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A Review on Regulatory Requirements for Herbal Medicines in India

Rishabh gupta[1], Prof.(Dr.) Mohd Wasiullah[2], Piyush Yadav[3] Sushil Yadav[*4]

1. *Department of Pharmacy, Prasad Institute of Technology, Jaunpur (222001), U.P, India.*
2. *Principal, Department of Pharmacy, Prasad Institute of Technology, Jaunpur (222001), U.P., India.*
3. *Principal, Department of Pharmacy, Prasad Polytechnic, Jaunpur (222001), U.P., India.*
4. *Associate Professor, Prasad Institute of Technology, Jaunpur (222001), U.P, India.*

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ABSTRACT-

Natural products have been used all across the world since the Vedic period. Though minerals and animal products have long been utilised as natural goods in some nations, herbal medicine is still used for basic health care by around 75-80% of the world population, primarily in developing countries. There are significant variances in the classification and categorization of herbal medications. According to the laws of the respective countries, they are currently classed in several categories such as pharmaceuticals, food, health items, nutritional supplements, cosmetics, and so on. Herbal products are also employed in several medical systems, such as the Allopathic, Homoeopathic, Unani & Siddha, and Ayurvedic systems of medicine in India. Herbal remedies[1] Herbal medicines are gaining popularity worldwide due to their potential benefits in preventing and treating various diseases. India has a rich tradition of using herbal medicines for centuries. The use of herbal medicines is also regulated by the government to ensure their safety, efficacy, and quality. This review aims to provide an overview of the regulatory requirements for herbal medicines in India.The regulatory framework for herbal medicines in India is provided by the Drugs and Cosmetics Act, 1940, and its amendments. The Act defines herbal medicines as drugs that are exclusively derived from plants, their parts, or their extracts, and are used for medicinal purposes. The Act also lays down the guidelines for the manufacturing, labeling, and marketing of herbal medicines.[2]

I. INTRODUCTION-

Herbal medicines have been utilised in India since the Vedic period, as mentioned in the Rigveda. It is referenced in the Charak Samhita. Herbs were initially utilised by people traditionally based on their experience, and gradually a group of professionals known as apothecaries emerged. Herbal remedies have been utilised for a long time in other nations, such as China.[3] Herbal remedies are utilised in the Ayurvedic, Siddha, Unani, and Homoeopathic systems of medicine in India. Ayurvedic medicine has been practised since 6000 B.C., Chinese herbal medicine has been practised since 5000 B.C., and modern medicine has been practised since 1800 A.D.This was popular due to the experience and abundance of plants in India due to its different agro-climatic conditions.[4]

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 for herbal medicines in India is designed to ensure that herbal products meet specific quality, safety, and efficacy standards.[5]

Standards of Drugs as per existing legislature of India

The Drugs and Cosmetics Act of 1940 prescribes medicinal standards, and particular monographs are prescribed in the various Pharmacopoeias. The Government of India recently produced four volumes of Ayurvedic Pharmacopoeia covering criteria for 326 medications, which is drastically inadequate in contrast to the amount of herbs utilised in the Ayurvedic school of medicine. The publication of the Herbal Pharmacopoeias, which contain criteria for 52 medications, was a positive step in this regard (IDMA, 2002). Unfortunately, neither herbal products nor herbal Pharmacopoeias have any legal validity in our country (Govt. of India, 2005). That there are a lot of fours

There are herbal products on the market, albeit categorising these goods according to the Drugs and Cosmetics Act is problematic.[6]

Quality: All drugs must be of standard quality, that is, they should be free from any harmful substances

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and must meet the specifications laid down in the Indian Pharmacopoeia or any other recognized pharmacopoeia.

Safety: All drugs must be safe for human use, and their potential risks and adverse effects should be adequately evaluated.

Efficacy: All drugs must be effective for their intended purpose and must provide the desired therapeutic effect.[7]

Packaging and labeling: All drugs must be properly packaged and labeled, including information on the drug's name, strength, dosage form, manufacturer's name, batch number, expiry date, and any necessary warnings or precautions.

Adulteration: All drugs must be free from any form of adulteration, such as the addition of any harmful substances, or contamination.[8]

Misbranding: All drugs must be labeled accurately, and any claims made about the drug's therapeutic effect must be supported by scientific evidence.

Standardization: All drugs must be manufactured according to standardized procedures, ensuring consistency in their quality, safety, and efficacy.[9] Compliance with these standards is essential to ensure the safety and efficacy of drugs in India. The regulatory authorities, such as the Central Drugs Standard Control Organization (CDSCO), are responsible for enforcing these standards and taking appropriate action against any non-compliant drugs or manufacturers.

