European Economic Letters
ISSN 2323-5233
Vol 15, Issue 1 (2025)
http://eelet.org.uk

# Combating Barriers in Herbal Medicine Regulation: A Study of India, United States, And European Union

**Dr. Rajesh Kumar,**
Assistant Professor, School of Law, UPES, Dehradun, India , rohitgandhir@gmail.com, 0000-0002-4338-5639

*Abstract*— India is a major source of herbal plants and medicines. The majority of the ] population prefers using plants and herbs since they have fewer adverse effects than other types of medication. According to an a survey conducted by the World Health Organization (WHO), around 80 percent of the universe depends on herbal medicine as their main source of healthcare[1]. Complementary or conventional medicine is making a resurgence, even in developed nations. In healthcare industry, including Ayurveda, Homeopathy, Siddha, Unani, and other local systems of medicine, herbal remedies are frequently utilized to cure human illnesses. Approximately half of the world's countries, including Japan, China and Germany, have their own policy and legislation on controls of traditional medicine, as per a report on a worldwide evaluation of different rules regarding traditional medicine and the regulation of herbal medicines. On the other side, reckless utilization of resources and implementation of new tools and technology threatens the sustainability of several plant species. The authors of this article investigate the limitations and difficulties associated with using herbal remedies. Second, a review of the US and EU laws and policies pertaining to the control of herbal medicines. Finally, problems with the current Indian framework and the necessity for new regulations are discussed.

***Keywords****: herbal drugs; regulatory guidelines; regulations; practices; quality; safety, legal framework*

## I. INTRODUCTION

Plants have traditionally been used to treat and counter a number of diseases. The utilization of herbal medicines (HMs) has been popularized over the passage of time and now it has claimed itself as a scientific revolution. In both emerging and developed nations, people of all genders, social groups, and races use herbal medicine. HM encompasses “herbs, herbal materials, herbal preparations, active compounds derived from plant parts, other plant materials, or mixtures and purely herbal products” that are specifically build to boost the immunity and serve as a treatment of diseases and contain. According to estimates, 80% of people worldwide utilise herbal remedies (HMs) as part of their basic treatment[2]. The growing global use of HMs is leading to increased recognition of public health concerns regarding their safety. As the level of consumption increases, safety issues become increasingly crucial. The low quality of the raw ingredients or the finished goods is the cause of many unfavorable effects of herbal medicine. Problems with various herbal medicine types vary. Additionally, using herbal products raises serious safety risks and toxicological issues. The relevant regulatory agencies must take necessary measures to safeguard public health by ensuring the safety and quality of all herbal medicines in use. Public health and safety are crucial considerations in the consumption of herbal treatments. The purpose of this article is to overview the existing scenario of herbal medicines regulation across India, the US and the EU. It also highlights the different challenges and constraints to rectifying herbal medicine.

.

## II. BACKGROUND OF THE STUDY

### *A. Concept of HMs*

The “World Health Organization” states [3], conventional medicine which includes herbal drugs is the amalgum of therapeutic experience that has continued to exist across generations of practising physicians within indigenous systems of medicine. As per the records, it is believed that the conventional medicines are being consumed for around centuries prior to the procurement of modern medicine. Traditional remedies consist of medicinal plants, minerals, organic matter, and other substances as the ingredients. The only kind of alternative medicine that can be properly classified as “herbal drugs” are those that principally rely on the therapeutic effects of medicinal plant preparations. Manuscripts from Syria, Egypt, Greece, Rome, and India date their use back around five thousand years. Several ancient Indian texts, including the Rigveda, Atharvaveda, Charak Samhita, and Sushruta Samhita, provided detailed accounts of the therapeutic uses of plants. Therefore, traditional medicines and herbal remedies have been derived from the wisdom and experience of ancient cultures.

Herbal Medicine: Conventional medicine entails wellness methods and techniques based on conventional wisdom and concepts including herbs as medicines, psychological remedies, and physiotherapy; administered alone or in conjunction to cure, diagnosis, avoid, or manage sickness and basic well-being. A term used to describe non-traditional approaches to health care in developed countries is "complementary and alternative medicine"[4]. Traditional remedies or phytotherapy, on the other hand, is the utilization of herbs for therapy and medical purposes to cure illnesses and enhance public health. According to the World Health Organization (WHO), herbal medicines are medical products that are labeled and contain an active ingredient, plant material from above or below ground, additional organic material, or a combination of these components[5]. Herbal medicine is the art or practice of maintaining health and preventing, treating, or curing disease through the use of herbs and herbal remedies[6]. It is far more likely that plants utilized as nourishment or as raw materials in traditional system of medicine will contain pharmaceutically active chemicals. The study and use of plants for their therapeutic properties in the prevention, diagnosis, and treatment of illness is known as herbal medicine[7]. The "conventional" methods of identifying and preparing herbs must be supplemented with much more exact and replicable processes to guarantee the effectiveness, security, and stability of the result, given the increasing demand of herbal medicine. Considering the economic interest, biological effects, and growing consumer demands, especially among the sick and old, natural medicines and medications require regulations[8].

