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Review Article

Overview of herbal drugs: Regulatory perspective with special emphasis on global market

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ABSTRACT

The market for herbal pharmaceuticals has grown significantly due to the growing demand for herbal medications worldwide, which is fueled by its perceived safety and natural source. However, regional differences in the regulatory frameworks governing these items provide difficulties for industry participants and impede the growth of the global market. This research offers a thorough analysis of the regulatory environment around herbal medications, looking at laws in important markets such as China, India, the US, and the EU. It draws attention to the intricate regulatory approval process and the necessity of international harmonization of safety, efficacy, and quality standards. Product quality and customer trust are frequently affected by differences in these regions' classification, licensing, and post-market surveillance regulations. The paper also discusses how new international regulatory initiatives, like the WHO's Traditional Medicine Strategy, are affecting the global standardization of herbal medication approval procedures. The paper also examines market trends, pointing to a growing demand for herbal treatments for the prevention of illness and the treatment of chronic conditions. Notwithstanding the strong market expansion, issues including product adulteration, a lack of therapeutic data, and restricted intellectual property rights still exist, calling for calculated regulatory changes to maintain consumer safety and market legitimacy. In addition to highlighting the significance of regulatory convergence, this report offers stakeholders practical advice on how to better manage the global herbal medication industry.

1. Introduction

Medicinal items made from plants and plant extracts are known as herbal pharmaceuticals, sometimes called herbal medicines or phytomedicines. These products have been used for centuries in traditional medical systems all over the world. In a broad sense, herbal medications are made from different plant parts, including leaves, roots, flowers, seeds, and bark, which are used for their medicinal properties and bioactive substances. These items serve as preventative or curative treatments for a variety of illnesses and come in a variety of forms, from unrefined botanical materials to more sophisticated forms including powders, tinctures, and capsules. The main characteristics that set herbal medications apart from traditional pharmaceuticals are their complex active component mixes and natural origin. Herbal medications often have several active ingredients, which makes their pharmacological actions complex but complementary to synthetic medications that only include one isolated chemical. The therapeutic adaptability and all-encompassing appeal of herbal medications in contemporary healthcare are greatly influenced by their multicomponent nature. [1–3]

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2. Historical Significance of Herbal Drugs

Herbal medicine has long played a significant role in many cultures and medical systems, such as Ayurveda, Kampo in Japan, Unani in the Middle East, and Traditional Chinese Medicine (TCM). [4] Ancient writings like China's The Yellow Emperor's Classic of Internal Medicine and India's Charaka Samhita highlight the continued use of plant-based remedies in the treatment of illness. Early medical practice was built on herbal medications, and their applicability has endured because of growing confidence in the efficacy, safety, and natural sources of plant-based treatments. Since many medications are derived from plant chemicals, such as morphine from opium poppies and aspirin from willow bark, modern pharmacology itself has roots in herbal medicine. Herbal medicines' cultural and medical significance is supported by their historical significance, which also helps explain why modern health care systems continue to embrace and value them. [5,6]

2.1. Current trends in herbal medicine usage

Herbal remedies have seen a rise in popularity recently, which is indicative of a move toward preventative and integrative health strategies. A number of variables are responsible for this trend. First, customers are looking for natural alternatives to synthetic medications, which are thought to have fewer adverse effects, as a result of a growing emphasis on holistic health and wellness worldwide. Second, patients are looking for complementary therapies, such as herbal medications, to control symptoms and enhance their quality of life due to the prevalence of chronic conditions like diabetes, hypertension, and cardiovascular ailments. [7] This inclination is consistent with an increasing amount of scientific studies confirming the effectiveness of specific herbal products, which has increased consumer trust in their potential as medicines. Herbal treatments are also being used more and more to treat lifestyle-related health problems like stress, sleeplessness, and digestive disorders, which solidifies their position in the medical field.

