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REGULATORY REQUIRMENTS OF HERBAL MEDICINES IN INDIA

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ABSTRACT

India plays a significant role in the global supply of medicinal plants and herbs. These plants are widely used in the treatment of various ailments, with many people preferring them due to their comparatively lower risk of side effects. Herbal remedies have been a cornerstone of various traditional medical systems, including Ayurveda, Siddha, Homeopathy, Unani and Traditional Chinese Medicine. Depending on their use, herbal products are categorized as complementary medicines, nutraceuticals, prescription drugs, over-the-counter (OTC) medicines, supplements, or conventional herbal medications. For herbal medicines to be sold commercially, they must comply with the regulatory standards set by different countries. However, this lack of uniformity in regulations often prevents herbal medicine manufacturers from offering standardized products globally. To address this challenge, international organizations like the World Health Organization (WHO) are collaborating to create harmonized and standardized guidelines for herbal medicines. In India, herbal products are regulated under the Drugs and Cosmetics Act of 1940 (DCA) and the associated Rules of 1945, with the AYUSH department overseeing the regulation and approval of these products. To legally manufacture or trade in herbal medicines, a manufacturing license is required. Efforts are ongoing to improve the regulatory processes and ensure the safety, quality and efficacy of Ayurvedic medicines.

KEYWORDS

AYUSH, Herbal drugs, India, Quality control, Regulation and Standardization.

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INTRODUCTION

In India, herbal medicines have been used for centuries, deeply rooted in traditional systems of medicine like Ayurveda, Siddha and Unani. With the growing demand for natural and alternative remedies, herbal medicines have gained significant attention both domestically and internationally. However, the increasing popularity of herbal

products has also raised concerns about their safety, efficacy and quality. To address these concerns and ensure consumer protection, India has established regulatory frameworks governing the production, sale, and distribution of herbal medicines.

The regulatory landscape for herbal medicines in India is primarily guided by the Ministry of AYUSH (Ayurveda, Yoga and Naturopathy, Unani, Siddha, and Homoeopathy) and Central Drugs Standard Control Organization (CDSCO) under the Drugs and Cosmetics Act, 1940. These regulations aim to ensure that herbal medicines are safe, effective, and manufactured according to quality standards.

Key aspects of the regulatory requirements for herbal medicines in India include:

Classification and Registration

Herbal products are classified into two categories - Ayurvedic**,** Siddha and Unani medicines (ASU) and herbal drugs. The registration process involves the approval of formulations, which must meet specific quality standards and be backed by traditional knowledge or scientific data.

Manufacturing Standards

Manufacturers of herbal medicines are required to follow good manufacturing practices (GMP) specified by the regulatory authorities. This ensures that the products are consistently produced and controlled according to quality standards.

Labeling and Packaging

Proper labeling is a key regulatory requirement. The labels must include details such as the product's composition, dosage, and instructions for use, as well as warnings related to contraindications or side effects.

Clinical Trials and Efficacy Proof

Herbal products must demonstrate clinical evidence of efficacy, especially when they are marketed as therapeutic. The approval process requires submitting clinical trial data or traditional usage data to establish the product's safety and effectiveness.

Pharmacovigilance and Safety Monitoring

Post-market surveillance and reporting of adverse drug reactions (ADRs) are mandatory to ensure the safety of herbal medicines after they are available in the market.

Standardization and Quality Control

One of the critical challenges in herbal medicine regulation is ensuring the consistency of active ingredients and quality control. Standardization involves developing quality control parameters such as identifying botanical species, active compounds, and ensuring they are free from contaminants.

Export and International Regulations

India also has to align its regulations with international standards to facilitate the export of herbal medicines. Exporting herbal products requires compliance with international guidelines such as those set by the World Health Organization (WHO) and the Codex Alimentarius.

The growing acceptance of herbal medicine both locally and globally underscores the importance of a robust regulatory framework that balances consumer safety with the need for innovation and market growth.

CLASSIFICATION OF HERBAL MEDICINE

Herbal medicines can be classified into four categories as per WHO, based on their origin, evolution and the forms of current usage.