Furthermore, the pharmaceutical actions of vegetation are due to the existence of mediators, which are natural molecules classed as either principal or intermediate. Human's development and expansion are facilitated by signaling molecules including glycogen, carbohydrate, carbohydrate, proteins, lipid, and nucleotides. To defend themselves from microbial pathogens or insect invasions, plants create bioactive substances such as opioids, quercetin, polyphenols, terpenes, corticosteroids, polysaccharides, tannin, volatile oils, etc. The pharmacological activity of plants is attributable to these naturally occurring substances, often known as phytochemicals which are important bioactive substances and are used as medications due to their therapeutic properties. The usage of these substances has decreased the likelihood of numerous illnesses, such as cardiovascular problems, nephrotoxicity illnesses, diabetes, malignancies, and neurological diseases. In contrast, plants possess pharmacological properties such as antioxidants, viral, antibacterial, and antifungal medication properties for humans use. Specifically, alkaloids possess anti - spasmodic, neuropsychiatric, painkiller, and diuretics properties; phytoconstituents are renowned for strong antiviral, antibacterial, and antifungal properties. Herbal Treatments: Current Tendencies and Long-Term prospects anthelmintic, bactericidal, antitumor, malaria, and anti-inflammatory characteristics; derivatives with antifungal and antimicrobial capabilities; phenolic compounds and polyphenols with antioxidants, anti - allergic, and antibacterial qualities; saponins with anti - inflammatory and immunizations[9].

### *B. Historical Background*

As early as 3000 BC, people began using plants and herbs for medicinal purposes. In the Old Chinese and Egyptian papyrus writings it has been found about various medicinal uses of herbs or plants. Traditional medicinal systems (including Siddha, Ayurveda, Unani, and TCM) that make use of herbal treatments have their roots in the long-established practice of employing plants in healing rituals among indigenous peoples of Africa and the Americas. Though a lot of allopathy medicines have developed either directly or indirectly from nature but the basic medicinal practices started from home or herbal medicines itself. Even now also, many a times at very many houses herbal cures are prevalent before the getting the doctor prescribed treatment.

The usage of herbal medicine in treating the diseases in not a new phenomenon. [10]. As a part of their heritage, folk medicine practices all around the world often include herbs. Here we will take a quick look at a handful of these traditions that use plants for medicinal purposes; these are only a few examples of the many important therapeutic practices that exist across the globe.

- Chinese herbal medicine

The ancient Chinese population employed traditional Chinese medicine. The majority of medicines come from plant sources, but animal and mineral parts have also been employed. Approximately 12,000 items used by traditional healers are currently in widespread use[11]. Botanical products can only be used after they have been processed in some way.

- Japanese traditional medicine

Traditional Japanese medicine incorporated a multitude of Chinese herbal remedies. The compilation of the earliest pharmacopoeia of Japanese traditional medicine took place in the ninth century. This pharmacopoeia categorized the herbs that are native to Japan[12].

- Conventional Indian medicine

Ayurveda is a medical system that has been around for approximately 5,000 years, but is predominantly practised in India. This method takes a more all-encompassing view of health, treating the whole person (physically, mentally, and spiritually). Diet and natural medicine are important parts of it[13].

The utilization of herbal medicines in developed and developing countries has enlarged significantly in the second half of the 20th century. One example of a source is the European Scientific Cooperative on Phytotherapy [14], German Commission[15] and the World Health Organization[16], that provide the monographs on chosen herbs with medicinal characterstics. The World Health Organization monographs, for instance, characterize the herb on its own by a variety of factors (such as euphemisms and colloquial names) as well as the herb aspect frequently utilized, its demographic distribution, experiments utilized to characterize the herb (such as both macroscopic and microscopic evaluation and pureness testing), the bioactive components (when widely recognized), oral dosage and dosage form, therapeutic properties, pharmaceutics, potential complications, and negative effects. In addition to the Nature Medicine Comprehensive Database[17] and NAPRALERT (NATURAL PRODCUTS ALERT), there are more sources that can provide descriptive information regarding herbal products currently in use (2001). Bhat has released info relevant additional accessible datasets (1995).

## III. CHALLENGES AND CONSTRAINTS IN HERBAL MEDICINE

The foremost constraint of herbal medicines is regard to the handling of herbal or medicinal plants. They are some others as follows[18]-

- Insufficient understanding of herbal remedies among national drug regulators: The dearth of knowledge among national drug officials on herbal medicines, coupled with the absence of efficient evaluation methodologies, contributes to the delay in formulating national policies, rules, and regulations for traditional medicines, contemporary/alternative medicines, and herbal medicines[19].
- Problems with Standardization: Herbal medicines must meet strict requirements for uniformity of composition and biological activity to be used safely and effectively[20]. Nevertheless, herbal medications often fall short of meeting this criterion, mostly due to a range of issues including
    - Limitations in plant identification
    - Differences in genes,
    - Climate change and other alterations,
    - Variation in how extracts are harvested and refined, and
    - A dearth of knowledge concerning key pharmacologic ingredients
- Perils in terms of security: An important observation has been made regarding the problems associated with the use of traditional and herbal medicines. These problems primarily arise from the classification of many of these products as foods or dietary supplements in certain countries. This classification overlooks the crucial aspect of safety in the production of herbal medicines and products for healthcare, which is a vital aspect of quality control. Therefore, these herbal remedies can be sold without undergoing thorough testing to guarantee their quality, effectiveness, and safety[21]. Similarly, traditional health practitioners sometimes lack formal training or licensing, and there is typically less stringent monitoring of quality checks and production standards. Subsequently, both national health authorities and the general public have exhibited growing apprehension regarding the safety of conventional and herbal remedies.
- Quality challenges: For a herbal remedy to be deemed effective, it is necessary to implement quality assurance measures to ensure that the product consistently delivers the intended outcomes. Despite the absence of proof on efficacy, quality assurance is crucial due to the significant issue of plant adulteration. Botanical substances, toxic metals, bacteria, microbiological poisons, insect-killing chemicals, and compounds used for fumigation are frequently found as adulterants. Therefore, quality plays a vital role in deciding safety[22].