Regulatory Aspects of Herbal Medicines in India-

The Drug and Cosmetic Act (D and C) 1940 and Rules 1945 govern herbal medicines, and the Department of AYUSH is the regulatory authority. A manufacturing licence is required to make or market herbal medicines. The D and C Act's Schedule T (Chapter IV-A) mandates Good Manufacturing Practise (GMP) for herbal medicine makers. The Ministry of AYUSH (9th November 2014) concentrated on the development of the AYUSH health care system, which was formerly known as the Department of Indian system of medicine and homoeopathy (March1995) and was renamed the Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha, and Homoeopathy. Sections 33C to 33O contain information on manufacturing, registration, sale, licence, GMP certificate, and fines.[10]

Approval process of herbal drugs-

A manufacturing premises should consist of a manufacturing area, office, workers room, raw material store, finished products store, quarantine room, packaging material store, bottle washing and drying room, packaging and labelling room and QC laboratory

Documents required for the approval of premises:

Forwarding letter

Application form filled and signed by the authorize d person

The firm details filled and signed by the authorized person

Original challan for license and fee as per the requi rement

- 1 copy of the premises plan – original
- Possession of the premises
- Constitution of the firm
- 4 copies – list of products
- 3 copies – draft table of each product
- 1 copy – List of machines, equipment's and laboratory equipment's
- 4 copies – Technical persons (with details)
- Raw materials and analysis methods details
- Consent letter of public testing laboratories
- Standard Operating Procedure (SOP) list
- Master Formula Record (MFR) of all products
- Product ingredient reference book (Xerox copy)

Global Herbal Regulation:

1-United States of America:

In the United States, herbal goods are classified as dietary supplements, foods, or drugs, and the "Dietary Supplement Health and Education Act" of 1994 governs herbal medicines, but the FDA does not conduct evaluations.[11]

2-United Kingdom:

In the United Kingdom, licencing requirements are outlined in Section 12 of the Medicine Act, which is overseen by the Medicine Control Agency (MCA). Traditional herb registration (THR) (Directorate 2004/24/EC) or market authorization (Directorate 2001/83/EC) aids in the registration of products in the UK, and companies registering under this scheme must provide quality data in accordance with GMP, safety, and efficacy based on long traditional use of over 30 years in the UK and 15 years in the EU.

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The THR certificate mark shall be present on the product label, together with the line "exclusively based on long term use."

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

The ASEAN laws were created in Bangkok on August 8, 1967, by the five member countries of Indonesia, Malaysia, the Philippines, Singapore, and Thailand, and were later expanded to include Brunei, Darussalam, Vietnam, Laos, and Myanmar, as well as Cambodia, which is governed by the Health Science Authority (HAS). Indigenous herbal medicine, herbal medicines in system, modified herbal medicines, and imported products with herbal medicine base are the different types of herbal medications.

4-Kingdom of Saudi Arabia:

The herbal medication legislation was established in 1996, with a distinct statute for herbal medicines. Manufacturing requirements are the same as for conventional medications and WHO GMP. Supporting data for traditional products includes pharmacopoeial and non-pharmacopoeial evidence.[12]

5-Kingdom of Saudi Arabia:

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6-The European Union:

The European Directive 2004/24/EC was implemented, and the phrase "traditional herbal medicine product" (THMP) was coined. Traditional medications must have bibliographic proof and preclinical safety data before they may be marketed. When the EU member states were inquired about the regulatory status of herbal medicines, it was discovered that the majority of countries do not have herbal medication rules.

7-Canada:

Herbal medications were classified as folk medicine in 1986. The herbal system is evaluated in accordance with WHO norms. It is the licence holder's responsibility to monitor adverse responses caused by their products and to report major adverse reactions to Health Canada. The Natural Health Product department of the Health Product and Food Branch (1999), overseen by the Ministry of Health (MOH), regulated herbal remedies and traditional medicines beginning in 2004. Prior authorisation is required to advertise herbal products in Canada, and it adheres to the standards set by the US Pharmacopoeia, the British Herbal Pharmacopoeia, the European Cooperation on Phytotherapy (ESCOP), and the World Health Organisation.[14]

8-Australia:

Herbal medicines are regulated by the Therapeutic Goods Administration (TGA), and the product must be registered with the Australian Registrar of Therapeutic Goods (ARTG). The registered medicines are deemed to be high danger, while the listed medicines are low risk. The registration application may be refused, conditionally accepted, or accepted. The registration is completed in CTD format.

9-Russia:

The National Policy was announced in 1991, and the laws and regulations were framed in 1993, the same as prescription medications, OTC medicines, or dietary supplements, and the GMP rules are the same as those used for conventional pharmaceuticals.[15]

10-South African Republic:-

Herbal medicines are controlled under the Medicine and Related Substances Act of 1965, and they are classified as supplementary medicines. Registration applications must be submitted through the South African CTD, and the approval process is time-consuming.[16]

11-Nigeria:

The National Agency for Food and Drug Administration and Control (NAFDAC) oversees herbal medicine regulation as well as registration and licencing.[17]

12-China:

Traditional Chinese Medicines have been practised for over 4000 years, with record in the Chinese Materia Medica. In China, there are special marketing requirements, such as a proper quality dossier and evaluation of safety and efficacy[18]

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13-Challenges with herbal drug regulations:

Quality control and other standardisation tests are required prior to the release of any drug onto the market to ensure its quality and safety. However, it has been discovered that many national drug regulatory authorities lack proper knowledge of herbal rules. To address these issues, the WHO has established standards for herbal medicines that will be relevant to regulatory organisations.[19]

II. CONCLUSION

Herbal medicines have a bright future because there are so many plants in the globe, and modern medicines are also made indirectly from medicinal plants. According to studies on herbal medicine regulation, there is a quality issue due to a lack of effective regulatory rules for herbal medications. The AYUSH department oversees Indian herbal drug regulations, which include issues in standardisation due to polyherbal nature, a lack of post-harvest facilities, raw material testing laboratories, and product traceability. Herbal rules exist globally, although not in a structured fashion. It was discovered that there is a lack of harmonisation in the regulatory standards for herbal products.

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