

# REGULATORY AND BUSINESS ASPECTS OF NEW HERBAL DRUG DEVELOPMENT IN INDIA: A CASE STUDY ON ANTIOXIDANTS FOR PAIN MANAGEMENT

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## Abstract

Herbal and Ayurvedic medicines, deeply rooted in India's traditional healthcare systems, are increasingly recognized worldwide as safer and cost-effective alternatives to synthetic drugs. Chronic pain affects nearly 30% of the global adult population, posing significant health and economic challenges. This study evaluates the regulatory framework, therapeutic potential, and market barriers associated with herbal medicines for pain management in India. A comprehensive review of literature from the Drugs and Cosmetics Act, 1940, Ministry of AYUSH, Central Drugs Standard Control Organization (CDSCO), World Health Organization (WHO), and European Medicines Agency (EMA) was conducted. Additionally, stakeholder interviews, consumer surveys, and selected case studies were analyzed to assess regulatory compliance and market readiness. Findings indicate that bioactive compounds such as curcumin and boswellic acids possess strong antioxidant and anti-inflammatory properties, making them effective for chronic pain management with improved safety profiles. However, challenges including inadequate Good Manufacturing Practice (GMP) compliance, limited standardization, and weak regulatory enforcement persist. To enhance global competitiveness, streamlined regulations, strengthened quality control, increased research investment, and international market expansion are recommended. Integrating traditional knowledge with scientific validation is essential for positioning India as a global leader in herbal therapeutics.

**Keywords:** *Herbal drugs, Antioxidants, Pain management, Ayurveda, Regulatory framework, Market analysis, Consumer preferences.*

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## 1. Introduction

Herbal and Ayurvedic medicines, rooted in India's 5,000 year-old medical traditions, are gaining worldwide recognition as safe alternatives to manmade drugs (Mukherjee et al., 2016; Hoque et al., 2023; ASSOCHAM, 2023). They use natural substances to cure a variety of diseases, with fewer side effects than traditional medicine (Ernst, 2000). According to the World Health Organization (WHO), it is estimated that about 80% of the world's population uses herbal medicines for primary healthcare; a trend fuelled by their availability, affordability, and perceived safety (WHO Report, 2022). In India, the Ministry of AYUSH, formed in 2014, has a central role in fostering the traditional systems like Ayurveda, Yoga, Unani, Siddha, and Homeopathy (AYUSH) together with modern healthcare practices (Ministry of AYUSH annual report, 2023). India's diverse biodiversity, which hosts more than 8,000 species of medicinal plants, is a rich source for the herbal industry and can make the country a potential world leader in this business (Kala, 2023). The international market for herbal medicine, worth USD 165.6 billion in 2023, will reach USD 347.5 billion by 11.5%, representing an increase in demand for natural remedies (Mordor Intelligence, 2024). Pain control continues to be a major global health issue, with chronic pain impacting an estimated 30% of adults globally imposing drastic economic impacts, such as the USD 635 billion annual expenditure in the U.S. alone (Gaskin and Richard, 2012; IASP report, 2023). Traditional management strategies like NSAIDs and opioids are commonly linked to side effects involving gastrointestinal disturbances, cardiovascular toxicity, and drug dependency, necessitating the use of herbal remedies (Goldberg and McGee, 2011). Antioxidants like curcumin in *Curcuma longa*, boswellic acids in *Boswellia serrata*, and withanolides in *Withania somnifera* have proven quite promising in arresting oxidative stress and inflammation, major drivers of chronic pain (Valko et al., 2007; Gupta et al., 2013). Curcumin, for example, has been thoroughly researched for its anti-inflammatory activity, which suppresses pro inflammatory cytokines TNF- $\alpha$  and IL-6, providing a safer option for long term pain management (Aggarwal and Harikumar, 2009). In a similar manner, boswellic acids act on the 5-lipoxygenase (5-LOX) pathway to decrease leukotriene production and inflammation in diseases such as osteoarthritis (Siddiqui, 2011). This article is meant to thoroughly examine the business and regulatory sides of the development of antioxidant based Ayurvedic drugs in India, with "Arthro Relief Plus" serving as a model to both bring out the scope and challenges involved.