- Experiencing Issues in Clinical Trials: One significant challenge in carrying out clinical research involving herbal drugs is their intricate character. In order to address this issue and gain public trust, researchers, manufacturers, and regulatory agencies must employ rigorous scientific methodologies and conduct clinical trials to ensure the quality and consistency of traditional herbal products across different batches. This will help integrate these products into the mainstream of today's healthcare system[23]. Herbal products primarily depend on rigorous quality control measures for both raw ingredients and production processes. This is necessary to guarantee consistent product quality across different batches. Since the final products lack well-defined identities and entail minimal purification steps throughout development, quality control becomes even more crucial. Contemporary technologies can be employed to regulate the quality and consistency of diverse herbal items. A meticulously designed clinical trial is the most dependable method to ascertain the reliability of a therapy solution.
- The difficulties of pharmacovigilance: The most widespread misconception is that herbal remedies do not require a doctor's supervision and can be used freely by the patient[24]. As a result of this misconception, many people all over the world attempt to treat their conditions on their own, despite the fact that doing so can have negative consequences. Herbal medicine pharmacovigilance requires widespread public education and understanding. Herbal pharmacovigilance faces additional obstacles due to the wide variety of herbal medicines available, such as determining the most suitable herb naming system (botanical, common, pharmaceutical, or herbal drug name) and validating the botanical identification of the herbal constituents.

### A. *Lacking of laws and regulation in India:*

The survey report highlights that the lack of regulatory requirements for several components of the production process of herbal medicines is a significant factor contributing to the inadequate quality and efficacy of herbal medicinal goods. A majority of over 60% of the survey participants indicated the need for the development or expansion of guidelines on the quality control of herbal medicines. While recommendations exist for preclinical safety assessment of ASU and other traditional medicines, additional guidelines should be established for the standardization of herbal preparations and the identification of active components using markers. In addition to quality control, Good Agricultural and Collection methods (GACP) and proper storage methods are crucial in the manufacturing of herbal drugs. In 2009, the National Medicinal Plants Board formulated rules specifically for India for good agriculture practices and excellent field collection techniques, in accordance with the GACP standards established by the World Health Organization. Nevertheless, our interviews uncovered a lack of awareness among the majority of producers and raw material merchants regarding these rules. Moreover, some associations or companies, cognizant of these requirements, deem them unfeasible due to insufficient education and awareness among farmers, as well as the resulting operational expenses. Our study of the interview indicated that the development of high-quality medications requires a source of standardized and approved raw materials and extracts that meet the norms of the Ayurvedic pharmacopoeia of India. A proposal was made to establish government-certified raw-material supply centers in each state, which would assist firms in obtaining genuine raw materials. The respondents also proposed more comprehensive regulatory standards for the standardization of raw materials and the control of quality throughout production[25]. There should be proper regulatory authorities to look after the same and quality check control should be mandated as the herbal drugs are consumed by many who still trust on traditional methods of cure.

## IV. ECONOMIC IMPORTANCE OF HERBAL MEDICINE

### A. Herbal Medicine Market

During the predicted timeline, the global herbal remedies industry is expected to grow at a compound annual growth rate (CAGR) of 11.16 percent, reaching $347.50 billion in 2029 from $165.66 billion in 2022[26]. The worldwide COVID-19 outbreak has already been unexpected and astonishing, with interest for herbal medicines exceeding expectations in all countries relative to which was before pandemic. According to the estimates, the worldwide economy expanded by “8.46% in 2020 compared to 2019[27].” Due to the increasing popularity of herbal medicines among the general population, pharmaceutical giants are showing a growing interest in the herbal medicine market. They are doing this by forming strategic collaborations with local producers. The market value of the Ayurveda industry in India is projected to increase from 335 billion rupees to 1,042.07 billion rupees by 2025[28] as shown in Figure 1. Herbal medicines have been used for many decades without any known negative effects. As a result, there is an increasing awareness of the benefits of these

medicines in the global market. Consequently, more people are choosing to use herbal medicines for common health problems such as fever, cough, cold, headache, minor burns, digestive issues, and similar concerns.

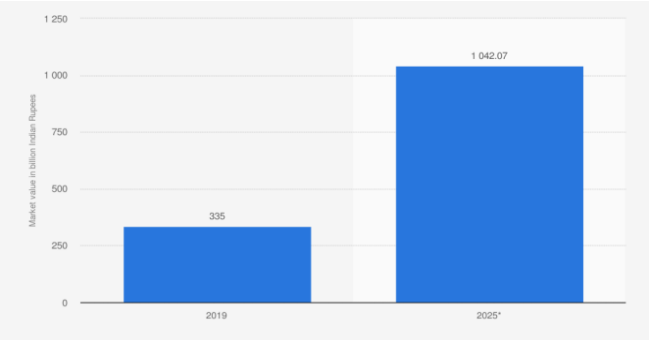


Fig. 1 Estimated 2019 and 2025 Ayurveda industry market value in India[28](in billion Indian Rupees)

B. The Positive aspects of Medicinal Herbs

Medicinal plants that are used for the treatment or prevention of illness are known as herbal medicines (HM). These medicines include herbs, herbal materials, herbal preparations, and completed herbal products[29]. In many rural Asian and African communities today, HM is still an essential part of the basic healthcare system. In addition, it is an integral part of the cultural heritage of many different cultures around the world. The traditional use and purported therapeutic benefits of many plants and herbal remedies date back many centuries. According to research, the complex chemical components of HMs are what give them their pharmacological effects. These actions have the potential to improve health or harm it [9]. HMs have been used for both the aggressive treatment of moderate to severe diseases and the prevention of disease[30], [31]. The current state of HM production and use is highly variable, impacting the functional effects. There are a lot of variables that might affect the dose form of herbal medications, including the patient's health, the way the substance is administered, cultural norms, and even philosophical perspectives. In traditional medicine and at home, people often use either fresh or dried plants to make herbal medicines (HMs). Infusions, decoctions, poultices, and powders made from these plants are frequently used to treat open wounds, and they are also a staple in many regional sweets and drinks. Many convenient versions of conventional commercial HMs drugs are usually available, including pills, capsules, tablets, powders/granules, lotions, ointments, and more. A more enticing, visually appealing, and accurately dosed pharmaceutical dosage form using HMs (herbal medicines) is thought to increase compliance. Prior to the use and promotion of HMs, what matters most are their safety and effectiveness. Considerations including impurities, inherent chemical components, industrial processing, and the efficacy and safety of the herbal material are the most important in determining the quality of herbal goods. Herbal substances contain chemical compounds that have shown great promise in treating a wide variety of diseases. These include both infectious diseases like HIV/AIDS, cancer, sickle cell disease, malaria, and others, and noninfectious diseases like diabetes, obesity, and infertility. Despite HMs' widespread acceptance and many benefits, they nonetheless need stringent regulation to guarantee that everyone, including healthcare providers, has access to reliable information about HM identification, quality, safety, and efficacy.

