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REGULATORY CHALLENGES IN AYURVEDIC MEDICINES: CURRENT SCENARIO AND FUTURE PERSPECTIVES IN INDIA

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ABSTRACT

Background: Ayurvedic medicine, with a history exceeding 5,000 years, remains central to India's healthcare landscape. Despite a growing global herbal medicines market, the regulatory environment governing Ayurvedic medicines presents multifaceted challenges impeding quality assurance, clinical evidence generation, pharmacovigilance, and international market access. **Objective:** To critically examine the current regulatory framework for Ayurvedic medicines in India, delineate principal regulatory challenges, compare Indian provisions with those of the USFDA and EMA, and propose evidence-based recommendations for reform. **Methods:** A narrative review was conducted using peer-reviewed literature, regulatory documents, pharmacopoeial standards, and government policy documents. All 21 references are drawn exclusively from the uploaded source documents. **Results:** The regulatory architecture is anchored in the Drugs and Cosmetics Act 1940, Schedule T GMP, Ministry of AYUSH policies, and Ayurvedic Pharmacopoeial standards. Key challenges include: lack of standardization, quality control deficiencies, variable GMP compliance among MSMEs, insufficient clinical evidence, labelling non-compliance (45% of proprietary formulations lacking Schedule E1 caution warnings), and inadequate pharmacovigilance. **Conclusion:** Strengthening the regulatory framework requires coordinated action across

standardization, GMP enforcement, evidence generation, pharmacovigilance, and international harmonization.

KEYWORDS: *Ayurvedic medicines, Drugs and Cosmetics Act, Schedule T, Good Manufacturing Practices, Ministry of AYUSH, pharmacovigilance.*

1. INTRODUCTION

Ayurveda, derived from the Sanskrit words 'Ayus' (life) and 'Veda' (knowledge), translates as the 'science of life'. It is an ancient healthcare system that originated in India with roots traceable to the Vedic period, practiced continuously for more than 5,000 years, making it one of the oldest continuously practiced medical systems in the world.[1] Its foundational principles revolve around maintaining equilibrium among the three doshas — Vata, Pitta, and Kapha — and their influence on individual constitution, health promotion, and disease management.[1] Classical texts including the Charaka Samhita and Sushruta Samhita, compiled between approximately the 4th century BCE and 2nd century AD, provide foundational accounts of Ayurvedic knowledge.[2]

Ayurveda adopts a holistic approach encompassing the physical, psychological, spiritual, and social dimensions of an individual.[3] A historical perspective published in Alternative Therapies in Health and Medicine describes Ayurveda as a comprehensive system of traditional medicine utilizing medicinal herbs, detoxification therapies, dietary regimens, yoga, and lifestyle management.[4]

The global herbal medicine market has expanded considerably in recent decades. International trade in medicinal plants and products was estimated at US$ 60 billion in 2000, with a 7% annual growth rate, and is projected to reach US$ 5 trillion by 2050.[5,23] In the United States, herbal product usage increased by 380% between 1990 and 1997, with botanical sales reaching US$ 14 billion by 2009.[5] The global pharmaceutical market was worth US$ 550 billion in 2004, with the herbal industry estimated to share approximately US$ 100 billion of this market.[6]

India occupies a distinctive position in the global herbal medicine landscape, possessing rich biodiversity, vast traditional knowledge, and the potential to meet global demand for herbal products.[7] According to the World Health Organization (WHO), approximately 65–80% of the world's population in developing countries depends essentially on plants for primary

health care.[8] However, the loss of biodiversity, the over-exploitation of medicinal plants, a lack of regulation, and inadequate infrastructure are identified as major impediments to the growth of herbal medicine globally.[7]

Regulation of Ayurvedic medicines in India is primarily governed by the Drugs and Cosmetics Act 1940, Schedule T Good Manufacturing Practices, and the Ministry of AYUSH.[11,12] Despite this framework, challenges including lack of standardization, quality control deficiencies, GMP non-compliance, absence of clinical evidence, misleading advertising, and inadequate pharmacovigilance continue to limit the sector's potential.[7,9] This narrative review synthesizes evidence from peer-reviewed literature and regulatory documents to provide a comprehensive analysis of the current regulatory scenario and proposes actionable recommendations for reform.

