



Regulatory Requirements for Herbal Medicines in India

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ABSTRACT

Natural products have been utilized worldwide since the Vedic era. Although minerals and animal-derived substances have also been traditionally used as natural resources in certain countries, herbal medicine continues to serve as a primary source of healthcare for approximately 75–80% of the global population, especially in developing nations. There are considerable differences in the classification and categorization of herbal medicines across regions. Depending on the regulatory frameworks of different countries, these products are currently categorized under various groups such as pharmaceuticals, food products, health supplements, nutraceuticals, cosmetics, and others.

Herbal formulations are also incorporated into several systems of medicine, including Allopathy, Homoeopathy, Unani, Siddha, and Ayurveda in India. Herbal medicines are increasingly gaining global recognition due to their potential effectiveness in the prevention and treatment of numerous diseases. India possesses a long-standing heritage of traditional herbal medicine usage.

The application of herbal medicines is regulated by governmental authorities to ensure their safety, quality, and therapeutic efficacy. This review aims to present an overview of the regulatory requirements governing herbal medicines in India. The regulatory structure is primarily based on the Drugs and Cosmetics Act, 1940, along with its subsequent amendments. According to this Act, herbal medicines are defined as drugs derived exclusively from plants, their parts, or extracts, intended for therapeutic use. The Act also establishes guidelines for the manufacturing, labeling, and marketing of herbal products.

I. INTRODUCTION

Herbal medicines have been practiced in India since the Vedic period, as documented in the Rigveda, and further elaborated in the Charaka Samhita. Initially, herbs were used by individuals based on traditional knowledge and experience, which eventually led to the emergence of specialized practitioners known as apothecaries. Herbal treatments have also been widely practiced in other countries, such as China.

In India, herbal medicines form an integral part of various traditional systems of medicine, including Ayurveda, Siddha, Unani, and Homoeopathy. Ayurvedic medicine dates back to around 6000 B.C., while Chinese traditional medicine has been practiced since approximately 5000 B.C., and modern allopathic medicine emerged around 1800 A.D. The widespread use of herbal medicines in India can be attributed to extensive traditional knowledge and the rich biodiversity supported by diverse agro-climatic conditions.

In India, herbal medicines are regulated by the Central Drugs Standard Control Organization (CDSCO) under the provisions of the Drugs and Cosmetics Act, 1940, and the Drugs and

Cosmetics Rules, 1945. The regulatory framework is designed to ensure that herbal products comply with established standards of quality, safety, and efficacy.

Standards of Drugs as per Existing Legislation in India

The **Drugs and Cosmetics Act, 1940** establishes the standards for medicinal products, and specific monographs are outlined in various pharmacopoeias. The Government of India has published four volumes of the Ayurvedic Pharmacopoeia, which include standards for 326 formulations. However, this number is considerably insufficient when compared to the vast range of herbs used in the Ayurvedic system of medicine.

The introduction of the Herbal Pharmacopoeia, which provides standards for 52 medicinal products, was a significant advancement in this field (IDMA, 2002). Despite this progress, herbal products and Herbal Pharmacopoeias currently lack strong legal recognition in India (Government of India, 2005). Furthermore, although numerous herbal products are available in the market, their classification under the Drugs and Cosmetics Act remains challenging and often unclear.

Key Standards for Drugs

Quality:

All drugs must conform to prescribed quality standards. They should be free from harmful impurities and comply with the specifications provided in the Indian Pharmacopoeia or any other recognized pharmacopoeia.

Safety:

All medicinal products must be safe for human consumption. Their potential risks, side effects, and toxicity must be thoroughly assessed and documented.

Efficacy:

Drugs must demonstrate effectiveness for their intended use and deliver the expected therapeutic outcomes.

Packaging and Labeling:

All drugs must be appropriately packaged and accurately labeled. Labels should include essential details such as the drug name, strength, dosage form, manufacturer's name, batch number, expiry date, and necessary warnings or precautions.