As people all across the world resorted to immune-boosting goods and preventive health measures during the COVID-19 epidemic, interest in herbal therapy has increased. The demand for herbal medicines and supplements that boost immunity, lower stress levels, and improve respiratory health has increased as a result of this trend. The consumption of medicinal herbs like ginseng, ginger, and ashwagandha has significantly increased in areas with strong herbal medicine traditions, including China and India, due to the possible health advantages of these plants during the epidemic. The trend toward preventive healthcare practices sparked by the epidemic is probably going to keep consumers interested in herbal remedies. [8]

2.2. The growing global market for herbal products

The global market for herbal medicines has grown significantly in tandem with these trends. Recent market studies indicate that the herbal medicine sector has grown gradually, and forecasts indicate that this expansion will continue in the years to come. Growing consumer awareness, the integration of herbal products into mainstream healthcare, and backing from governmental and medical institutions that acknowledge the value of traditional medicine in public health are the key drivers of this expansion. [7,9,10] The World Health Organization (WHO), for example, has aggressively supported the incorporation of complementary and alternative medicine into health systems, highlighting the necessity of regulatory frameworks to guarantee the efficacy, safety, and quality of herbal medications. The market for herbal products has therefore developed from a small-scale, regional sector to a global one with well-established distribution networks, including e-commerce platforms that enable herbal items to be purchased anywhere in the world.

The product landscape of the worldwide herbal market is varied and includes cosmetics containing herbal extracts, traditional medicinal items, and dietary supplements. Customers are looking for herbal supplements for energy, joint support, cognitive enhancement, and immune health, which has led to a notable increase in the dietary supplement market. Additionally, as part of the clean beauty movement, herbal cosmetics—from skincare to hair care products—have gained popularity. The wide range of applications for herbal products in several facets of health and wellbeing is reflected in this market diversity, which has aided in their widespread use. [11,12]

2.3. Challenges and the need for regulatory convergence

Notwithstanding the encouraging prognosis, there are significant regulatory obstacles facing the worldwide herbal business. Countries have very different regulations for herbal goods, which leads to differences in labeling, safety requirements, and quality control. Herbal products are subject to less rigorous approval procedures than pharmaceutical pharmaceuticals in some areas, where they are regulated similarly to nutritional supplements. They must, however, pass stringent testing and registration requirements in other nations. Consumer safety, market accessibility, and product quality are all impacted by this discrepancy in regulatory frameworks. For instance, differences in classification (such as as food, supplement, or medication) may have an impact on the marketing of herbal goods and how customers view them. Furthermore, uneven quality standards among markets can result in problems like adulteration, contamination, and false advertising, eroding consumer confidence and reducing the potential for the

herbal product industry globally. [13–15]

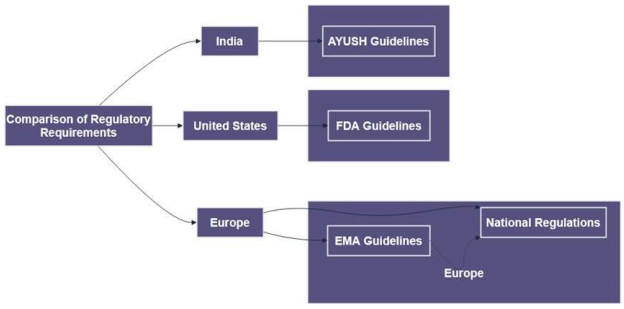

Figure 1: Comparison of regulatory frameworks for herbal grugs in major regions of World [13–15]

Given these difficulties, stakeholders are focusing on regulatory convergence in an effort to establish a unified worldwide market for herbal medications. International organizations are working to establish standardized standards for the quality, safety, and effectiveness of herbal medicines. One such initiative is the WHO's Traditional Medicine Strategy. These efforts highlight the value of cooperative regulation, especially in light of the rising demand for herbal products worldwide. Standardized laws can increase herbal products' acceptability, safety, and accessibility, opening up new markets and encouraging innovation in the herbal medicine sector.

In the larger health care sector, the herbal medication industry holds a special place. Herbal medications, which have their roots in centuries-old medicinal procedures and are being driven by current health trends, are a fast expanding market segment worldwide. The need for regulatory harmonization and clarity is growing as consumer demand for natural and alternative health products increases. Examining the existing regulatory environment for herbal medications with an emphasis on regional differences, difficulties, and standardization prospects is the goal of this research. This article illustrates the possibility for a more robust and integrated herbal drug sector that can satisfy the demands of a worldwide consumer base while maintaining product quality and safety by giving a broad overview of market trends and regulatory viewpoints. [16,17]

3. Importance of Herbal Drugs

With therapeutic effects spanning both traditional and modern medicine, herbal medications have played a crucial part in health care systems around the world. In order to comprehend the significance of herbal medicines, it is necessary to examine their development from traditional cures to modern therapeutic alternatives, as well as how their safety profiles and perceived advantages make them a useful supplement or substitute for synthetic treatments.