## V. QUALITY CONTROL AND GUIDELINES FOR HERBAL MEDICINE

A. Quality control

Reliability in formulation and microbial properties are prerequisites for the secure and efficient application of medicinal medicines. Quality is the foremost factor in determining the efficacy and safety of natural remedies; nevertheless, botanical arrangements rarely encounter quality requirements, which allude to methodologies and indicators for evaluating and confirming the potency of herbal natural resources or derivatives or compositions thereof[32]. In broad sense, one or two indicators or pharmaceutically active constituents in herbal ingredients and/or medicinal herbs combinations are used for evaluating the purity and reliability of herbal remedies, identifying the mono herb or herbal remedies procedures, and determining the quantification ayurvedic proportion of a natural product. Several ingredients are primarily accountable for a botanical product's medicinal effects; hence, this type of analysis does not provide a comprehensive overview of the

product. These numerous components may function “symbiotically” and are difficult to divide into individual active ingredients. Of addition, the pharmacological contents in the component herbs of herbal medicine products may differ based on harvesting season, botanical origins, dehydration procedures, and other variables. To guarantee the accuracy and consistency of clinical and pharmaceutical data analysis, to comprehend their therapeutic potential and possible adverse effects of chemical ingredients, and to improving service quality assurance, it shows that it is important to identify the majority of the phytochemical components of herbal products[33]. Sensory evaluation is a technique for ensuring the effectiveness of herbal supplements (macroscopic and microscopic examinations). Medicinal substances' macroscopic identification is determined by comparing form, size, coloration, structure, surface characteristics, odour, taste, and other sensory attributes to a primary source materials. Technique entails roughly similar microscopic evaluation of breakages in addition to dry powder, primitive, botanical materials[34] and explanatory verification utilising improvisatory methodologies including such “thin layer chromatography, HPLC, GCnMS, LCnMS, near-infrared (NIR), and spectrophotometer, etc[35]. Nevertheless, in any traditional remedies and its essence, there really are thousands of unidentified and reduced constituents. Additionally, there is typically variation among the same botanical ingredients. Therefore, obtaining accurate chromatography fingerprints that reflect pharmaceutically active and biologically distinct constituents is neither simple nor trivial. The complicated active ingredients of herbal remedies preparations can be divided into a large number of comparatively simple sub-fractions, owing to chromatography’s highly effective separating capacity. Moreover, the current advances of surnames capillary electrophoresis and mass spectroscopy, including such “elevated fluid chromatographyndiode array detection (HPLCn DAD), gas chromatographynmass spectrometry (GCnMS), capillary electrophoresis-diode array detection (CE-DAD), HPLCnMS, and HPLCn NMR,” could provide the supplemental spectral features, that will be extremely useful for the qualitative data analysis and even for the w hen hyphenated electrophoresis is coupled with metabolomic techniques, chromatography fingerprints can be visualised in a clear manner. Without a doubt, a chemical fingerprint generated by hyphenated chromatographic will emerge as the key quality control instrument for herbal medications. Nevertheless, the use of biochemical fingerprint for product testing of herbal medications is limited to tackling the issue of evaluating the comprehensive uniformity and/or variation and monitoring the permanence of the existing herbal goods. The intricate connection between chromatographic fingerprinting and the effectiveness of herbal remedies (QRFE) is currently not taken into consideration, despite the fact that it appears to represent the most significant part of herbal remedies quality assurance. In reality, the quality assurance of herbal remedies is a multidisciplinary topic of study. To establish a framework for the quality assurance of traditional herbal therapies and to develop innovative treatments comprised of numerous organic chemicals, biochemistry, physiology, healthcare, and even analytics must be integrated[36].

### B. WHO guidelines

In 1992, the “WHO Regional Office for the Western Pacific” convened a panel of specialists to produce stringent and basic concepts for assessing herbal remedies (WHO, 1993). This organisation acknowledged the significance of herbal remedies to the wellbeing of several individuals around the globe, noting, “Some herbal medications have undergone scientific experiments, whereas others are utilised for pragmatic reasons to maintain, recover, or promote outcomes.” There is still a need for science investigation on most herbal remedies, yet the knowledge gained through centuries of conventional use shouldn't be disregarded. Since there is insufficient information generated by conventional scientific methods to give information of safety and effectiveness regarding most herbal supplements currently still being used, the reasonable utilisation and further advancement of herbal supplements and that is supported by, further achieved through a number of scientific papers of these product lines, as well as the advancement of requirements for such experiments. The purpose of the guidelines was to aid national federal regulators, research organizations, and producers in evaluating documentary evidence, filings, and intelligence reports pertaining to such product offerings by defining the fundamental criteria for determining the performance, protection, and effectiveness of herbal medicines. It was suggested that such evaluations include factors such as protracted use throughout the nation (at least several decades), any explanation in healthcare or pharmacological publications or related material, supporting documents of understanding concerning the application of a herbal remedies, and advertising permissions for similar items. Examination of the toxicological effects of compounds that occur naturally may disclose completely undiscovered concerns, even though continuous and presumably harmless use of a material is usually evidence of its health. In addition, it was suggested that regulatory agencies have the jurisdiction to urge to additional information on toxic effects by revoking or trying to limit the permits of authorised products possessing highly suspicious substances, or by categorising the compounds to restrict their use to valid prescription only. The recommendations emphasised the necessity for an evaluation of effectiveness that encompasses the pharmacological and

physiological consequences of the bioactive components, as well as labeling that encompasses a numerical list of the active ingredients, dosage, and contraindications[37]