2. REGULATORY FRAMEWORK FOR AYURVEDIC MEDICINES IN INDIA

The regulation of Ayurvedic medicines in India has evolved through a series of legislative enactments, institutional developments, and pharmacopoeial initiatives. The framework is multi-tiered, involving central legislation, state-level drug control authorities, and specialized bodies under the Ministry of AYUSH.

2.1 Drugs and Cosmetics Act, 1940

The Drugs and Cosmetics (D&C) Act 1940 constitutes the primary legislative instrument governing the import, manufacture, distribution, and sale of drugs in India, including Ayurvedic, Siddha, and Unani (ASU) medicines.[14] Ayurveda, Siddha, and Unani drugs were formally included within the purview of the D&C Act in 1964.[13] The Act mandates licensing requirements for manufacturing units, establishes standards for safety and efficacy through quality control measures, and classifies ASU drugs into classical and proprietary categories.[17,22] Drug regulation is described as the only tool used to ensure the quality, safety, and efficacy of drugs, and the healthcare industry in India is significantly regulated under the D&C Act.[22] Schedule E1 of the Act classifies poisonous substances, mandating specific precautionary labelling for formulations containing such ingredients.[13]

2.2 Drugs and Cosmetics Rules, 1945

The Drugs and Cosmetics Rules 1945 provide detailed procedural requirements for licensing, manufacturing, testing, labelling, and distribution of ASU drugs. Rule 161 and Rule 161A specify comprehensive labelling requirements mandating: list of ingredients with botanical

names, quantity of each ingredient, batch number, manufacturing date, expiry date, and Schedule E1 caution statements.[13] If the label of any drug is false or misleading in any particular, it is classified as 'misbranded' under Section 33E of the Act.[13] The Rules also incorporate the Drugs and Magic Remedies (Objectionable Advertisements) Act 1954, which prohibits therapeutic claims for 56 specified diseases including diabetes, cancer, and AIDS; whoever contravenes this Act on first conviction may be punished with imprisonment extending to 6 months or fine or both.[16,22]

2.3 Schedule T — Good Manufacturing Practices

Schedule T of the D&C Rules 1945 prescribes GMP for ASU medicines, notified through GSR No. 560(E) on June 23, 2000, under Rule 157, and revised through GSR No. 198(E) on March 7, 2003.[11] GMP compliance became mandatory for all new ASU manufacturing facilities from June 23, 2000, with existing units given a two-year grace period.[11] Schedule T mandates: factory premises free from contamination; buildings with hygienic conditions and adequate lighting; segregated storage for raw materials, packaging, and finished goods; quality control laboratory facilities; Standard Operating Procedures (SOPs); and detailed batch production documentation; and GMP certification (Schedule T, Rule 155-B).[11,17,22] Registered Vaidyas, Siddhas, and Hakeems who prepare medicines for direct dispensing to their own patients — without market sale — are exempted from Schedule T under the IMCC Act 1970.[11]

2.4 Ministry of AYUSH

The Ministry of AYUSH was established to provide focused institutional attention to traditional Indian medicine systems. Its predecessor, the Department of ISM&H, was established in March 1995, renamed as the Department of AYUSH in November 2003, and upgraded to a full Ministry in 2014.[12]

Its seven mission areas are: information, education and communication; drug administration; human resource development; medicinal plants; research and development; international collaborations; and AYUSH services.[12] Key regulatory initiatives under the Ministry include: the National AYUSH Mission (NAM), launched in 2014, which envisages enforcement of quality control of drugs; the National Medicinal Plants Board (NMPB); the Traditional Knowledge Digital Library (TKDL), which documents Ayurvedic knowledge to prevent misappropriation and erroneous patenting; Good Clinical Practice (GCP) guidelines

for clinical trials in ASU medicine; and mandatory testing for heavy metals — mercury, arsenic, lead, and cadmium — in all purely herbal Ayurvedic drugs for export purposes.[12]

2.5 Pharmacopoeial Standards

The Ayurvedic Pharmacopoeia of India (API), published by the Pharmacopoeia Commission for Indian Medicine and Homoeopathy (PCIM&H), and the Ayurvedic Formulary of India (AFI) serve as primary official references for quality standards of Ayurvedic drugs.[12] The Indian Pharmacopoeia 2022 (9th edition), effective from December 1, 2022, contains 223 general chapters and 3,152 drug monographs.[15] India is the world's third-largest drug producer in terms of volume, exporting approximately US$ 19 billion worth of pharmaceutical products to more than 200 countries.[15]

3. REGULATORY CHALLENGES

Table 1 below provides a summary of the major regulatory challenges in Ayurvedic medicines identified from the uploaded literature. Each challenge is discussed in detail in the sub-sections that follow.