Herbal medications are now acknowledged for their capacity to treat a broad range of ailments, and their significance only increases as a result of growing scientific support, improvements in regulations, and public demand for all-natural, holistic health remedies. [18,19]

3.1. Traditional vs Modern herbal medicine

Herbal medicine is based on ancient customs that date back thousands of years. Many nations' cultural, spiritual, and philosophical beliefs are ingrained in traditional herbal medicine systems including Ayurveda, Traditional Chinese Medicine (TCM), Kampo (Japan), and Native American medicine. These systems have produced sophisticated conceptions of plant-based treatments, taking into account both their function in reestablishing mental and physical equilibrium as well as their unique therapeutic effects. Herbs are frequently used in these traditional contexts to create formulations that are particular to the patient's constitution, symptoms, and general health. Herbal medicines have gained popularity in the context of preventative healthcare because of traditional medicine's holistic approach, which places an emphasis on preserving health rather than just curing illness. [20]

Modern herbal medicine, on the other hand, has developed as a result of pharmacological research, extraction techniques, and scientific breakthroughs that aim to identify and comprehend particular bioactive substances in plants. In an effort to deliver consistent therapeutic advantages, the contemporary method frequently concentrates on determining standardized dosages and particular plant chemicals that show quantifiable effects. As seen by items like standardized extracts, capsules, and tinctures made for exact dosage and effectiveness, modern herbal therapy incorporates both traditional applications and scientifically supported discoveries. Due to their scientifically proven benefits in treating ailments like inflammation, anxiety, insomnia, and digestive problems, herbal medications have transitioned from traditional medicine to the mainstream market. Nonetheless, there are issues with contemporary herbal medicine as well, namely with relation to regulatory discrepancies, standardization, and quality control. Notwithstanding these obstacles, the amalgamation of contemporary research with traditional knowledge has bolstered the legitimacy and effectiveness of herbal remedies, hence reinforcing their significance in contemporary healthcare. [21–23]

3.2. Benefits of herbal drugs

The variety of advantages that distinguish herbal medications from traditional pharmaceutical treatments is one of the main factors contributing to their popularity. The idea that herbal remedies typically have less adverse effects than synthetic ones is one of the most frequently

mentioned advantages. Herbal medications include a complex matrix of chemicals that frequently function in concert since they are made from whole plants or natural extracts. This reduces the possibility of side effects that come with high-dose, single-compound medications. Herbal medications' multi-compound makeup enables a broader, kinder action on multiple biological systems, while many conventional medications only target one pathway, which can result in certain negative effects. The holistic approach to treatment that herbal medications take is another advantage. Instead of just treating symptoms, herbal medications seek to bring the body back into balance, which is consistent with an integrated health philosophy that views the patient as a whole. When treating chronic illnesses and lifestyle-related ailments, when treating the underlying causes—such as stress, poor food, and sleep deprivation—can be more successful than symptom-focused therapies, this strategy is especially pertinent. Antioxidants, anti-inflammatory substances, and adaptogens—all of which support the body's ability to adjust to stress and foster disease resistance—are also abundant in many herbal medications. [24–27]

Herbal alternatives with antibacterial qualities, such garlic and oregano oil, have gained interest due to the growing worry over antibiotic resistance. These alternatives have broad-spectrum activity without causing resistance. In a similar vein, the usage of adaptogens such as ginseng, rhodiola, and ashwagandha represents a move toward natural solutions that support mental and physical health by assisting the body in managing stress without the dependency dangers associated with traditional antidepressants or anxiolytics. Herbal medications' usage in preventive healthcare, where they are incorporated into everyday routines to enhance immune function, digestion, cardiovascular health, and other areas, is another factor driving their appeal. [28–30]