Category 1: Indigenous herbal medicines

This category of herbal medicines is historically used as local community or region and is very well known through long usage by the local population in terms of its composition, treatment and dosage.

Category 2: Herbal medicines in systems

Medicines in this category have been used for a long time and are documented with their special theories and concepts and accepted by the countries. For example, Ayurveda, Unani and Siddha would fall into this category of TM.

Category 3: Modified herbal medicine

These are herbal medicines as described above in categories 1 and 2, except that they have been modified in some way-either shape, or form including dose, dosage form, mode of administration, herbal medicinal ingredients, methods of preparation and medical indications. They have to meet the national regulatory

requirements of safety and efficacy of herbal medicines.

Category 4: Imported products with an herbal medicine base

This category covers all imported herbal medicines including raw materials and products. Imported herbal medicines must be registered and marketed in the countries of origin. Safety and efficacy data have to be submitted to the national authority of the importing country and need to meet the requirements of safety and efficacy of regulation of herbal medicines in the recipient country.

OBJECTIVES

Regulatory requirements for quality, safety and efficacy of herbal medicines.

WHO Guidelines on safety monitoring of herbal medicines.

INDIAN REGULATIONS OF HERBAL MEDICINE

In India, the AYUSH (Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy) regulatory body oversees various aspects related to the licensing, formulation, manufacturing, and packaging of products under Schedule "T" (Good Manufacturing Practices - GMP). They also monitor the export of Ayurvedic, Siddha, and Unani products. Herbal products fall under the category of proprietary medicines regulated by Ayurveda, Siddha, and Unani systems of medicine.

On the other hand, the Central Drugs Standard Control Organization (CDSCO) governs the regulatory framework for Phyto Pharmaceuticals, as outlined in the 2015 notice published in the Gazette. The provisions of this regulation cover the submission of scientific data concerning the quality of these products.

The process for allowing the sale of an herbal product includes a thorough examination of its safety and efficacy. Phyto Pharmaceuticals are medicines that function similarly to synthetic chemical substances, especially in cases where traditional medicines' mechanisms are unclear or uncertain.

AYUSH Phyto Pharmaceuticals are seen as well-balanced drugs. The strategy behind them emphasizes the importance of continually revalidating the material specifications of plants used. The legal framework governing these activities includes:

The Central Council of Indian Medicine Act, 1973

The Central Council of Homoeopathy Act, 1973

The Drugs and Cosmetics Act, 1940, along with its related rules

The Medicinal and Toiletries Preparation Acts and Rules.

These regulations help to ensure the safe and effective use of herbal and traditional medicines within India.

MINISTRY OF AYUSH

The Ministry of AYUSH was established on November 9, 2014, with the aim of fostering the growth and promotion of the AYUSH healthcare system. Prior to this, it was known as the Department of Indian Medicine and Homeopathy (ISM and H), which was founded in March 1995. Later, it was renamed the Department of Ayurveda, Yoga, and Naturopathy, Unani, Siddha, and Homeopathy (AYUSH), with a focus on advancing education, research and development in these traditional healthcare systems. The Ministry of AYUSH is responsible for overseeing the manufacturing, marketing, and promotion of ASU (Ayurveda, Siddha, and Unani) medicines across India.

Objective of AYUSH

To upgrade the educational standards in the Indian system of medicine and homeopathy colleges in India.

Strengthen existing research institution.

DRUG AND COSMATIC ACT 1940

Herbal drugs are regulated under the Drug and Cosmetic Act (D and C) was passed in 1940 (10April1940) and Rules 1945 in India, where regulatory Unani, Siddha medicine are clearly laid down in Chapter IV-A. There are 18 different section are present from section 33C to 330 Table 1.

These all sections provide all information related to ASU drugs regulations for manufacture, sale, registration, GMP certificate, licensing and penalties.