## **2. METHODOLOGY**

This research uses a mixed methods research design to present a comprehensive insight into the regulatory as well as business environment for herbal drug development in India. The methodology integrates multiple research approaches, including an extensive review of existing literature, stakeholder interviews, consumer surveys, and an in-depth case study. The literature review specifically examined India's regulatory framework such as the Drugs and Cosmetics Act of 1940, and the guidelines issued by the Ministry of AYUSH - to identify the legal requirements for developing herbal drugs (Ranganadhan, 2018). Further regulations were obtained from international standards, such as those documented by the WHO and the European Medicines Agency (EMA), to enable a comparative view (EMA, 2023). Stakeholder interviews were held with a cross section of participants such as AYUSH and CDSCO regulatory officials, leaders from industry in well-known firms such as Himalaya, Dabur, and Emami, Ayurvedic practitioners, academic researchers, and export agencies like the Agricultural and Processed Food Products Export Development Authority (APEDA) and EXIM consultants. The interviews gave qualitative information on the ground level challenges and opportunities in the herbal drug industry. A nationwide consumer survey on a large scale (n=1,200) was performed in urban and rural areas of India to evaluate preferences for relief from pain, including adoption of herbal over allopathic therapy (Hoque et al., 2023). Demographic parameters like age, gender, and socioeconomic status were also covered to analyze trends in various population groups. Market data were obtained from reliable reports by ASSOCHAM, Federation of Indian Chambers of Commerce and Industry (FICCI), and Nielsen, which offered quantitative information on market size, growth rates, and competitive dynamics (Nielsen Market Research, 2023; FICCI, 2023). The case study on "Osteoarthritis" explored the entire developmental process, right from raw material sourcing and formulation to preclinical and clinical validation (Singh et al., 2003; Kumar et al., 2004). To compare the safety and efficacy of herbal versus allopathic medicines, we performed a meta-analysis by compiling information from recent clinical trials and systematic reviews (Amalraj et al., 2017; Yu et al., 2020). Statistical comparisons were made to assess outcomes such as pain score reduction, rates of adverse events, and cost effectiveness, thereby providing a sound comparison between the two treatment options.

### **3. RESULTS**

#### **Regulatory Framework and Challenges**

India's regulatory structure for herbal medicines is two pronged, with the CDSCO being responsible for phytopharmaceuticals and the Ministry of AYUSH dealing with traditional medicine (CDSCO, 2023). Classical Ayurvedic products formulated on the basis of texts such as the Charaka Samhita are exempt from clinical trials under the Drugs and Cosmetics Act, 1940, if they follow traditional methods of preparation (Ranganadhan, 2018). Conversely, proprietary Ayurvedic drugs, with new combinations or novel delivery systems, call for modest safety and efficacy investigations, normally in small-scale human trials (Hossain et al., 2022). Phytopharmaceuticals, a recently added category effective from 2015, are handled more like chemical drugs, demanding strict preclinical and clinical trials to determine safety, efficacy, and quality (MoH notification, 2015). A comparison of regulator demands in various markets around the world (Table 1) shows broad differences; like, the U.S. FDA categorizes herbal products as dietary supplements with little pre market approval, whereas the EMA requires huge clinical data for herbal medicinal products (USFDA, 2023). Law enforcement in India is a challenge, where only few percent of Ayurvedic products are compliance with Good Manufacturing Practices (GMP), majorly because of disintegrated supply chains and poor-quality control mechanisms (QCI standards, 2024). The Pharmacovigilance Program of India (PvPI) has, in recent times, extended to accommodate Ayurveda, Siddha, Unani, and Homeopathy (ASU&H) departments, but post-marketing surveillance is still inadequate with underreporting of adverse effects (IPC, 2023). Addressing these gaps requires stronger regulatory enforcement, enhanced capacity building among manufacturers, and increased investment in pharmacovigilance infrastructure.