Table 1: Major Regulatory Challenges in Ayurvedic Medicines.

Regulatory Challenge	Key Issues from Uploaded Literature	References
Lack of Standardization	Biological variability of raw materials; no universal marker compounds; 95% raw material from uncultivated sources; inadequate analytical method validation	[7,17,18]
Quality Control Issues	Inconsistent supply chains; adulteration; heavy metal contamination; lack of validated detection methods; inadequate testing infrastructure; unskilled collection	[9,12,17,19]
GMP Non-Compliance	>80% of industry are MSMEs with resource constraints; inadequate laboratory facilities; inconsistent SOPs; poor batch documentation; insufficient trained personnel; GMP certification under Schedule T Rule 155-B not uniformly obtained	[11,12,17,22]
Clinical Evidence Gaps	No mandatory pre-market clinical data for classical formulations; RCT methodology incompatible with individualized Ayurvedic practice; Rule 158B only partially addresses this since 2010	[3,8,12,16]
Labelling Non-Compliance	45% of proprietary labels missing Schedule E1 caution warnings; 14% of classical labels non-compliant for ingredient information; systematic misbranding under D&C Act Section 33E	[13]

Misleading Advertising	1,434 regulatory notices in Maharashtra alone (2013-14); unsubstantiated claims for 56 prohibited diseases; celebrity endorsements; digital/social media inadequately regulated	[16]
Pharmacovigilance Deficits	Under-developed National Pharmacovigilance Programme; 'natural = safe' misconception; herb-drug interactions underreported; composition variability complicates adverse event attribution	[9,17,19]
International Barriers	Indian standards not recognized in EU/US; THMPD requires 30-year EU traditional use documentation; FDA requires clinical trial evidence; heavy metal testing mandatory for export; AYUSH products classified as supplements not medicines in most global markets	[7,12,20,21,22]

3.1 Lack of Standardization

Standardization represents the most fundamental regulatory challenge in the Ayurvedic medicines sector. Herbal formulations are complex mixtures whose compositions vary significantly according to plant species, growing conditions, harvesting practices, geographical location, seasonal variation, post-harvest processing, and storage conditions.[18] The WHO, FDA, and EMA have formulated guidelines for quality control of herbal medicines, but international harmonization remains problematic due to the complexity of herbal preparations and the absence of universal standards.[18]

A critical deficiency identified in the literature is the lack of validated testing methods to detect adulteration and absence of universally accepted biologically active markers for product standardization.[17] Approximately 95% of raw materials used in ASU manufacturing are sourced from uncultivated areas, where disorganized collection leads to significant quality variation and adulteration risk.[17] Advanced analytical methods including chromatography (HPLC, TLC), spectroscopy (NMR), and DNA barcoding are available for plant material identification but their universal adoption across the fragmented industry remains limited.[18]

3.2 Quality Control Issues

Quality control challenges are multidimensional, encompassing raw material sourcing, manufacturing process control, testing infrastructure, and post-market surveillance.[17] Supply chains for quality-certified herbal raw materials are frequently inconsistent, and awareness of Good Agricultural Practices (GAP) among cultivators remains limited.[17] Testing for heavy metals — mercury, arsenic, lead, and cadmium — is mandatory for export but inconsistently enforced for the domestic market.[12]

The FSSAI Act 2006 also governs safety and quality of herbal supplements, enforcing standards for freedom from contaminants.[17] Calixto established that plants contain hundreds of constituents, some are very toxic, and adverse effects of phytotherapeutic agents are well-documented by controlled clinical studies.[9] This makes quality control not merely a regulatory concern but a direct public health imperative.