SCHEDULE T - Good Manufacturing Practice for Ayurvedic, Siddha and Unani medicine

In India, obtaining approval for the manufacture or sale of ASU (Ayurvedic, Siddha, and Unani) drugs requires the manufacturer to acquire a Good Manufacturing Practices (GMP) certificate. As per Rule 157 of the Drugs and Cosmetics Act, to obtain this certificate, the applicant must submit an application on a plain sheet of paper, providing detailed information about the existing infrastructure of the manufacturing unit. This includes details about available instruments, equipment, and the qualifications of the technical staff. Once the licensing authority completes a thorough verification based on the requirements of Schedule T, the certificate will be issued within three months in Form 26-E-I.

To ensure the production of high-quality Ayurvedic, Siddha and Unani medicines, the implementation of Good Manufacturing Practices became mandatory with the revision of Schedule T in 2003 (Government of India, 2005). The key requirements outlined in Schedule T are as follows:

Raw Materials

The raw materials used in manufacturing must be authentic, meet the prescribed quality standards, and be free from contamination.

Manufacturing Process

The manufacturing process must follow the prescribed standards to maintain product quality.

Quality of Finished Products

The drugs released for sale must meet the acceptable quality standards.

To achieve these objectives, the manufacturer must ensure the following:

A well-designed factory with sufficient space.

Proper machinery and equipment.

A quality control laboratory equipped with the necessary instruments and staffed by qualified personnel.

Established methodologies and procedures that adhere to the prescribed manufacturing process.

Regulatory Guidelines for Herbal Medicine

In India, herbal medicines are regulated under the Drugs and Cosmetics Act of 1940 and its amendments. AYUSH periodically updates regulations for ASU (Ayurveda, Siddha, and Unani) drugs. Prior to 2013, there were no specific guidelines for conducting clinical trials, but in March 2013, AYUSH introduced Good Clinical Practice (GCP) guidelines for ASU drugs.

GCP guidelines ensure that clinical trials involving human subjects are designed, conducted, analyzed, and reported in a scientifically and ethically sound manner. The core principle of GCP is that the well-being of the study participants should always take priority over the interests of science or society. These guidelines, based on the CDSCO's 2001 GCP document, must be followed throughout all stages of ASU drug research in India. If not adhered to, clinical trials may be suspended by regulatory authorities.

Additionally, the guidelines outline compensation provisions for participants in the event of adverse effects, including death, during the trial. Since 2017, it has also been mandatory for herbal product labels to include manufacturing and expiry dates.

Globally, there is an increasing demand for Ayurveda and other traditional medicines. In India, approximately 80% of rural populations use herbal medicines. The Indian herbal industry uses around 960 plant species and has an annual turnover exceeding Rs 80 billion. About 3% of India's pharmaceutical exports consist of AYUSH products, with 70% of exports being raw materials and 30% finished herbal products. However, India's share of the global herbal export market remains below 1%, despite the longstanding presence of AYUSH in traditional medicine.

STANDARDS OF HERBAL DRUGS AS PER EXISTING LEGISLATURE OF INDIA:

Standards of medicines are prescribed in the Drugs and Cosmetic Act 1940 and individual monographs has been prescribed in the respective

Pharmacopoeias. Recently the Govt. of India has published 4 volumes of Ayurvedic Pharmacopoeia encompassing standards of 326 drugs, which is grossly inadequate in comparison to the number of herbs used in the Ayurvedic system of medicines. A positive step has been taken in this direction by publishing of the Herbal Pharmacopoeias, having standards of 52 drugs (IDMA 2002).

In India, herbal products and herbal pharmacopoeias lack formal statutory recognition (Govt. of India, 2005). Despite the widespread availability of herbal products, it is challenging to classify them under the Drugs and Cosmetics Act and Rules. Some herbal medicines are marketed as food or nutritional supplements with medicinal claims.

A survey of herbal product status, referencing international pharmacopoeias (WHO, 1998, 2001, 2005), revealed varying regulations worldwide. In countries like China, the UK, Canada, and Germany, herbal products are classified as drugs, while in others, such as the USA and the Netherlands, they are regarded as nutritional supplements, with specific legislation governing them (Marwick, 1995).