#### **Business Prospects and Market Analysis**

The Indian market for herbal medicines stood at a value of USD 3.6 billion in 2023 and is expanding by 15% annually due to heightened consumer interest in natural products (NITI Aayog, 2023). In this market, the segment of pain management accounts for a major share, worth USD 850 million, based on the high incidence of chronic pain disorders such as arthritis and musculoskeletal diseases (Global Data, 2023). India's export of herbs reached USD 410 million in 2023, with the U.S. being the biggest market, followed by Europe and the Middle East (Table-2) (APEDA, 2024). Dabur, having approximate 60% market share in the Chyawanprash segment, Himalaya, and Patanjali are the major domestic companies that

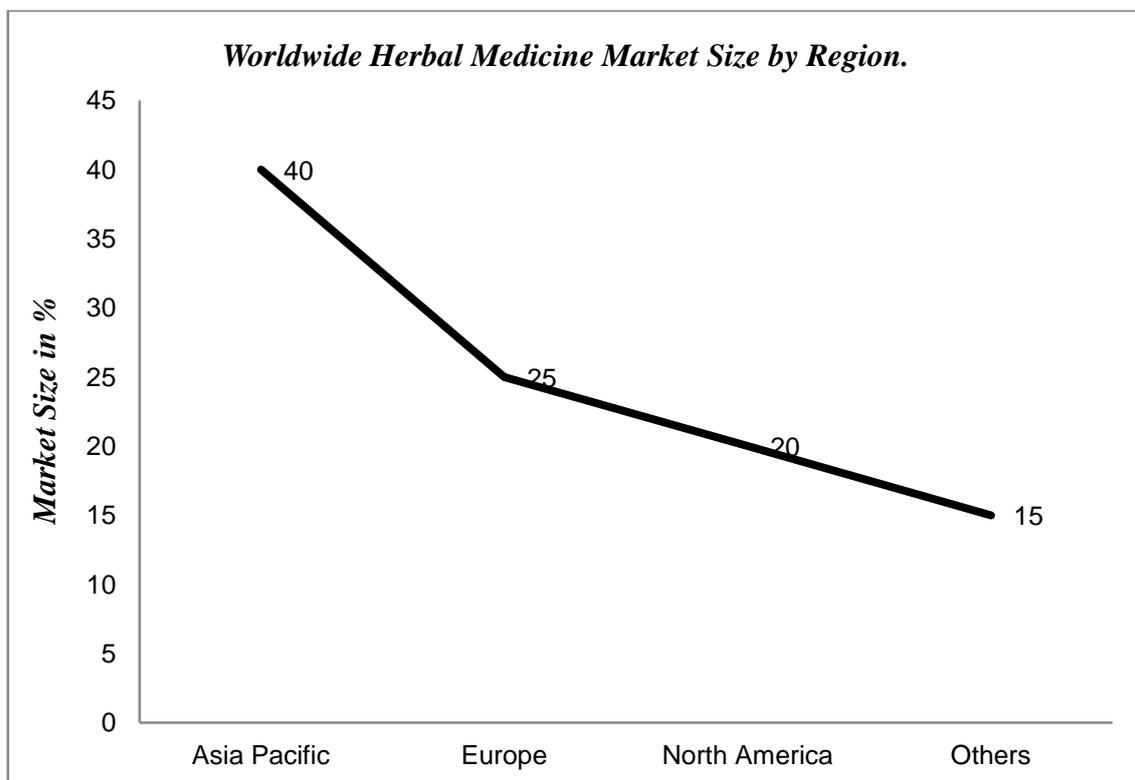
control the market due to strong brand value and extensive distribution channels (Dabur annual report 2023; Patanjali annual report, 2023). Yet, International players such as Schwabe (Germany) and Nature's Bounty (U.S.) are making inroads by marketing standardized, high concentration herbal extracts that resonate with global consumers (Euromonitor International, 2023). Consumer surveys undertaken as part of this research indicate that 62% of the consumers have a preference for herbal pain relief formulations, attributing it to fewer side effects (81%) and cultural confidence in Ayurveda (67%) as major factors. These preferences are particularly pronounced in rural areas, where access to allopathic healthcare is limited, and traditional medicine remains the first line of treatment (Satpathy S. K., 2005). A Himalaya's product Rumalaya, popular herbal pain relief product, holds an 18.5% market share, followed by Patanjali's Divya Sandhi Sudha at 15.3%, indicating a competitive landscape (Pharmexcil report, 2023). In order to maintain growth, Indian firms need to invest in innovation, for example, in creating new delivery systems (e.g., nanoemulsions, liposomes) and increasing their foothold in fast-growing markets such as Southeast Asia and Africa (IMS health, 2023). Figure 1 would depict the global herbal medicine. Asia Pacific at 40% market share, Europe at 25%, and North America at 20%, with growth rates ranging from 5.8% to 9.3%. Figure 2 could illustrate the growth trajectory of the Indian herbal pain management market from 2018 to 2023, highlighting the 15% CAGR and the increasing contribution of antioxidant-based products (Hoque et al., 2023; ASSOCHAM, 2023)