3.3. Widely used herbal drugs

Both traditional and modern medicine have made extensive use of and acknowledged the therapeutic benefits of certain herbal medications. The variety of medicinal effects offered by plant-based treatments is demonstrated by each of these plants, demonstrating the broad spectrum of ailments that herbal medications can treat. These illustrations highlight the adaptability and therapeutic value of herbal medications, which are still used in both clinical and self-care settings. For instance, turmeric is widely used as a supplement to treat arthritis and promote general health because of its well-known anti-inflammatory and antioxidant qualities. Similar to this, ginger is a common treatment for nausea and gastrointestinal distress due to its antiemetic and digestive qualities, particularly during pregnancy or after surgery. Adaptogens, such as ginseng and ashwagandha, are examples of herbs that boost energy and stress resilience, with additional advantages for immune system and mental clarity. In contemporary herbal medicine, ashwagandha is especially noteworthy because it is commonly suggested for hormone balancing, stress reduction, and energy enhancement. Echinacea is used extensively in preventative medicine because of its immune-boosting qualities, especially during the cold and flu season. [31–33]

Known for its antispasmodic and digestive properties, peppermint is frequently used to treat respiratory and irritable bowel syndrome (IBS). Herbal medicines are becoming more and more popular as natural health remedies since each of these herbs has special bioactive components and therapeutic effects. Their importance in the global health scene is further supported by the examples, which highlight the potential of herbal medications to treat a variety of illnesses, from acute infections and inflammation to chronic stress and mental health support. Herbal medications' historical significance, unique advantages, and wide range of uses all contribute to their significance. Due to their safety, holistic effects, and ability to address current health requirements, both traditional and modern herbal medicine are expected to become more widely used in mainstream healthcare as they continue to develop. Herbal medications are poised to grow in value as a part of the global health care system with continued research and better regulatory frameworks. They provide natural, affordable, and efficient alternatives for treating and preventing illness. [34]

4. Regulatory Framework for Herbal Drugs

Herbal drug regulations are complicated and vary greatly by country, reflecting cultural customs, consumer preferences, and legal requirements. The World Health Organization (WHO) and the United States are two important regulatory agencies that handle this intricacy. Among them are the European Medicines Agency (EMA) and the Food and Drug Administration (FDA). The lack of a single international framework makes it difficult to standardize herbal medications, despite the fact that these organizations are essential in setting requirements for their efficacy, safety, and quality. There are notable differences in product classification, approval procedures, and market accessibility as a result of the distinct approaches used by each regulatory body when it comes to herbal pharmaceuticals. [15,35]

4.1. Overview of regulatory bodies

The WHO plays a key role in creating global standards for herbal remedies and encouraging their safe incorporation into national healthcare systems, especially in nations with long histories of using herbal remedies. In an effort to standardize procedures worldwide, the WHO has created frameworks for quality control, safety monitoring, and

Table 1: Examples of widely used herbal drugs. [28–33]

Herb	Primary Bioactive Compounds	Therapeutic Benefits	Applications
Turmeric	Curcumin	Anti-inflammatory, antioxidant, potential anti-cancer	Arthritis, digestive health, cardiovascular health
Ginger	Gingerol, shogaol	Antiemetic, anti-inflammatory, digestive support	Nausea, indigestion, inflammation
Garlic	Allicin	Antimicrobial, cardiovascular support, immune enhancement	Hypertension, infections, immune support
Ashwagandha	Withanolides	Adaptogenic, stress reduction, immune support	Anxiety, stress, energy levels
Ginseng	Ginsenosides	Adaptogenic, energy booster, cognitive support	Fatigue, mental clarity, immune support
Chamomile	Apigenin	Sedative, anti-inflammatory, digestive relaxant	Insomnia, digestive discomfort, anxiety
Echinacea	Alkylamides, polysaccharides	Immune stimulant, anti-inflammatory	Common cold, immune health
Peppermint	Menthol	Antispasmodic, digestive aid, respiratory relief	IBS, respiratory issues, muscle pain
St. John's Wort	Hypericin, hyperforin	Antidepressant, anti-inflammatory	Depression, mood stabilization
Aloe Vera	Polysaccharides, vitamins	Skin healing, digestive health, immune support	Wound healing, skin care, digestive aid

research on herbal medications through programs like the WHO Traditional Medicine Strategy. The WHO's function is consultative, though, and it helps nations create their own policies rather than actually enforcing laws. Under the Dietary Supplement Health and Education Act (DSHEA) of 1994, the FDA primarily regulates herbal items in the US as dietary supplements. Because herbal medications are excluded from the stringent pre-market approval procedure that pharmaceuticals must undergo, manufacturers are ultimately responsible for ensuring the safety of their products. Herbal products can be promoted with structure-function claims (e.g., "supports immune health"), but they cannot be said to diagnose, treat, or cure diseases. The FDA keeps an eye on these items after they are put on the market and may take action if problems like contamination or exaggerated health claims occur. [2,36,37]