In India, there are ambiguities regarding the classification of herbal drugs, and no clear policies exist for food supplements. Although the Indian government introduced the Food Safety Act in 2006 to address this issue, experts believe it has not been effectively implemented. Additionally, in some cases, simply listing a drug in textbooks is deemed sufficient by current regulations, even when these texts lack proper definitions (Govt. of India, 2005).

Standards of Ayurvedic Drugs

Standards required to be complied with in manufacturing for sale or distribution of Ayurvedic, Siddha and Unani Drugs are laid down in Drugs and Cosmetics Rules, which are given in the table below.

To date, only four volumes of the Ayurvedic Pharmacopoeia have been published, covering around 326 herbs. This is insufficient given the vast number of herbs used in Ayurveda (IDMA, 2002). The preparation methods in a list of 57 texts, most of which are outdated except for the Ayurvedic Formulary of India (Part I) and the Ayurvedic Pharmacopoeia of India, are often used as the basis for manufacturing Ayurvedic drugs. However, this provision is open to misuse, as 55 of these texts lack proper legal definitions.

The monographs in the Ayurvedic Pharmacopoeia only address a few basic parameters, which are considered inadequate for effective standardization (Govt. of India, 1990; 1999; 2001; 2004). In contrast, the British Herbal Pharmacopoeia includes detailed chemical characterization methods such as TLC, GC and electrophoresis, which are not required by the Ayurvedic Pharmacopoeia. Additionally, the pharmacological characterization in Ayurveda is minimal compared to other pharmacopoeias.

Currently, no statutory standards exist for combination products, except for Asavas and Aristas, which are only regulated for alcohol content under the Drugs and Cosmetics Act.

Standards of siddha drugs

As per Drugs Act, simply mentioning of manufacturing process in a list of 30 books allows production of Siddha Drugs. Amongst these 30 books, 29 are old texts and Siddha Formulary of India (Part I) is the only book published by the Govt. of India recently.

Standards of Unani Tibbs System of Drugs

As per the Drugs Act were mentioning of manufacturing process in a list of 13 books allows production of Unani & Tibbs drugs. Amongst these 13 books, 12 are old texts and 8 the only modern book is National Formulary of Unani Medicine (Part I) published by Govt.

Standards of Homoeopathic Medicines:

Standard of Homoeopathic medicines has been prescribed in Second schedule of the Drugs and Cosmetics Act, 1940, which is given in Table.

FUTURE PROSPECTS OF HERBAL MEDICINES

With the rapid growth in the use and market for herbal medicines worldwide, both in developing and developed countries, there is increasing concern

about their safety, efficacy, quality, and regulation. Public demand for evidence of the safety and effectiveness of herbal products is rising. Research in herbal medicine, particularly phytochemical and pharmacological studies, is essential to identify active ingredients and support claims regarding their safety and efficacy (34).

To ensure the safety and quality of herbal medicines, their production, sale, and use should be regulated by official laws, similar to allopathic medicines. Proper quality control will ensure that herbal medicines offer therapeutic benefits while minimizing risks. The use of adulterated ingredients or improper formulations must be prevented, as they could lead to harmful or low-quality products.

Strict adherence to Good Manufacturing Practices (GMP) is necessary for herbal product production. If regulated properly, herbal medicines have the potential to become effective alternatives or substitutes for synthetic drugs in the future.

The herbal medicine sector is rapidly expanding and holds significant economic value. Plants can also serve as raw materials for the semi-synthetic production of drugs, such as plant steroids (e.g., diosgenin for oral contraceptives) and antibiotics derived from microorganisms (e.g., Streptomyces for streptomycin, neomycin and tetracycline).

As global demand for herbal medicines continues to rise, countries like India and China, with their rich variety of medicinal plants, will play a crucial role in meeting this demand.

The global demand for herbal medicines is steadily rising and is expected to continue growing in the coming years, driven by the increasing sales of herbal products. As a result, researchers, healthcare professionals and pharmaceutical companies will rely heavily on countries like China, India, and others that are rich in medicinal plants and serve as the main suppliers. Herbs will remain an important source for pharmaceutical ingredients and raw materials for producing semi-synthetic compounds used in industries such as cosmetics, perfumes, and food.