Adulteration:

Drugs must be free from adulteration, including contamination or the addition of any harmful or unauthorized substances.

Misbranding:

Medicinal products must be correctly labeled, and any claims regarding their therapeutic benefits should be supported by valid scientific evidence. Standardization:

All drugs must be produced following standardized procedures to ensure uniformity in quality, safety, and efficacy across batches.

Adherence to these standards is crucial to ensure the safety, quality, and therapeutic effectiveness of drugs in India. Regulatory authorities such as the **Central Drugs Standard Control Organization (CDSCO)** are responsible for monitoring compliance and taking necessary actions against substandard or non-compliant products and manufacturers.

Regulatory Aspects of Herbal Medicines in India

The **Drugs and Cosmetics Act, 1940** and the **Drugs and Cosmetics Rules, 1945** regulate herbal medicines in India. The **Ministry of AYUSH** serves as the primary regulatory authority overseeing these products. A valid manufacturing license is mandatory for the production and marketing of herbal medicines.

Schedule T (Chapter IV-A) of the Drugs and Cosmetics Act specifies the requirements for **Good Manufacturing Practices (GMP)** that must be followed by manufacturers of herbal formulations. The Ministry of AYUSH, established on 9th November 2014, focuses on the promotion and development of traditional healthcare systems. Previously, it was known as the Department of Indian Systems of Medicine and Homoeopathy (established in March 1995), and was later renamed to include Ayurveda, Yoga & Naturopathy, Unani, Siddha, and Homoeopathy.

Sections 33C to 33O of the Act provide detailed provisions related to manufacturing, registration, licensing, sale, GMP certification, and penalties for non-compliance.

Approval Process of Herbal Drugs

A manufacturing facility for herbal medicines must include the following essential sections:

- Production area
- Administrative office
- Workers' facilities
- Raw material storage area
- Finished goods storage area
- Quarantine section
- Packaging material storage
- Bottle washing and drying area
- Packaging and labeling section
- Quality Control (QC) laboratory
- Documents Required for Approval of Premises

The following documents must be submitted for obtaining approval:

- Covering (forwarding) letter
- Duly filled and signed application form by the authorized person
- Complete firm details signed by the authorized representative
- Original challan as proof of payment of the prescribed license fee
- One copy of the premises layout plan (original)
- Proof of possession or ownership of the premises
- (supporting literature copies)

Global Herbal Regulation

1. United States of America:

In the United States, herbal products are categorized as dietary supplements, food products, or drugs. They are primarily regulated under the *Dietary Supplement Health and Education Act (DSHEA), 1994*. Under this framework, manufacturers are responsible for ensuring product safety; however, the Food and Drug Administration does not conduct pre-market evaluation of dietary supplements.

2. United Kingdom:

In the United Kingdom, licensing requirements are specified under Section 12 of the *Medicines Act* and are supervised by the Medicines Control Agency (now part of the MHRA). Herbal products can be registered through

the **Traditional Herbal Registration (THR)** scheme under Directive 2004/24/EC or through marketing authorization under Directive 2001/83/EC.

Manufacturers must provide data on quality (in compliance with GMP), safety, and efficacy, which is primarily based on long-standing traditional use (at least 30 years, including 15 years within the EU). Products approved under this scheme must carry a THR certification mark and the statement indicating “traditional use.”

3. Association of South East Asian Nations (ASEAN):

The Association of Southeast Asian Nations was established in Bangkok on August 8, 1967, by Indonesia, Malaysia, the Philippines, Singapore, and Thailand, and later expanded to include Brunei, Vietnam, Laos, Myanmar, and Cambodia.

Herbal medicines in ASEAN countries are regulated under harmonized guidelines and may be classified into:

- Traditional or indigenous herbal medicines
- Herbal medicines within established systems
- Modified herbal formulations
- Imported herbal products

Regulatory oversight in some regions is handled by agencies such as the Health Sciences Authority.