3.3 GMP Compliance Challenges

More than 80% of ASU manufacturing enterprises are MSMEs that face disproportionate challenges in meeting infrastructure, personnel, documentation, and laboratory requirements under Schedule T.[12] Key compliance deficiencies include: inconsistent SOPs; inadequate batch production documentation; insufficient storage conditions for temperature-sensitive materials; limited adoption of advanced QC technologies; and inadequate training of manufacturing personnel.[17]

The Ministry of AYUSH has initiated cluster-based approaches through the National AYUSH Mission to support MSME manufacturers in achieving GMP compliance.[12] Key licensing provisions for ASU manufacturers include application for grant or renewal under Rule 153, conditions for grant or renewal under Rule 157, GMP certification under Schedule T and Rule 155-B, and provision of free sale certificate and non-conviction certificate under Rule 158-C.[22] Regular GMP and GAP training programmes, developed in collaboration with academic institutions, have been identified as essential for addressing workforce capability gaps.[17]

3.4 Scientific and Clinical Evidence Gaps

Ayurvedic proprietary and patent (P&P) products can currently be placed on the Indian market without mandatory clinical evidence — a situation the National Policy 2002 identified as requiring reform.[16] The fundamental challenge is that conventional randomized controlled trial (RCT) methodology is not easily applicable to Ayurvedic treatment, which is inherently individualized according to each patient's prakriti and dosha constitution, rather than standardized across a homogeneous population.[3,8]

Drug Rule 158B, enacted in August 2010, introduced a requirement for proof of effectiveness for proprietary ASU drug licensing.[12] The reverse pharmacology approach — translating Ayurvedic clinical experiences into systematic drug discovery — has been identified as a scientifically valid and culturally appropriate evidence-generation pathway.[16] Non-

Communicable Diseases account for approximately 60% of all deaths in India (5.87 million), representing a major area where validated clinical evidence is urgently needed.[16]

3.5 Labelling and Advertisement Issues

The labelling compliance survey by Chauhan, Kolhe, and Acharya evaluated 318 labels — 161 classical and 157 proprietary — from 26 Ayurvedic retailers against the D&C Act Rule 161 checklist.[13] The survey found that 14% of classical formulation labels were non-compliant for ingredient listing, and Schedule E1 caution warnings were missing on 11% of classical and 45% of proprietary medicine labels.[13] A review of the Ayurvedic Formulary of India identified 372 classical formulations containing Schedule E1 drug ingredients, underscoring the breadth of the public safety risk.[13]

In the advertising domain, Maharashtra State FDA served 1,434 notices under the Drugs and Magic Remedies Act 1954 to print and electronic media in 2013–14 alone.[16] Many television channels broadcast misleading advertisements with tall claims for conditions such as diabetes and cancer, with celebrities serving as brand ambassadors making unrealistic therapeutic claims.[16] Social and digital media channels currently remain largely outside the coverage of the 1954 legislation.

3.6 Pharmacovigilance Challenges

The National Pharmacovigilance Programme for ASU drugs has been established but requires substantial strengthening in infrastructure, capacity, and culture of adverse drug reaction (ADR) reporting.[17] The widespread public perception that Ayurvedic medicines are inherently safe because they derive from natural sources is empirically unfounded: plants contain hundreds of constituents and some are very toxic, and adverse effects of phytotherapeutic agents are confirmed by controlled clinical studies.[9]

Potential herb-drug interactions represent an additional pharmacovigilance concern, compounded by patients not disclosing traditional medicine use to allopathic healthcare providers.[19] Heinrich emphasizes that ensuring quality along the entire supply chain — from primary producers to end-users — is a prerequisite for meaningful pharmacovigilance, as adverse events arising from adulteration or contamination may be misattributed to the pharmacological action of the product.[19]

3.7 Export and International Regulatory Challenges

In the European Union, the Traditional Herbal Medicinal Products Directive (THMPD) 2004/24/EC provides a simplified registration pathway requiring 30 years of traditional use evidence (at least 15 years within the EU), a comprehensive quality dossier demonstrating supply chain GMP compliance, and expert safety reports.[21] Therapeutic claims are restricted to traditional use statements only.[21] This pathway is difficult for Indian Ayurvedic products to access because the required EU traditional use documentation is largely absent.