To support the growth of medicinal plants, it is crucial for governments to encourage the use of quality chemical fertilizers. Additionally, immediate efforts must be made to conserve biological diversity and preserve the cultural knowledge related to the use of these resources.

Table No.1: List of ASU drug regulation different section

S.No	Sections	Title
1	33C.	Ayurvedic, Siddha and Unani drugs Technical Advisory Board.
2	33D.	The Ayurvedic, Siddha and Unani drugs Consultative Committee.
3	33E.	Misbranded drugs.
4	33EE.	Adulterated drugs.
5	33EEA.	Spurious drugs.
6	33EEB.	Regulation of manufacture for sale of Ayurvedic, Siddha and Unani drugs.
7	33EEC.	Prohibition of manufacture and sale of certain Ayurvedic, Siddha and Unani drugs.
8	33EED.	Power of Central Government to prohibit manufacture, etc., of Ayurvedic, Siddha and Unani drugs in Public interest.
9	33F.	Government Analysts.
10	33G.	Inspectors
11	33H.	Application of provisions of sections 22, 23, 24 and 25.
12	33-I.	Penalty for manufacture, sale, etc., of Ayurvedic, Siddha and Unani drugs in contravention of this chapter.

13	33J	Penalty for subsequent offences.
14	33K.	Confiscation.
15	33L.	Application of provisions to Government departments.
16	33M.	Cognizance of offences
17	33N.	Power of central Government to make rules.
18	33O.	Power to amend first schedule.

Table No.2: Book of Standards

S.No	Pharmacopoeia	No. of monograph
1	Homoeopathic Pharmacopoeia (8vol)	1000
2	Ayurvedic Pharmacopoeia (3vol)	158
3	Herbal Pharmacopoeia	52

Table No.3: Standards of ayurvedic drugs

S.No	Class of drugs	Standards to be complied with
1	Single drug included in Ayurvedic pharmacopoeia	The standards for identity, purity and strength as given in the editions of ayurvedic pharmacopoeia of India for the time being in force.
2	Asavas and Arista	The upper limit of alcohol as self-generated alcohol should not exceed 12% v/v excepting those that are otherwise notified by the Central Government from time to time

Table No.4: Standards of Homoeopathic Medicines as per Drugs and Cosmetics Act

S.No	Class Drugs	Standard to be complied with
1	Drugs included in the Homoeopathic Pharmacopoeia of India	Standards of identity, purity and strength specified in the edition of the Homoeopathic Pharmacopoeia of India for the time being and such standards as may be prescribed.
2	Drugs not included in the Homoeopathic Pharmacopoeia of India but which are included in the Homoeopathic Pharmacopoeia of the United States of America or the United Kingdom or the German Homoeopathic Pharmacopoeia	Standards of identity, purity and strength specified in the edition of the Homoeopathic Pharmacopoeia of India for the time being and such standards as may be prescribed
3	Drugs not included in the Homoeopathic Pharmacopoeia of India or the Homoeopathic Pharmacopoeia of the United States of America or the United Kingdom or the German Homoeopathic Pharmacopoeia	The formula or list of ingredients displayed in the prescribed manner on the label of the container and such other standards as may be prescribed by the Central Government.