4. Kingdom of Saudi Arabia:

In Saudi Arabia, herbal medicine regulations were introduced in 1996 through a separate legislative framework. Manufacturing requirements are similar to those for conventional pharmaceuticals and must comply with WHO-GMP standards.

Supporting evidence for traditional herbal products may include pharmacopoeial as well as non-pharmacopoeial documentation to establish safety and efficacy.

5. European Union:

The European Union implemented Directive 2004/24/EC, introducing the concept of **Traditional Herbal Medicinal Products (THMPs)**. To obtain approval,

products must provide:

- Bibliographic evidence of traditional use
- Preclinical safety data

Although regulations exist at the EU level, the implementation and strictness of herbal medicine regulation may vary across member states.

6. Canada:

In Canada, herbal medicines were initially classified as folk medicines in 1986. Later, regulatory oversight was strengthened under the Natural Health Products framework.

The Health Canada is responsible for regulating these products through the Natural Health Products Directorate (established in 1999). Since 2004, herbal medicines require pre-market authorization.

Manufacturers must monitor and report adverse drug reactions. Standards are aligned with recognized references such as the US Pharmacopoeia, British Herbal Pharmacopoeia, ESCOP, and WHO guidelines.

7. Australia:

In Australia, herbal medicines are regulated by the Therapeutic Goods Administration. Products must be listed or registered in the Australian Register of Therapeutic Goods (ARTG).

- **Listed medicines:** Low-risk products
- **Registered medicines:** High-risk products Applications may be approved, conditionally approved, or rejected.

The registration process follows the Common Technical Document (CTD) format.

8. Russia:

In Russia, the national policy on herbal medicines was introduced in 1991, with detailed regulations established in 1993. Herbal products are regulated similarly to prescription drugs, over-the-counter medicines, or dietary supplements. GMP standards are equivalent to those applied to conventional pharmaceuticals.

9. South Africa:

In South Africa, herbal medicines are governed under the *Medicines and Related Substances Act, 1965* and are classified as complementary medicines.

Registration applications must be submitted in CTD format, and the approval process is often lengthy due to stringent regulatory requirements.

11. Nigeria:

In Nigeria, herbal medicines are regulated by the National Agency for Food and Drug Administration and Control. This authority is responsible for the registration, licensing, and quality control of herbal products to ensure their safety and compliance with national standards.

12. China:

In China, Traditional Chinese Medicine (TCM) has been practiced for more than 4000 years, with documented records in the *Chinese Materia Medica*. Herbal products are subject to specific regulatory requirements, including the submission of a comprehensive quality dossier and thorough evaluation of safety and therapeutic efficacy before approval for marketing.

13. Challenges in Herbal Drug Regulation:

Ensuring the quality, safety, and efficacy of herbal medicines requires rigorous quality control and standardization tests prior to their release into the market. However, many national regulatory authorities face limitations due to insufficient expertise and lack of well-defined regulatory frameworks for herbal products.

To address these concerns, the World Health Organization has developed international guidelines and standards for herbal medicines, which serve as a reference for regulatory agencies worldwide.

II. CONCLUSION

Herbal medicines hold significant potential for future healthcare due to the vast availability of medicinal plants across the globe. Moreover, many modern pharmaceutical drugs are either directly or indirectly derived from plant sources.

Despite this potential, studies on herbal drug regulation highlight persistent issues related to quality assurance, largely due to inadequate or inconsistent regulatory frameworks. In India, herbal medicines are regulated under the supervision of the Ministry of AYUSH. However, several challenges remain, including:

- Difficulties in standardization due to the complex (polyherbal) nature of formulations
- Inadequate post-harvest handling and storage facilities
- Limited availability of raw material testing laboratories
- Lack of proper product traceability systems

Although regulatory systems for herbal medicines exist globally, they are not uniformly structured. A major concern identified is the lack of harmonization in regulatory standards across different countries, which affects the global acceptance and quality assurance of herbal products.

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