## VI. Current Regulations And Standards For Regularizing Herbal Medicine

Medicinal herbs are crucial to the creation of novel pharmaceuticals. In accordance with the WHO, around 25 percent of current medications are developed from traditional medicinal plants. Numerous others are synthesized analogues based on plant-isolated model molecules. N ow the World Health Organization recognises herbal remedies as a necessary element of primary medical care[38]. Modern medicine has been revolutionised by the application of plant-based medicines. Vinblastine derived from "Catharanthus rosesus" is similarly effective in the treatment of "Hodgkins, choriocarcinoma, non-Hodgkins lymphomas, leukaemia in children, testicular, and neck cancer[39]" . Phophyllotoxin, which is extracted from Phodophyllum emodi, is effective against testicles, lung, and lymphoid cancers. Taxol extracted from Taxus brevifolius is utilized to cure lung and prostate cancer with metastases. In addition, in 1953, a chemical termed serpentine was discovered from the rhizome of Rauwolfia serpentina, which was a strategy is important for controlling blood pressure and lowering blood pressure[40]. During 1950-1970, the US pharmaceutical companies developed around 100 novel medications derived from plants, notably "deserpidine, reseinnamine, reserpine, vinblastine, and vincristine". From 1971 to 1990, novel pharmaceuticals identified from botanicals included "ectoposide, eguggulsterone, teniposide, nabilone, plaunotol, Z-guggulsterone, lectinan, artemisinin, and ginkgolides[41]." In addition, other scientists have discovered a number of additional chemical substances produced from natural sources in past few decades, including "quinine, digoxin, aspirin, ephedrine, atropine, and colchicine[42]".

### A. India

In India, Herbal medicines are regulated by the Drug and Cosmetic Act (D and C) 1940 and Rules 1945[43], in which provisions for regulation of Ayurveda, Unani, and Siddha medicine are specified. In addition, it regulates the integrity, composition, licencing, production, manufacturing, labelling, packaging, and exportation of herbal medicines. The Department of AYUSH regulates herbal medicines and stipulates that every production or advertising of medicinal herbs must occur only after acceptance of the permit application to produce the designated herbal medicine. In Category "T" of the D and C Act, current good manufacturing criteria for the preparation of herbal medicines are specified.

The Government of India acknowledged the "Traditional Indian System of Medicine (ISM) in 1959[44], and the Drug and Cosmetic Act"[43] was amended accordingly. The first ever EWG was established in 1962. Act 13 of 1964 established a distinct chapter for Ayurvedic, Siddha, and Unani medicines. In 1983, 1987, 1994, and 2002, the statute was changed further. In 2006 and 2008, D and C Rules 1945 released recommendations for the assessment and evaluation of pharmaceuticals subject to ISM. It saw the establishment of the "Central Council of Indian Medicine (CCIM)", which formulated and executed several laws as well as curriculum and courses for ISM (i.e., Ayurveda, Siddha, and Unani). In 2012, the Sowa Rigpa system of medicine was included into the CCIM. In 1995, the Department of Indian Medicine and Homeopathy (ISM & H) was established in order to develop the ISM. In 2003 and 2014, the Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy (AYUSH) was designated as a distinct ministry (Ministry of Ayush, n.d.). In 2009, the Department of AYUSH, in conjunction with QCI, implemented a certification process for AYUSH pharmaceuticals. Concerns have been raised over years concerning the quality, usefulness, and security of AYUSH products. In responding to these concerns, a new method for independent licensing of AYUSH products has been established in partnership with QCI.

The accreditation process of the Department of AYUSH comprises two tiers. The initial certification is AYUSH Standard Mark, which adheres to existing legal criteria. The supplementary certification is AYUSH Premium Mark, which comprises the following possibilities:

Option A, according to the WHO Guidelines provided in the Accreditation Criteria publication, the GMP parameters and concentrations of pollutants must be met.

Option B is more stringent than option A in that it needs to conform to the regulatory frameworks of any importation. The Department of AYUSH in India prioritizes instruction, administration, innovation, the expansion of ISM, and general management. This includes many independent agencies and a small number of subsidiary offices, such as institutional arrangements, scientific councils, universities, profession councils, pharmacopoeia institutes, and institutions. In 2002, the "National Policy on Indian Systems of Medicine and Homoeopathy" was enacted[45]. The primary goal of this strategy is to utilize AYUSH in delivering exceptional condition and to encourage healthcare to the public through the provision of

safe and efficient solutions and pharmaceuticals that adhere to the Pharmacopoeial standards, which are consistent with the excellence of AYUSH goods.