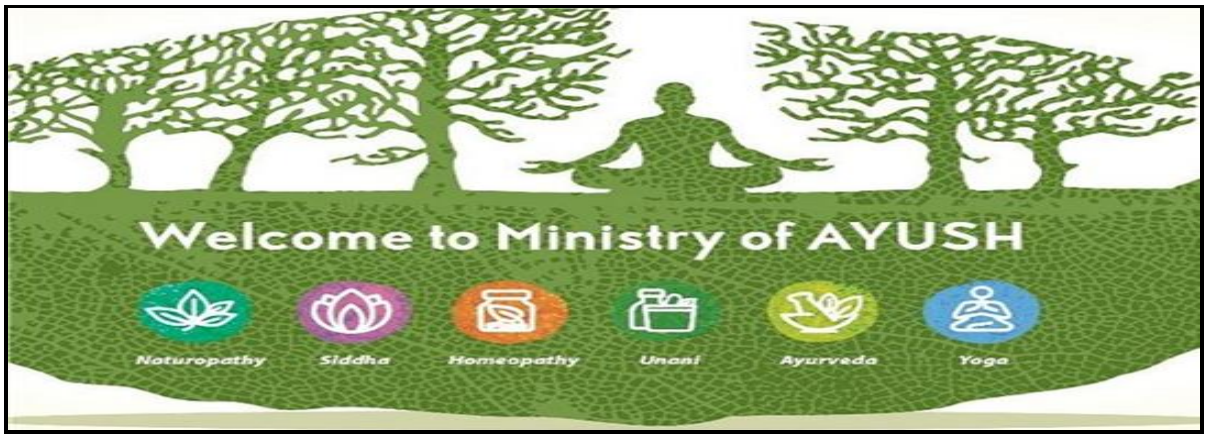

Figure No.1: Ministry of Ayush

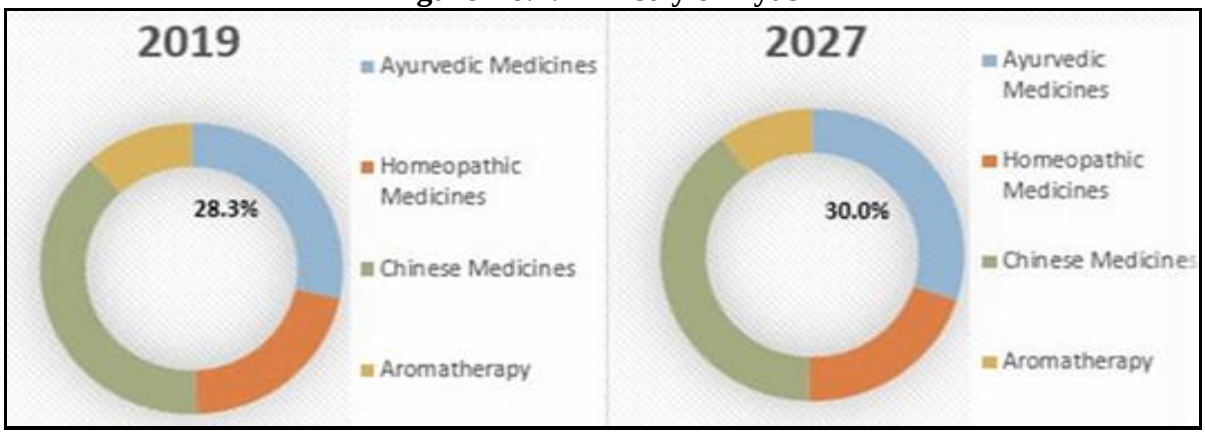

Figure No.2: Global Herbal Medicinal Products Market Share (%), by Product Type, 2019 and 2027

CONCLUSION

This review provides a comprehensive overview of the regulatory requirements for herbal medicines in India. Herbal medicines have been used globally for centuries and have gradually evolved in terms of quality, safety, and efficacy. The regulatory status of herbal medicines varies across countries. In India, herbal medicines are primarily used in Ayurveda, Siddha, Unani, and Homeopathy. The AYUSH department has introduced a certification scheme for AYUSH drug products, and India has developed guidelines for conducting clinical trials on herbal medicines. However, the registration process remains poorly regulated and challenges persist in creating and enforcing national legislation to ensure the quality, safety, efficacy and pharmacovigilance of these products.

To import or manufacture new phytopharmaceutical drugs in India, a license is required. Applicants must complete Form 44 for Import Registration and Marketing Authorization as per the Drugs and Cosmetics Rules. This application, along with R and D data, CMC data, and non-clinical and clinical trial data, should be submitted to the Drugs Controller General (India) at the Central Drugs Standard Control Organization under the Ministry of Health and Family Welfare for assessment.

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CONFLICT OF INTEREST

I declare that I have no conflict of interest.

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