

Regulatory Frameworks and Challenges in Herbal Medicine Development

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Editorial

Approximately 80% of the global population now relies on herbal medicines for various purposes, including home remedies, over-the-counter treatments, and as raw materials in pharmaceutical manufacturing. The widespread use of herbal medicines has drawn significant attention to the importance of ensuring their quality, which must be regulated by standardized pharmacopoeial guidelines and Good Manufacturing Practices (GMP). However, the international trade and marketing of herbal medicines face considerable challenges due to the lack of uniform quality standards among regulatory authorities across different countries. These inconsistencies not only complicate the regulatory process but also limit public access to reliable herbal products [1]. Traditional medicines—commonly referred to as herbal drugs (HDs)—have been used for centuries, particularly in developing countries, where they continue to play a vital role in healthcare systems. The global herbal drug market is expanding rapidly each year, generating billions of U.S. dollars in revenue. To ensure the safety and efficacy of these products, national drug regulatory agencies establish specific guidelines for the registration, manufacturing, and post-market surveillance of novel herbal drugs.

The therapeutic potential and safety of herbal drugs are largely determined by their complete chemical composition. Therefore, according to modern pharmacopoeias and traditional references such as the *Materia Medica*, the quality of herbal medicines should be assessed through robust standardization methods. Unfortunately, the official methodologies outlined in existing compendia are often inadequate for evaluating herbal formulations that contain mixtures of multiple herbs or extracts. The inherent complexity of such preparations—comprised of numerous bioactive compounds whose quality can vary due to source materials, processing techniques, and environmental conditions—poses a major challenge in assuring consistency, safety, and therapeutic efficacy [2]. Herbal medicines are now considered essential components of global healthcare systems, offering not only curative benefits but also serving as valuable resources for preventive health and wellness. Nevertheless, like all medicinal products, herbal medicines can produce both beneficial and adverse effects. Therefore, it is crucial to adopt a cautious and informed approach to their use. To safeguard public health, there is an urgent need to develop a dedicated herbal pharmacovigilance system aimed at identifying, assessing, and mitigating adverse reactions associated with herbal products. Such a system would support the responsible use of herbal medicines and contribute to the overall enhancement of public trust in traditional healthcare practices [3].

The integration of medicinal plants in both allopathic and Siddha medicine offers promising avenues for complementary therapeutic strategies. By demonstrating how medicinal plants can be utilized for healing, there is a significant opportunity to facilitate a collaborative approach between traditional and allopathic medicine. One of the most noteworthy advancements in drug discovery is the growing recognition of medicinal plants as supplementary therapeutic agents. Traditional healing systems such as Siddha medicine, Ayurveda, and Traditional Chinese Medicine (TCM) have long acknowledged the therapeutic potential of plants, minerals, and other natural substances. These systems provided the foundational knowledge that contributed to the development of modern pharmacology, offering valuable insights into the use of plant-based remedies [4]. As alternative healthcare systems gain popularity globally, the herbal products market has expanded rapidly.

However, this growth is hindered by several key challenges, including biodiversity loss, unsustainable harvesting and overuse of medicinal plants, industrialization, biopiracy, and the lack of infrastructure for quality control. To ensure the sustainable growth of herbal medicine in the 21st century, it is crucial to prioritize the conservation of medicinal plant species, conduct research rooted in traditional knowledge, implement rigorous quality control mechanisms, and maintain comprehensive documentation of herbal therapies. These efforts will support the continued relevance and safety of herbal medicine in modern healthcare. In recent years, nanotechnology has emerged as a powerful tool for enhancing the efficacy of herbal medicines. Traditional herbal treatments face challenges such as poor bioavailability, low solubility, and limited therapeutic efficacy. Nanotechnology offers innovative solutions to these issues by employing nanoscale drug delivery systems, such as solid lipid nanoparticles, polymeric nanoparticles, and nanostructured lipid carriers. These systems effectively encapsulate active ingredients, protecting them from degradation and improving their bioavailability. As a result, nanotechnology has shown substantial promise in enhancing the therapeutic effects of herbal treatments, managing chronic illnesses, and expanding their applications within both the healthcare and food industries [5].

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