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REGULATORY REQUIREMENTS FOR HERBAL MEDICINES

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ABSTRACT

Natural products have been utilized worldwide since the Vedic era. Although minerals and animal-derived substances have also been used as natural resources in certain regions, herbal medicine continues to serve as a primary form of healthcare for nearly 75–80% of the global population, particularly in developing countries. There are considerable differences in the classification and categorization of herbal drugs. Depending on the regulatory policies of different countries, they are presently categorized under various groups such as pharmaceuticals, food products, health products, dietary supplements, cosmetics, and others.

Herbal formulations are also used across multiple systems of medicine in India, including Allopathy, Homeopathy, Unani, Siddha, and Ayurveda. Herbal remedies are increasingly gaining global recognition due to their potential role in the prevention and management of numerous diseases. India possesses a long-standing heritage of herbal medicine usage spanning centuries.

The use of herbal medicines is regulated by governmental authorities to ensure their safety, effectiveness, and quality standards. This review intends to present an overview of the regulatory framework governing herbal medicines in India. The legal structure for herbal drugs in India is established under the Drugs and Cosmetics Act, 1940, along with its subsequent amendments. According to this Act, herbal medicines are defined as substances derived entirely from plants, their parts, or extracts, and are intended for therapeutic use. The Act also specifies guidelines related to the production, labeling, and distribution of herbal medicinal products.

INTRODUCTION

Herbal medicines have been used in India since the Vedic era, as documented in the *Rigveda*, and are also described in the *Charaka Samhita*. Initially, herbs were used by individuals

based on traditional knowledge and personal experience, which later led to the development of a specialized group of practitioners known as apothecaries. Herbal treatments have also been widely practiced in other countries, including China.

In India, herbal therapies are an integral part of various traditional systems of medicine such as Ayurveda, Siddha, Unani, and Homeopathy. Ayurvedic medicine dates back to around 6000 B.C., Chinese herbal medicine to approximately 5000 B.C., while modern medicine began developing around 1800 A.D. The widespread use of herbal medicine in India can be attributed to rich traditional knowledge and the vast availability of medicinal plants due to 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, along with the Drugs and Cosmetics Rules, 1945. The regulatory system is structured to ensure that herbal products comply with established standards of quality, safety, and therapeutic effectiveness.

Standards of Drugs as per Existing Legislation in India

The Drugs and Cosmetics Act, 1940 establishes the regulatory framework for maintaining the standards of medicinal products in India. It specifies quality requirements, while detailed monographs are provided in official pharmacopoeias such as the Indian Pharmacopoeia Commission publications.

The Government of India has published multiple volumes of the Ayurvedic Pharmacopoeia, covering standards for approximately 326 drugs. However, this number remains significantly limited compared to the vast range of medicinal plants used in traditional Ayurvedic practice. The introduction of Herbal Pharmacopoeias, which include standards for around 52 herbal drugs (IDMA, 2002), represents a progressive step toward standardization.

Despite these efforts, herbal pharmacopoeial standards and many herbal products still lack full statutory enforcement in India (Govt. of India, 2005). The categorization of herbal products under existing legal provisions remains complex due to their dual nature as both traditional remedies and commercial products.

Essential Drug Standards

To ensure public health and safety, all medicinal products, including herbal drugs, must comply with the following key standards:

1. **Quality:**

Medicines must conform to established specifications and be free from impurities, contaminants, and toxic substances. Compliance with recognized pharmacopoeial standards is mandatory.

2. **Safety:**

Drugs should be evaluated for potential toxicity, side effects, and interactions. Preclinical and clinical data should support their safe use.

3. **Efficacy:**

All drugs must demonstrate therapeutic effectiveness for their intended indications through scientific validation or traditional evidence.

4. **Packaging and Labelling:**

Proper packaging ensures product stability and prevents contamination. Labels must include critical details such as drug name, dosage form, strength, manufacturer details, batch number, expiry date, and safety warnings.

5. **Adulteration Control:**

Medicinal products must be free from adulterants, substitution, or contamination with harmful substances.

6. **Misbranding Prevention:**

Claims made on labels or advertisements must be truthful, scientifically supported, and not misleading.

7. **Standardization:**

Uniformity in composition, processing, and quality must be maintained through validated manufacturing procedures.

