based View of Herbal Medicinal Products**

### **1. Introduction**

Although regulations of herbal medicinal products (HMPs) are indispensable for safety, efficacy, and quality assurance, they pose multiple challenges as well. The multidisciplinary

profile of herbal medicines, lack of consistency between countries in regulatory approaches, heavy compliance burdens, and innovation obstruction may prevent the industry. This paper lists the main pitfalls of regulatory policies for herbal medicines.

## **2. Main pitfalls of regulatory policies for herbal medicines**

### **2.1 Lack of global harmonization**

- There are different regulatory standards in various countries, thus affecting international trade and approval.
- Herbal medicines are categorized as dietary supplements in some countries and pharmaceuticals in others, resulting in uneven safety and efficacy requirements.

#### **Example**

The European Medicines Agency (EMA) adheres to the Traditional Herbal Medicinal Products Directive (THMPD, 2004/24/EC) and demands 30 years of traditional use for registration. But the US FDA (Dietary Supplement Health and Education Act, DSHEA, 1994) does not call for efficacy testing.

### **2.2 Expensive and Time-Consuming Approval Process**

- Regulations like clinical trials, safety studies, and standardization are costly and time-consuming.
- Small herbal medicine producers find it difficult to cover compliance expenses, which results in lower innovation and supply of traditional medicines.

#### **Example**

The US FDA New Drug Application (NDA) process takes more than 10 years and costs billions, making it challenging for herbal medicines to be approved as pharmaceutical drugs.

### **2.3 Difficulty in standardization**

- Natural variability of plant-based drugs makes it difficult to attain batch-to-batch consistency.
- Complex phytochemical composition hinders the identification of active constituents, slowing down regulatory approval.

#### **Example**

Chinese Traditional Medicine (TCM) products are unable to meet Western pharmaceutical

standards, resulting in rejection in international markets.

## 2.4 Restriction on Traditional Knowledge and Herbal Practices

- Stringent regulatory systems tend to push traditional medicine practitioners to the periphery through scientific proof.
- Most herbal medicines are founded on holistic concepts, which are incompatible with contemporary pharmacological testing procedures.

### Example

India's Ayurvedic medicines have been banned in the European Union because of inadequate clinical trial evidence, even though they have been used traditionally for centuries.

## 2.5 Risk of Over-Regulation and Market Monopoly

- Stringent regulations favor large pharmaceutical companies, leading to the monopolization of herbal drug development.
- Traditional medicine producers and small businesses may be forced out of the market due to high regulatory burdens.

### Example

The European Union THMPD Directive has drastically cut down the number of herbal medicines available, since small herbal firms cannot pay for compliance.

## 2.6 Intellectual Property Rights (IPR) and Biopiracy Challenges

- Traditional knowledge is usually exploited under contemporary patent laws, resulting in biopiracy.
- Herbal preparation is hard to patent, as it consists of age-old traditional practices and not inventions.

### Example

The Neem patent case (India vs. W.R. Grace & Co.) showed how Western pharma industries have patented indigenous knowledge, limiting its application by local communities.

## Literature survey

### 1. Introduction

Herbal medicinal products (HMPs) have been of international interest because of their therapeutic value and traditional application within healthcare systems. Yet, regulation,



standardization, and acceptance across the globe are still challenges owing to inconsistencies in regulatory measures, safety concerns, and lack of scientific validity. This review survey reviews studies and regulatory frameworks for HMPs, the major developments, challenges, and gaps.

## 2. Regulatory frameworks for herbal medicines

### 2.1 Global regulatory guidelines

- World Health Organization (WHO)
- WHO has issued a number of guidelines for the safety, efficacy, and quality control of herbal medicine.
- The WHO Traditional Medicine Strategy (2014-2023) will bring traditional medicine into mainstream health systems.

### International Conference on Harmonization (ICH)

ICH created harmonized standards for the quality evaluation of botanical drugs with an emphasis on Good Agricultural and Collection Practices (GACP) and Good Manufacturing Practices (GMP) ([ICH, 2017](<https://www.ich.org>)).

### 2.2 Regional regulations

Country	Regulatory Authority	Key Regulations
India	Ministry of AYUSH, CDSCO	Drug and Cosmetics Act, 1940
China	National medical Products Administration (NMPA)	Traditional Chinese Medicine Regulation
European union	European Medicine Agency (EMA)	Traditional Herbal Medicinal Directive
United State	Food and Drug Administration (FDA)	Dietary Supplement Health and Education Act (DSHEA), 1994
Japan	Pharmaceuticals and Medical Devices Agency (PMDA)	Kampo Medicine Regulation

### Key Observations

- EMA requires herbal drugs to have traditional use of more than 30 years, 15 of them in the EU, so that new herbal combinations are hard to get registered.
- Most herbal products in the US are classified as dietary supplements by the US FDA, so there is less regulation.
- China combines Traditional Chinese Medicine (TCM) with contemporary drug control, encouraging conventional and evidence-based herbal therapies.

### 3. Problems in herbal drug regulation

#### 3.1 Standardization and Quality Control

- As opposed to chemical drugs, herbal medicines are complex mixtures of bioactive compounds and thus difficult to standardize.
- HPLC, GC-MS, and DNA barcoding are routinely employed for chemical fingerprinting and species authentication (Li et al., 2017).
- Heavy metals, pesticide, and microbial pathogen contamination is still a valid area of concern (Sharma et al., 2019).