Herbal medications, on the other hand, are categorized by the EMA as either herbal medicinal products (HMPs) or traditional herbal medicinal products (THMPs), which require different amounts of proof based on their intended use. HMPs need clinical evidence to back up their claims, but the THMP categorization permits easier registration based on traditional use. European herbal drug regulations are stricter than those in the United States since the European Medicines Agency (EMA) requires quality criteria and safety evaluations. A more organized market for herbal medications has resulted from the European Union's emphasis on product safety and effectiveness, which has improved consumer protection but also raised the price and difficulty of entering the market. [38,39]

4.2. Variations in regulation across regions

Regional differences in herbal medication regulations are significant. Herbal medications are essential to health care systems in Asia, especially in nations like China, Japan, and India, and are frequently governed by frameworks for traditional medicine. Similar to pharmaceuticals, Traditional Chinese Medicine (TCM) is subject to strict rules enforced by China's National Medical Products Administration (NMPA). [40,41]

A regulatory framework for Ayurvedic and other traditional medicines has been formed by India's Ministry of AYUSH (Ayurveda, Yoga & Naturopathy, Unani, Siddha, and Homeopathy). It requires adherence to quality standards but frequently depends on traditional knowledge for safety and efficacy. Under Japanese pharmaceutical regulations, Japan controls Kampo medicine, treating some herbal items as prescription drugs with dose restrictions. As previously mentioned, the THMP registration method in the EU includes a strict system for herbal medications that prioritizes quality and safety. But because herbal medications are categorized as dietary supplements in the United States, there are less pre-market regulations, which facilitates faster market entry but also raises questions about the safety and consistency of the products. Herbal medications are frequently categorized as food products in areas without specific regulatory frameworks, which results in less regulation and possible safety hazards. International

Table 2: Overview of region wise regulatory body with requirements. [37–43]

Region	Regulatory Body	Product Classification	Approval Requirements
United States	FDA	Dietary supplements	Manufacturer responsible for safety; no pre-market approval
European Union	EMA	Traditional/Herbal Medicinal Products	Evidence of safety and efficacy; quality control
China	NMPA	Traditional Chinese Medicine (TCM)	Regulated as pharmaceuticals; clinical trials for new products
India	Ministry of AYUSH	Ayurvedic, Unani, Siddha medicines	Quality standards; traditional use evidence
Japan	Ministry of Health, Labour and Welfare	Kampo Medicine	Regulated under pharmaceutical laws

trade is made more difficult by this diversity, and consumers may have to deal with products of varying quality depending on where they are produced. [44,45]

4.3. Challenges in Standardizing Regulations

The variety of regulatory classifications and standards resulting from various cultural viewpoints on herbal medicine is the main obstacle to standardizing herbal drug laws worldwide. Companies' capacity to effectively enter several markets is impacted by this lack of harmonization since they have to deal with different approval procedures and adjust to regional standards. A product that has been approved as a traditional herbal medicine in Europe, for instance, might not fulfill FDA criteria in the United States, or vice versa. This could result in regulatory bottlenecks and limit the availability of safe, effective herbal medications worldwide. The standardization and quality monitoring of herbal products present yet another significant obstacle. Establishing consistent quality standards is made more difficult by the intricacy of plant-based formulations, which might include hundreds of active components. Differences in product potency and purity might result from variations in plant sources, processing techniques, and storage conditions. These differences can lead to problems like contamination, adulteration, or mislabeling in areas with laxer rules, which erode customer confidence and raise safety concerns. [46–48]

International agencies such as the WHO promote regulatory convergence in order to solve these issues, pushing nations to enact uniform standards for efficacy, safety, and quality. However, because traditional knowledge systems must be respected while maintaining scientific rigor, worldwide regulatory harmonization is still a difficult endeavor. Some areas have responded by taking a hybrid strategy that combines evidence-based standards with traditional knowledge. This method could be used as a model to balance regulatory consistency with cultural variation. [49,50]