Regulatory bodies such as the Central Drugs Standard Control Organization are responsible for monitoring compliance and taking action against violations.

Regulatory Aspects of Herbal Medicines in India

Herbal medicines are governed under the Drugs and Cosmetics Act, 1940, and the Drugs and Cosmetics Rules, 1945. The Ministry of AYUSH serves as the primary authority overseeing traditional systems of medicine including Ayurveda, Yoga, Naturopathy, Unani, Siddha, and Homeopathy.

Manufacturing of herbal medicines requires a valid license, and compliance with Good Manufacturing Practices (GMP) as outlined in Schedule T (Chapter IV-A) is mandatory.

Sections 33C to 33O of the Act provide detailed provisions regarding licensing, manufacturing, quality control, and penalties.

The Ministry of AYUSH, established in 2014 (previously ISM&H in 1995), plays a significant role in strengthening traditional healthcare systems and promoting standardization.

Approval Process for Herbal Drugs

A licensed manufacturing facility must include:

- Production area
- Administrative office
- Storage for raw materials and finished products
- Quarantine area
- Packaging and labeling sections
- Quality Control (QC) laboratory
- Equipment and washing/drying facilities

Key documents required for approval include:

- Application form and forwarding letter
- Premises layout plan
- Ownership/possession proof
- Firm constitution details
- Product list and formulation details
- Equipment and machinery list
- Technical staff qualifications
- Raw material specifications and testing methods
- SOPs (Standard Operating Procedures)
- Master Formula Records (MFR)
- Agreements with testing laboratories

Global Regulatory Framework for Herbal Medicines

Herbal drug regulation varies significantly across countries:

1. **United States:**

Under the Dietary Supplement Health and Education Act of 1994, herbal products are classified as dietary supplements. The Food and Drug Administration does not require pre-market approval but monitors safety post-marketing.

2. United Kingdom:

Governed by the Medicines Act 1968, herbal products require Traditional Herbal Registration (THR) based on long-standing usage and compliance with quality and safety standards.

3. ASEAN Countries:

Regulations differ across member nations, but herbal medicines are categorized into traditional, modified, and imported products, with oversight from regional health authorities.

4. Saudi Arabia:

Herbal medicines follow WHO-GMP standards and require supporting pharmacopoeial and scientific evidence.

5. European Union:

Directive 2004/24/EC introduced the concept of Traditional Herbal Medicinal Products (THMPs), requiring documented traditional use and safety data.

6. Canada:

Herbal products are regulated as Natural Health Products under Health Canada, requiring pre-market approval and safety monitoring.

7. Australia:

The Therapeutic Goods Administration regulates herbal medicines, classifying them into low-risk (listed) and high-risk (registered) categories.

8. China:

Traditional Chinese Medicine (TCM) has a well-established regulatory system with strict requirements for quality, safety, and efficacy.

9. Other Countries (Russia, South Africa, Nigeria):

Regulations align herbal medicines with pharmaceutical standards, including GMP compliance and licensing procedures.

Challenges in Herbal Drug Regulation

- Lack of uniform global regulatory standards
- Variability in raw material quality
- Issues in standardization due to polyherbal formulations
- Insufficient quality control infrastructure
- Limited scientific validation of traditional claims
- Inadequate pharmacovigilance systems
- Adulteration and substitution of herbal materials

The World Health Organization has developed guidelines to harmonize regulatory approaches and improve quality assurance worldwide.

CONCLUSION

Herbal medicines hold immense potential due to the vast biodiversity of medicinal plants and their historical significance in healthcare systems. A significant proportion of modern pharmaceuticals are derived directly or indirectly from plant sources, highlighting the importance of herbal research.

However, the growth of the herbal industry is hindered by challenges such as inconsistent regulatory frameworks, lack of standardization, inadequate quality control, and limited global harmonization. In India, the Ministry of AYUSH plays a central role in addressing these issues, yet further advancements are needed in areas like raw material authentication, post-harvest processing, and traceability systems.

Globally, while regulatory mechanisms exist, they are often fragmented and differ significantly between countries. There is a pressing need for internationally harmonized guidelines to ensure the safety, efficacy, and quality of herbal medicines. Strengthening scientific validation, improving regulatory enforcement, and promoting global cooperation will be essential for the sustainable growth and acceptance of herbal therapeutics in modern healthcare systems.

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