B. European Union

Two different sorts of Community exist when it comes to monographs: conventional use and quite well usage (marketing permission) (simplified registration). The well-established usage component pertains to safety and effectiveness evidence, whereas the conventional use component is predicated on adequate security data and potential effectiveness. On the foundation of safety and effectiveness evidence of natural compounds, HMPC developed a comprehensive herbal monograph, a prerequisite for well-established use, marketing permission, traditional use, and certification of herbal remedies. HMPC will record all scientific analyses done on the existing long-term usage and expertise of herbal supplements as well as non-clinical and therapeutic information in the society. The vast majority of marketing authorisation for herbal medicinal goods is granted independently by European Union member states, although under directive 2004/24/EC, information regarding herbal supplements and their authorization is standardised across the European Union. The "Traditional Herbal Directive 2004/24/EC" was issued by the "European Parliament and Council on March 31, 2004". It simplifies the legislative procedure for herbal therapeutic goods.

C. United States

Herbs are classed as nutritional supplements in the United States by the "Dietary Supplement Health and Education Act (DSHEA) of 1994[46]." Unlike medications, nutritional supplements are developed, promoted, and distributed without a safety and effectiveness assessment, which is the opposite of the pharmaceutical companies. According to FDA guidelines[47], if authorities determine that a nutritional supplement is unsafe for human use, it can be taken off the market. Until a producer releases a nutritional supplement on the marketplace, the FDA should receive proof of its safety and effectiveness[48]. There are 2 types of herbal drug products: those available over-the-counter (OTC) and those that require a New Drug Application (NDA) assessed by the CDER of the USFDA. Herbal pharmaceuticals naturally contain components as bioactive components and are classified as herbal pharmaceuticals. These items are then offered after receiving NDA or ANDA approval, or as a competing product[49]. 21 CFR parts 331-358 of FDA regulation state[50] that a herbal medicinal product is suitable for placement in the antibiotic monograph if it has been sold for an extended period to identify the internal and external. A request must be prepared in accordance with 21 CFR 10.30 if the herbal medicine product maker seeks to update a monograph to incorporate a new herbal component. Just after publishing of the last OTC drug monograph for a particular herbal drug products to meet the needs sign, any individual may advertise the very same product even though it includes the very same active substance and is used for the very same indication; however, the person must submit labelling and also another engaged moiety in accordance with the monographs. Despite the absence of patent protection, the USFDA will provide the inventor of a new herbal drug product five years of marketing authorization beginning on the approval date if the medication is approved through an NDA. In accordance with 314.108(a)(21 CFR 314.108 - New Medication Product Exclusivity., n.d.), a natural medicinal drug combining many chemical ingredients may qualify as a new organic compounds. Unless the 2nd applicant submits a 505(b) (1) application and completes all the studies required to prove the safety and efficacy of the product, FDA will not acclaim the request and in the majority cases will not even evaluate it when the initial producer has successfully qualified the commodity as a novel chemical organisation and allows for the identification (Wu et al., 2010). If an organic drug product maker wishes to commercialise a product that isn't listed in the present OTC drug monograph, the applicant should submit an NDA after demonstrating the product's safety and efficacy rather than demanding that the appropriate regulatory agency alter the monograph.

## VII. FINDINGS AND CONCLUSION

According to the findings of the research that was properly done to uncover the insufficiency of the regulatory rules for many parts of the manufacturing of herbal remedies, the safety and efficiency of herbs used in medicine are severely compromised. More than sixty percent (approximately) of people surveyed recommended the development or elaboration of guidelines for the quality assurance of herbal remedies. Although recommendations have been established for the series of experiments of the efficacy of ASU or other medicinal products, additional recommendations should indeed be created for the standardisation of herbal preparations and marker-based characterization of active ingredients. Excellent Agriculture and Collecting Methods (GACP) and decent storage practises are also vital in herbal medication manufacture, in addition

to quality assurance. In 2009, the National Medicinal Plants Board of India published country-specific standards for good agricultural practices and good field collection procedures, in accordance with WHO-designed GACP. Nevertheless, our investigations found that the majority of manufactures and suppliers of raw materials are unaware of these regulations. In addition, many organisations and businesses that are aware of these principles deem them unfeasible because of the absence of education and awareness among producers as well as the related operating costs. The findings of the study indicate that Ayurvedic pharmacopoeia of India-compliant standardised and verified raw ingredients and preparations are required for the creation of high-quality medicines. Establishing government-accredited raw material procurement centres in each state would aid companies in acquiring real crude ingredients. Respondents also requested more detailed regulatory requirements for raw material standardisation and manufacturing quality standards[25]. There should be proper regulatory authorities to look after the same and quality check control should be mandated as the herbal drugs are consumed by many who still trust on traditional methods of cure. Herbal medicines provide a holistic approach toward cure with minimal or zero sickness. And it does not have any side effects as such which includes improvement of immunity and prevention of diseases. It's only that as per the Unani medicinal approach physicians can suggest Dieto-therapy as the first line of treatment with other modalities of treatment. It's both for prophylactic and therapeutic for maintenance of health as well as for treating diseases. Proper diets and consumption techniques should be prescribed by legislative authorities and quality checks to be done which not only cures the diseases but also protect it from further occurrence. The mechanism of action and toxicity is required to further examine before it's out for marketing in large samples for precisely ameliorating for other adverse effects. As more double blind randomised clinical trials are actually required for investigating its after effects of herbal treatments too.

## REFERENCES

[1] "WHO Global Centre for Traditional Medicine ." Accessed: Aug. 17, 2022. [Online]. Available: https://www.who.int/initiatives/who-global-centre-for-traditional-medicine/

[2] M. Ekor, "The growing use of herbal medicines: issues relating to adverse reactions and challenges in monitoring safety," *Front. Pharmacol.*, vol. 4, 2014, doi: 10.3389/FPHAR.2013.00177.

[3] WHO, "Traditional, Complementary and Integrative Medicine." Accessed: Sep. 19, 2022. [Online]. Available: https://www.who.int/health-topics/traditional-complementary-and-integrative-medicine#tab=tab_1

[4] M. Gunjan and A. Ahmad, "MARKETING TRENDS & FUTURE PROSPECTS OF HERBAL MEDICINE IN THE World Journal of Pharmaceutical Research," no. August, 2015.