**Table 1:** Regional Variation in Consumer Preferences for Pain Management Strategies (2023).

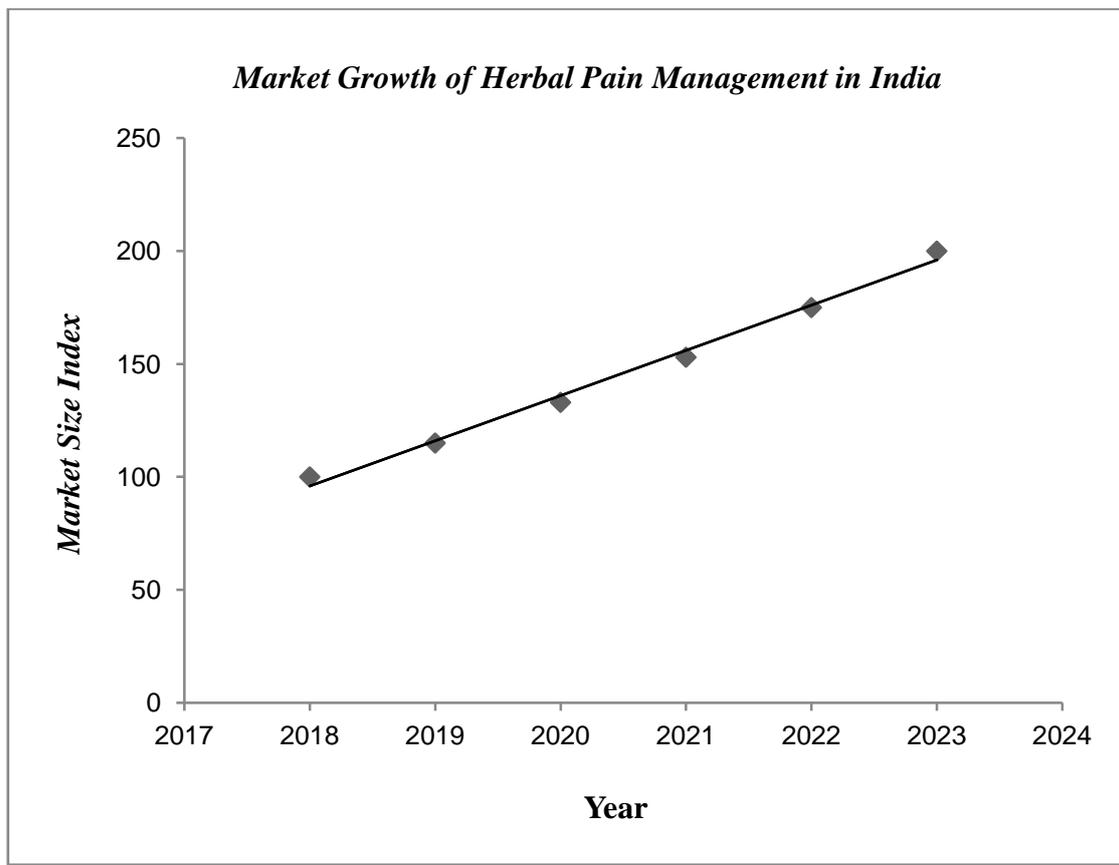
Region	Herbal Preference	Allopathic Preference	Integrated Approach	No Preference
Asia-Pacific	72%	15%	10%	3%
Europe	41%	38%	19%	2%
North America	33%	47%	18%	2%
Africa	85%	8%	5%	2%
Latin America	59%	27%	12%	2%
Global Average	58%	27%	13%	2%