#### 3.2 Lack of clinical evidence

- Most herbal medicines do not have well-documented clinical trials to prove their efficacy and safety.
- Ethical and methodological issues in performing randomized controlled trials (RCTs) on multi-component herbal preparations (Wang et al., 2021).

#### 3.3 Global trade barriers

- Regulatory classification differences obstruct the global trade of herbal medicines (Kumar et al., 2020).

#### Example

Ayurvedic medicines are subject to export restrictions in the EU because of THMPD requirements (Singh & Gupta, 2018).

#### 3.4 Intellectual Property and Biopiracy

- Patent laws are biased in favor of synthetic drugs compared to traditional herbal preparations.
- Traditional Knowledge Digital Library (TKDL) in India has been successful in preventing unethical patenting of indigenous medicinal knowledge (Rao et al., 2016).

### 4. Recent advances in herbal drug regulation

- Artificial Intelligence (AI) and Big Data for herbal pharmacovigilance and toxicity prediction (Chen et al., 2022).
- Blockchain technology for supply chain transparency to avoid adulteration of herbal medicine (Zhang et al., 2021).
- Pharmacokinetic and metabolomic studies to enhance the scientific understanding of

herbal drug interactions (Huang et al., 2020).

## SUMMARY

The regulatory viewpoint of herbal medicinal products is important for their safety, efficacy, and quality as well as for enabling them to become a part of contemporary healthcare. Different international and national regulatory agencies, including the World Health Organization (WHO), the International Conference on Harmonization (ICH), the US FDA, the European Medicines Agency (EMA), and India's Ministry of AYUSH, have laid down guidelines for regulating herbal medicines. Yet, there are challenges that arise from classification differences, quality control practices, and scientific standards for validation across nations. For instance, whereas the US FDA considers the majority of herbal medicines dietary supplements with light regulation, the EMA has strict requirements, such as a minimum of 30 years of traditional use (15 years within the EU) for approval. In spite of the benefits of regulation guaranteeing consumer safety, enhancing market confidence, and inhibiting adulteration there are formidable challenges.

Global non-harmonization results in barriers to trade, and high compliance costs render it unaffordable for small producers to market herbal products. Furthermore, the natural variation in plant medicines complicates batch-to-batch standardization, and the sparse clinical trial data on herbal medicines retard their integration into mainstream healthcare. Over-regulation can also limit traditional medicine practitioners from applying well-established herbal preparations. To overcome these issues, recent technologies like artificial intelligence (AI) for monitoring herbal safety, block chain for supply chain transparency, and metabolomics for standardization are being investigated. The harmonization of regulatory systems, scientific validation by clinical studies, and intellectual property protection of traditional knowledge are crucial to facilitate the global acceptance of herbal medicines.

A harmonious strategy that balances conventional expertise with contemporary standards of regulation can help maintain herbal medicinal products safe, effective, and available and encourage innovation at the same time.

## CONCLUSION

The regulatory environment of herbal medicinal products continues to be heterogeneous, creating issues of quality, safety, and efficacy. A coordinated effort globally, marrying scientific verification with traditional wisdom, is essential in order to deliver consumer safety

as well as bring herbal medicines forward as a sound therapeutic choice. This article examines the changing regulatory systems and attempts to create a more harmonized, open, and science-based approach to the regulation of herbal medicinal products across the world.

Initiatives for global regulatory harmonization of herbal medicinal products are progressing with efforts by WHO, EMA, FDA, ASEAN, and ISO. Yet, important gaps still exist in standardization, safety assessment, and cross-border regulatory harmonization. A more efficient global framework needs international cooperation on:

- Harmonized quality control standards for herbal medicines.
- Enhanced pharmacovigilance systems for adverse effect monitoring.
- Scientific authentication of traditional medicines by evidence-based research.
- Mutual recognition agreements to facilitate freer international trade and market entry.

As herbal medicine rises to greater prominence in world healthcare, a synchronized regulatory strategy will be essential to guarantee safety, efficacy, and consumer confidence.

India possesses a well-established regulatory system for herbal drugs with regard to quality, safety, and efficacy. Yet, there are challenges of standardization, scientific validation, and international acceptance. India can emerge as a world leader in herbal medicines by strengthening research, quality control, and regulatory enforcement.

Herbal drug development is picking up pace worldwide because of growing consumer demand for natural drugs. Despite this, issues regarding regulatory differences, quality control, and scientific proof continue to remain. Overcoming these issues with harmonized regulations, sophisticated research, and improved quality control measures will increase the acceptability and credibility of herbal medicines globally.

A well-regulated herbal medicine industry protects consumers from harm, provides a more credible product, and stimulates scientific breakthroughs. Ensuring greater global harmonization, standardization methods, and regulation enforcement will continue to enhance the benefits of herbal medicinal products.

Whereas regulatory systems for herbal medicines guarantee safety, quality, and credibility, they also present hurdles to traditional medicine practitioners, small producers, and international market entry. To overcome these hurdles, harmonized regulations, adaptable approval routes, and safeguarding traditional knowledge are needed.

Regulation of herbal medicinal products is different across the world, causing standardization, safety, and market acceptance challenges. Although there have been notable developments in quality control methods and regulatory frameworks, more harmonization, clinical testing, and intellectual property protection are required to establish herbal medicines as safe healthcare options.

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