5. Global Market Analysis

The growing demand for natural, plant-based health treatments is propelling the worldwide herbal drug market's rapid expansion. Over the next ten years, this market, which is valued at over $100 billion, is anticipated to expand at a compound annual growth rate (CAGR) of roughly 6-8%. The market for herbal goods has increased globally due to a number of factors, including growing awareness of the negative effects of modern medications, a greater focus on preventative health, and cultural familiarity with traditional medicine in places like Asia. Because of its long history with herbal medicine, especially in nations like China and India, Asia holds the largest market share. Meanwhile, as consumer attitudes shift more in favor of natural medicines, North America and Europe are also seeing increase. [51]

Comprehensive overview of themarket dynamics for herbal drugs. [42–51]

Key firms with a worldwide and regional presence dominate the sector. Reputable market leaders in Asia include Dabur, Himalaya Herbals, and Patanjali Ayurved. These businesses profit from long-standing customer trust and cultural identification. Globally, companies like Nature's Bounty, Gaia Herbs, and NOW Foods have gained a lot of traction, particularly in areas where herbal medications are categorized as nutritional supplements, which makes it easier to enter the market. Consumer expectations for quality and transparency are being reshaped by newer, niche businesses that specialize in organic, ethically sourced, and specialty goods. These brands are also increasing competition and diversity. The market for herbal drugs is growing as a result of several phenomena. Concerns about synthetic ingredients, the desire for products with fewer negative effects, and the growing consumer trend for natural and organic health products are some of the main motivators. In order to meet the need for customized health products, e-commerce has allowed producers to access a wider audience worldwide. The market size, growth rates, major players, and trends influencing the worldwide herbal medication industry are compiled in the (Table 3). [52–54]

Table 3:

Aspect	Details
Market Size	Estimated at over $100 billion globally
Growth Rate (CAGR)	6-8% projected growth over the next decade
Leading Regions	Asia (China, India), followed by North America and Europe
Key Players	**Asia**: Dabur, Himalaya Herbals, Patanjali Ayurved **Global**: Nature's Bounty, Gaia Herbs, NOW Foods
Market Trends	Increasing preference for natural and organic products Consumer concerns about synthetic additives & drug side effects Rising focus on preventive healthcare and wellness Expansion through e-commerce platforms
Challenges	Regulatory inconsistencies across regions Standardization issues due to varying product classifications
Future Opportunities	Growth in personalized and specialty herbal products Potential for new market entrants with sustainable, organic, and niche offerings

6. Regulatory Challenges

Because of differences in quality control, safety, efficacy, and intellectual property rights, the global market for herbal medications poses particular regulatory issues. These elements make it more difficult to standardize herbal products for wider acceptability and integration in international healthcare systems and complicate the regulatory environment. [17]

6.1. Issues with quality control and standardization

Two major issues in the regulation of herbal medications are quality control and uniformity. Because of their inherent variety and intricate makeup, herbal medications frequently lack consistent standards, in contrast to conventional pharmaceuticals, which have set processes and quality benchmarks. Variations in plant species, geographical origin, harvesting practices, and processing processes might result in different quantities of bioactive compounds in herbal products, which can affect their safety and therapeutic efficacy. In order to resolve these discrepancies, standardization initiatives set quality standards for raw materials, processing, and finished formulations. However, because different nations may have varying standards and testing criteria, regulatory frameworks still find it challenging to enforce these norms globally, making it challenging to guarantee product uniformity and reliability across national boundaries. [13,17,55]

6.2. Safety and efficacy concerns

Since herbal medications are made from natural sources with intricate chemical compositions, safety and effectiveness are key considerations in their regulation. Because of their natural nature, herbal pharmaceuticals are frequently thought to be harmless; yet, this belief can result in uncontrolled use, negative side effects, and possible interactions with prescription drugs. In order to determine the safety and effectiveness profiles of herbal products, regulatory bodies around the world stress the necessity of thorough clinical testing. However, many herbal medications still lack well-designed clinical studies, and in many places, traditional wisdom is used in place of scientific data. Furthermore, because some nations want extensive proof while others may merely require historical usage data, the global variation in accepted safety and efficacy data often leads to regulatory disparities. These disparities make it more difficult for herbal medications to be accepted globally and incorporated into traditional healthcare systems. [25,56,57]