[5] A. Parveen, B. Parveen, R. Parveen, and S. Ahmad, "Challenges and guidelines for clinical trial of herbal drugs," *J. Pharm. Bioallied Sci.*, vol. 7, no. 4, p. 329, Oct. 2015, doi: 10.4103/0975-7406.168035.

[6] "Herbal medicine Definition & Meaning - Merriam-Webster." Accessed: Sep. 13, 2022. [Online]. Available: https://www.merriam-webster.com/dictionary/herbal medicine

[7] "Herbal medicine | definition of herbal medicine by Medical dictionary." Accessed: Sep. 13, 2022. [Online]. Available: https://medical-dictionary.thefreedictionary.com/herbal+medicine

[8] F. Chau, K. Fung, C. Koon, K. Lau, S. Wei, and P. Leung, "Bioactive Components in Herbal Medicine Experimental Approaches," *Herb. Med. Biomol. Clin. Asp.*, 2011, Accessed: Sep. 13, 2022. [Online]. Available: https://www.ncbi.nlm.nih.gov/books/NBK92759/

[9] S. Bent, "Herbal Medicine in the United States: Review of Efficacy, Safety, and Regulation," *J. Gen. Intern. Med.*, vol. 23, no. 6, p. 854, Jun. 2008, doi: 10.1007/S11606-008-0632-Y.

[10] Volker Schulz and Rudolf Hänsel, "Rational Phytotherapy: A Physician's Guide to Herbal Medicine ." Accessed: Sep. 18, 2022. [Online]. Available: https://books.google.co.in/books?id=BHyWNDkB7zkC&printsec=frontcover#v=onepage&q&f=false

[11] X. Sun, D. Lin, W. Wu, and Z. Lv, "Translational Chinese Medicine: A Way for Development of Traditional Chinese Medicine," *Chin. Med.*, vol. 02, no. 04, pp. 186–190, 2011, doi: 10.4236/CM.2011.24029.

[12] H. Saito, "Regulation of herbal medicines in Japan," *Pharmacol. Res.*, vol. 41, no. 5, pp. 515–519, 2000, doi: 10.1006/PHRS.1999.0645.

[13] K. Morgan, "Medicine of the gods : basic principles of Âyurvedic medicine," p. 79, 1994.

[14] "European Scientific Cooperative on Phytotherapy." Accessed: Sep. 18, 2022. [Online]. Available: https://escop.com/about-escop/

[15] K. Carle, R. dan Gomma, "Medicinal uses of Matricariae Flos," *Br. J. Phyther.*, vol. 2, no. 4, pp. 147–153, 1991, Accessed: Sep. 21, 2022. [Online]. Available: https://archive.org/details/completegermanco0000unse

[16] World Health Organization., "WHO monographs on selected medicinal plants. Vol. 1," 1999, doi: 10.3/JQUERY-UI.JS.

[17] J. M. Jellin, "Natural Medicines Comprehensive Database," *J. Med. Libr. Assoc.*, vol. 90, no. 1, p. 114, 2002, Accessed: Sep. 18, 2022. [Online]. Available: /pmc/articles/PMC64772/

[18] Thillaivanan S, "Challenges, Constraints and Opportunities in Herbal Medicines-A Review," *~ 21 ~ Int. J. Herb. Med.*, vol. 2, no. 1, pp. 21–24, 2014, [Online]. Available: http://scholarsresearchlibrary.com/archive.html

[19] X. ZHANG, "Regulatory Situation of Herbal Medicines A worldwide Review The evaluation of these products and ensuring their safety and efficacy through registration and regulation present important challenges".

[20] S. Singh and V. K. Shukla, "Current regulations for Herbal Medicines in India," *Int. J. Drug Regul. Aff.*, vol. 9, no. 2, pp. 30–34, 2021, doi: 10.22270/ijdra.v9i2.466.

[21] World Health Organization (WHO), "WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems," *World Heal. Organ. Geneva*, p. 82, 2004, [Online]. Available: https://apps.who.int/medicinedocs/documents/s7148e/s7148e.pdf

[22] WHO, “Guidelines for the appropriate use of herbal medicines,” WHO Regional Publication. Accessed: Mar. 01, 2023. [Online]. Available: https://apps.who.int/iris/bitstream/handle/10665/207021/9290611243_eng.pdf?sequence=1&isAllowed=y

[23] Z. O. Omogbadegun, “Framework for overcoming barriers of complementary and alternative medicine acceptance into conventional healthcare system,” *nternational Journal of Medicinal Plants and Alternative Medicine*, vol. 1(7). pp. 118–136, 2013. Accessed: Mar. 01, 2023. [Online]. Available: https://www.academia.edu/5116752/Framework_for_overcoming_barriers_of_complementary_and_alternative_medicine_acceptance_into_conventional_healthcare_system

[24] P. Wal, A. Wal, S. Gupta, G. Sharma, and A. K. Rai, “Pharmacovigilance of herbal products in India,” *J. Young Pharm.*, vol. 3, no. 3, pp. 256–258, 2011, doi: 10.4103/0975-1483.83780.

[25] N. Sahoo and P. Manchikanti, “Herbal Drug Regulation and Commercialization: An Indian Industry Perspective,” *https://home.liebertpub.com/acm*, vol. 19, no. 12, pp. 957–963, Dec. 2013, doi: 10.1089/ACM.2012.0275.