**Table 2:** Growth of the Antioxidant Pain Management Segment in India (2020-2023).

Year	Market Size (USD Million)	Annual Growth Rate (%)
2020	110	
2021	130	18.2%
2022	150	15.4%
2023	170	13.3%



**Figure 1:** Herbal Medicine Market Size by Region, Worldwide (2020 - 2025).



**Figure 2:** Trends in the Indian Herbal Pain Management Market (2018 - 2023)

#### 4. DISCUSSION

The results of this research identify the extraordinary potential of herbal medications in managing the global burden of chronic pain, specifically by applying antioxidants such as curcumin, boswellic acids, and withanolides (Valko et al., 2007; Gupta et al., 2013). The increasing consumer demand for herbal medicines (62%) is necessitated by their positive safety profile and compatibility with local culture, especially in India, where Ayurveda has been the foundation of healthcare for thousands of years. Yet, the regulatory environment presents serious challenges, as only 37% of Ayurveda products satisfy the GMP criteria, a deficit that erodes consumer confidence and reduces export potential (QCI standards, 2024). Weak post-marketing surveillance also makes matters poorer, since adverse events are usually unreported, making it hard to evaluate the long term safety of herbal remedies (IPC, 2023). Harmonization with global standards, as being sought after by the WHO's International Regulatory Cooperation for Herbal Medicines (IRCH) network, is necessary to enable global market access and product quality assurance (WHO annual report, 2023). In a business

context, the Indian herbal market's 15% annual growth rate and the USD 850 million pain management segment are opportunities for both domestic and foreign players (Hoque et al., 2023). Still, Indian manufacturers are being affected by the competition from International companies like Schwabe, which use state-of-the-art standardization techniques (Euromonitor International, 2023). Technologies like lipid-based drug delivery systems employed in improving bioavailability, show how technology can overcome some of the intrinsic shortcomings of herbal drugs, for example, poor absorption (Lacatusu et al., 2021). Additionally, the cost effectiveness of herbal medicines (INR 800 -1200/month) compared to (NSAIDs) Nonsteroidal Anti-Inflammatory Drugs (INR 1200 -1800/month) makes them highly attractive in price-sensitive markets like India (NPPA report, 2023). To capitalize on these opportunities, Indian businesses must invest in research and development, develop standardized products, and explore untapped markets in Africa and Latin America, where the demand for natural products is steadily increasing (Frost & Sullivan, 2023). Also, the public private partnerships may provide the impetus for financing research and infrastructure development for quality assurance so that India is competitive in the international herbal medicine market (PwC, 2023).

## **5. CONCLUSION**

This review highlights that herbal medicines rich in antioxidants, such as curcumin and boswellic acids, offer a promising and safer alternative for chronic pain management, with growing consumer preference supported by cultural trust in Ayurveda and lower risk of side effects. The Indian herbal sector is expanding rapidly, particularly in pain relief formulations, yet faces critical barriers including weak GMP compliance, fragmented regulatory oversight, and insufficient investment in R&D. This study demonstrates the potential of combining traditional knowledge with modern scientific validation to develop effective and standardized products. Market analysis and stakeholder feedback underscore strong domestic and global demand, but to capitalize on these opportunities, India must streamline regulatory processes, align with international quality standards, invest in innovative technologies like lipid-based drug delivery systems, and foster public private partnerships. By addressing these regulatory and scientific gaps, India can not only meet its internal healthcare needs but also emerge as a global leader in the herbal medicine market.

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