6.3. Intellectual property issues and traditional knowledge protection

Herbal medication intellectual property rights (IPR) are complicated, particularly when it comes to traditional knowledge. Numerous herbal remedies have their origins in traditional customs that have been handed down through the ages, and communities hold community knowledge rather than private property. Unauthorized use of traditional knowledge by commercial entities, or biopiracy, presents moral and legal dilemmas. Herbal medications may not satisfy the novelty or inventive step standards required for patentability, making them difficult to protect through intellectual property rights like patents. As a result, some nations have put in place systems to safeguard traditional knowledge. For example, India's Traditional Knowledge Digital Library (TKDL) records native medical expertise to guard against infringement. Global equity and access to these resources are significantly impacted by the regulatory problem of striking a balance between the need to promote innovation and economic development in the herbal medication industry and the preservation of traditional knowledge. In order to address these regulatory issues and promote a trustworthy worldwide herbal drug industry, an international strategy is needed to standardize quality, safety, and intellectual property norms. [58,59]

7. Case Studies

The difficulties and lessons learned in creating a worldwide uniform framework for herbal goods are brought to light by looking at case studies of regulatory strategies in various

geographical areas as well as the successes and failures of herbal medications on the market. These instances highlight the necessity of strict yet flexible rules to guarantee the effectiveness and safety of herbal medications on a worldwide scale. [7,55]

7.1. Regulatory approaches in different countries

The many ways that nations strike a balance between customs and contemporary safety and effectiveness standards are exemplified by the various regulatory regimes for herbal medications. The Ministry of AYUSH oversees the regulatory control of herbal medicines in India. It establishes quality standards through pharmacopoeias and certification criteria and offers recommendations for traditional medicines such as Ayurveda, Siddha, and Unani. The China Food and Drug Administration (CFDA) has strict guidelines for traditional Chinese medicine (TCM) products, including registration procedures and clinical validation to guarantee safety and efficacy. China also incorporates traditional medicine into healthcare. The Dietary Supplement Health and Education Act (DSHEA) of 1994, in contrast, governs herbal medications as dietary supplements in the US. This means that while producers are accountable for product safety, they are exempt from proving efficacy before entering the market. Given that every method takes into account distinct cultural, scientific, and market-driven factors, these regulatory variations underscore the difficulties in attaining uniformity in the regulation of herbal drugs. [60,61]

7.2. Success stories of herbal products in the market

The potential of herbal medications when they satisfy regulatory requirements and cater to consumer wants is demonstrated by the market success of a number of herbal products. For example, standardized for curcumin content, supplements of turmeric (Curcuma longa) have become very popular as anti-inflammatory products, and there is a lot of evidence to support their health benefits. In a similar vein, ginseng, which is standardized and regulated in places like South Korea, has gained international recognition as a herbal product due to its alleged benefits for energy and cognitive function. These achievements highlight how regulatory backing and scientific confirmation can increase customer trust and promote the expansion of the herbal product sector. [62,63]

7.3. Failures and lessons learned from poorly regulated products

The market failure of some herbal goods serves as a warning about the negative effects of insufficient regulation. Kava (Piper methysticum), a herb utilized for its calming properties in the South Pacific, is a well- known example. Following allegations of hepatotoxicity, which were ascribed to the use of unconventional plant components and the absence of standardized doses, kava products were widely banned in Europe and Canada. The abuse of ephedra (Ephedra sinica) in dietary supplements, which resulted in serious cardiovascular adverse effects and was eventually outlawed in the United States, is another example. FDA, the Food and Drug Administration, 2004. These incidents highlight the dangers of inadequate clinical testing, inconsistent dosages, and poor quality control, highlighting the necessity of strict regulatory monitoring to avoid negative health effects and guarantee customer safety. The global herbal drug market may learn a lot from these case studies about the necessity of standardized regulatory procedures that uphold traditional knowledge while guaranteeing safety and effectiveness. The experiences of numerous nations and goods demonstrate the necessity of clear regulatory frameworks for both promoting sustainable growth in this industry and facilitating the safe integration of herbal medications into healthcare systems. [64,65]

8. Future Directions

The way that laws governing herbal drugs are developing suggests that there are many chances to use technology, promote innovation, and harmonize international standards. To create a strong regulatory system that guarantees the quality, safety, and effectiveness of herbal products globally, these future directions are crucial. [66]