[26] “Herbal Medicine Market Size CAGR Report.” Accessed: Sep. 12, 2022. [Online]. Available: https://www.polarismarketresearch.com/industry-analysis/herbal-medicine-market

[27] “Global Market Exhibited Growth .” Accessed: Sep. 12, 2022. [Online]. Available: https://www.fortunebusinessinsights.com/herbal-medicine-market-106320

[28] “India: Ayurveda industry market value 2025 | Statista.” Accessed: Sep. 21, 2022. [Online]. Available: https://www.statista.com/statistics/1252538/india-ayurveda-industry-market-value/

[29] V. M. Shinde, K. Dhalwal, M. Potdar, and K. R. Mahadik, “Application of Quality Control Principles to Herbal Drugs.,” *undefined*, vol. 1, no. 1, pp. 4–8, Jul. 2009, doi: 10.5138/IJPM.2009.0975.0185.05786.

[30] Mohammed Mosihuzzaman, “Herbal medicine in healthcare--an overview .” Accessed: Sep. 16, 2022. [Online]. Available: https://pubmed.ncbi.nlm.nih.gov/22816312/

[31] L. M. Coleman, L. L. Fowler, and M. E. Williams, “Use of Unproven Therapies by People with Alzheimer’s Disease,” *J. Am. Geriatr. Soc.*, vol. 43, no. 7, pp. 747–750, Jul. 1995, doi: 10.1111/J.1532-5415.1995.TB07043.X.

[32] J. H. Cardellina, “Challenges and Opportunities Confronting the Botanical Dietary Supplement Industry†,” *J. Nat. Prod.*, vol. 65, no. 7, pp. 1073–1084, 2002, doi: 10.1021/NP0200515.

[33] M. Ray F. Evert University of Wisconsin and M. Susan E. Eichhorn University of Wisconsin, *RAVEN BIOLOGY OF PLANTS*.

[34] WHO, “Quality control methods for medicinal plant materials World Health Organization Geneva,” *Who*, 1998, doi: 10.1016/j.pbi.2015.01.003.

[35] “Toxicology 2002: Vol 181-182 Table of Contents : Free Download, Borrow, and Streaming : Internet Archive.” Accessed: Sep. 14, 2022. [Online]. Available: https://archive.org/details/sim_toxicology_2002_181-182_contents_0

[36] Y. Z. Liang, P. Xie, and K. Chan, “Quality control of herbal medicines,” *J. Chromatogr. B. Analyt. Technol. Biomed. Life Sci.*, vol. 812, no. 1–2, pp. 53–70, Dec. 2004, doi: 10.1016/J.JCHROMB.2004.08.041.

[37] World Health Organization., “WHO guidelines for assessing quality of herbal medicines with reference to contaminants and residues.,” p. 105, 2007.

[38] “Plant-Based Drugs and Medicines by Leslie Taylor .” Accessed: Sep. 13, 2022. [Online]. Available: https://www.scribd.com/document/558442686/Plant-Based-Drugs-and-Medicines-by-Leslie-Taylor

[39] N. R. Farnsworth and A. S. Bingel, “Problems and Prospects of Discovering New Drugs from Higher Plants by Pharmacological Screening,” pp. 1–22, 1977, doi: 10.1007/978-3-642-66682-7_1.

[40] R. P. Samy and P. Gopalakrishnakone, “Current status of herbal and their future perspectives,” *Nat. Preced.*, no. May, 2007, doi: 10.1038/npre.2007.1176.1.

[41] C. Z. Andrew Vickers, “ABC of Complementary Medicine,” *Focus Altern. Complement. Ther.*, vol. 5, no. 3, pp. 231–231, 2010, doi: 10.1111/j.2042-7166.2000.tb02553.x.

[42] A. Chopra and V. V. Doiphode, “Ayurvedic medicine: core concept, therapeutic principles, and current relevance,” *Med. Clin. North Am.*, vol. 86, no. 1, pp. 75–89, Jan. 2002, doi: 10.1016/S0025-7125(03)00073-7.

[43] “THE DRUGS AND COSMETICS ACT, 1940 and Rules 1945.” Accessed: Sep. 19, 2022. [Online]. Available: https://www.cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/acts_rules/2016DrugsandCosmeticsAct1940Rules1945.pdf

[44] R. Lodha and A. Bagga, “Traditional Indian systems of medicine,” *Ann. Acad. Med. Singapore*, vol. 29, no. 1, pp. 37–41, 2000.

[45] “Ministry of Ayush.” Accessed: Sep. 19, 2022. [Online]. Available: https://cdn.ayush.gov.in/wp-content/uploads/2021/03/02-Governing-Body-of-IPGTRA-as-per-GAU-Act.pdf

[46] “Dietary Supplement Health and Education Act of 1994.” Accessed: Sep. 19, 2022. [Online]. Available: https://ods.od.nih.gov/About/dshea_Wording.aspx

[47] “Dietary Supplements | FDA.” Accessed: Sep. 19, 2022. [Online]. Available: https://www.fda.gov/food/dietary-supplements

[48] S. Bent, “Herbal Medicine in the United States: Review of Efficacy, Safety, and Regulation: Grand Rounds at University of California, San Francisco Medical Center,” *J. Gen. Intern. Med.*, vol. 23, no. 6, p. 854, Jun. 2008, doi: 10.1007/S11606-008-0632-Y.

[49] K. M. Wu, J. Dou, H. Ghantous, S. Chen, A. Bigger, and D. Birnkrant, “Current regulatory perspectives on genotoxicity testing for botanical drug product development in the U.S.A.,” *Regul. Toxicol. Pharmacol.*, vol. 56, no. 1, pp. 1–3, Feb. 2010, doi: 10.1016/J.YRTPH.2009.09.012.

[50] “eCFR :: 21 CFR Part 358 -- Miscellaneous External Drug Products for Over-the-Counter Human Use.” Accessed: Sep. 19, 2022. [Online]. Available: https://www.ecfr.gov/current/title-21/chapter-I/subchapter-D/part-358