8.1. Potential for harmonization of regulations globally

Regulatory harmonization would greatly assist the worldwide herbal drug business by facilitating more efficient procedures for product approval, distribution, and monitoring. Currently, different regulatory standards in different nations make it difficult for manufacturers to comply with a variety of compliance requirements and impede the seamless movement of herbal goods in global markets. Standardizing approaches to quality, safety, and efficacy is the goal of initiatives like the World Health Organization's (WHO) guidelines on complementary and traditional medicines. Establishing international pharmacopoeias and quality standards holds promise for additional harmonization. This might promote the adoption of herbal products worldwide and offer a uniform regulatory framework that honors both conventional wisdom and scientific validation. [35–55,57–67]

8.2. Role of technology and research in improving regulatory processes

Better quality control, traceability, and validation of therapeutic claims are made possible by technological and research methodology advancements that are revolutionizing the regulatory processes for herbal medications. Blockchain technology, for example, can improve supply chain transparency and guarantee that herbal items are obtained and produced in approved facilities. Additionally,

by identifying important bioactive ingredients and guaranteeing batch-to-batch consistency, genomic, metabolomic, and chemometric technologies offer novel approaches to standardize and validate herbal products. By examining substantial datasets on side effects and efficacy research, artificial intelligence (AI) and machine learning algorithms might help regulators further evaluate the risk profiles of herbal medications. In addition to streamlining regulatory procedures, these technological developments increase customer safety and confidence in herbal goods. [68,69]

8.3. Opportunities for innovation in herbal product development

There are several chances for innovation in the herbal medicinal industry due to the growing demand for natural and plant-based goods. To improve the bioavailability and therapeutic effectiveness of herbal substances, new delivery methods are being investigated, including targeted delivery mechanisms and nanoformulations. There is also growing interest in research on synergistic formulations, which blend many herbs to maximize health effects. More accessible solutions that appeal to a wider range of consumers are made possible by innovations in product formats, such as topical treatments, functional beverages, and capsules. Additionally, eco-friendly packaging and sustainable sourcing methods meet the growing customer demand for items that care about the environment. The herbal drug sector can satisfy contemporary customer wants while adhering to regulations by fusing scientific research, traditional knowledge, and creative product design. Integrating standardized international standards, utilizing state-of-the-art technology, and encouraging product innovation are critical to the future of herbal medication research and regulation. These strategies uphold the legitimacy and therapeutic worth of herbal medicine in modern healthcare while also promoting the safe growth of herbal goods on the international market. [70,71]

9. Conclusion

Due to rising consumer interest in natural remedies and a growing corpus of scientific research demonstrating their potential as therapeutics, the global market for herbal medications is expanding quickly. But this expansion also presents serious regulatory issues since, because of their intricate, varied compositions and long history in traditional medicine, herbal medications need special regulation that sets them apart from regular pharmaceuticals. With different national approaches to quality assurance, safety, and intellectual property protection for herbal goods, this review has brought attention to the complex regulatory environment. Some countries, like the United States, classify herbal pharmaceuticals as dietary supplements, while other countries, like China and India, incorporate traditional systems into regulated healthcare frameworks. This creates inconsistent standards that make it difficult to enter international markets.

One viable strategy to deal with these issues is through the global harmonization of regulatory standards. Standardizing quality and efficacy requirements through international cooperation, aided by guidelines from agencies such as the WHO, could facilitate the cross-border flow of herbal medications and increase customer confidence. By enhancing quality assurance and enabling real-time safety monitoring, technological innovations like blockchain for traceability, AI-driven data analytics, and sophisticated genomic technologies have the potential to improve regulatory procedures. By bridging the gap between conventional wisdom and contemporary scientific validation, these methods can help increase the legitimacy of herbal products. The development of herbal products has a lot of room for innovation in the future, including sustainable processes, innovative delivery systems, and improved formulations. The herbal drug business can move closer to a regulated worldwide market that provides safe, efficient, and easily available natural therapies by striking a balance between scientific rigor and respect for traditional practices. By doing this, this industry can support a comprehensive healthcare model that honors both the therapeutic legacy of plant-based medicine and contemporary pharmacology. To realize this goal, a cooperative, technologically advanced regulatory strategy will be necessary to guarantee that herbal medications fulfill the exacting requirements required to promote global health outcomes.

10. Author's contribution

All authors have significantly contributed to the work, whether by conducting literature searches, drafting, revising, or critically reviewing the article. They have given their final approval of the version to be published, have agreed with the journal to which the article has been submitted, and agree to be accountable for all aspects of the work

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12. Conflict of interest

None.

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