In the United States, botanical drug products are regulated under the USFDA Botanical Drug Development Guidance, which requires progressive preclinical and clinical evidence for marketing authorization as a drug.[20] Rousseaux and Schachter establish that regulatory authorities globally expect sufficient proof of efficacy, safety, and quality through critical review of preclinical and clinical data as well as chemistry and manufacturing documentation.[20] Sharma and Pundarikakshudu note that drugs of AYUSH systems are popular globally but mostly classified as herbal products, natural health products, or dietary supplements rather than traditional medicines, which significantly affects the regulatory pathway available to manufacturers.[22]

The Ministry of AYUSH has identified export promotion as a priority, making mandatory the testing for heavy metals in all purely herbal Ayurvedic drugs for export, and developing the TKDL and AYUSH clusters programme to support international competitiveness.[12] Sen, Chakraborty, and De identify lack of regulation and infrastructure, alongside biopiracy and biodiversity loss, as major impediments to the international growth of herbal medicine.[7]

4. COMPARATIVE ANALYSIS OF INDIA, USFDA AND EMA REGULATIONS

A comparative analysis of the regulatory frameworks governing Ayurvedic and herbal medicines in India, the United States, and the European Union reveals significant divergences in regulatory philosophy, evidential requirements, and registration pathways. Table 2 summarizes these key differences.

In India, Ayurvedic medicines are regulated primarily on the basis of traditional use and pharmacopoeial standards, without mandatory pre-market clinical efficacy data for classical formulations.[12,14] In the United States, botanical drug products require progressive clinical evidence for marketing authorization, while herbal products sold without drug claims may be marketed as dietary supplements with the disclaimer that neither safety nor efficacy has been

evaluated by the FDA.[20,22] The United States and European Union are identified as the largest and most potential markets for medicines globally, categorized as regulated markets, whereas countries such as Brazil, CIS nations, Africa, and ASEAN constitute semi-regulated or emerging markets.[22]

In the European Union, the THMPD 2004/24/EC requires 30 years of documented traditional use, a comprehensive quality dossier, and expert safety reports — with therapeutic claims restricted to traditional use statements only.[21] Heinrich illustrates this regulatory variability through the example of Ginkgo biloba: until 2008 in the UK it was considered a food, while in Germany it has consistently been classified as a medicinal product, and in the USA it is a food supplement.[19]

Table 2: Comparative Analysis of India, USFDA and EMA Regulatory Frameworks.

Parameter	India	USFDA	EMA
Regulatory Basis	D&C Act 1940; Ministry of AYUSH[12,14]	Botanical Drug Development Guidance[20]	Directive 2004/24/EC (THMPD)[21]
Pre-market Evidence	Traditional use; no mandatory clinical trial for classical drugs[12]	Progressive preclinical & clinical trial data required[20]	30 years traditional use; no clinical trial for THMPD pathway[21]
GMP Requirements	Schedule T GMP; mandatory since 2000[11]	21 CFR Parts 111, 210, 211; CGMP[20]	EU GMP; mandatory along entire supply chain[21]
Quality Standards	Ayurvedic Pharmacopoeia; Indian Pharmacopoeia 2022[12,15]	United States Pharmacopeia; FDA quality guidance[20]	European Pharmacopoeia; EMA quality guideline[21]
Labelling	Rule 161/161A; Schedule E1 caution mandatory[13]	FDA labelling requirements; Supplement Facts panel[20]	Restricted to traditional use statements; PIL required[21]
Advertising	DMR Act 1954; 56 prohibited disease claims[16]	FTC regulation; FDA enforcement of drug claim prohibitions[20]	Claims restricted to traditional use statements only[21]
Pharmacovigilance	National Pharmacovigilance Programme for ASU; developing[17]	MedWatch; CFSAN adverse event reporting system[20]	EudraVigilance; periodic safety update reports[21]
International Recognition	Not mutually recognized in EU/US; major export barrier[7]	FDA authorization required for US market[20]	THMPD registration valid across all EU member states[21]

5. DISCUSSION

This narrative review confirms that while India possesses an established legislative and institutional framework for regulating Ayurvedic medicines, significant implementation gaps persist. The primary challenge is not the absence of regulatory provisions, but rather the inconsistency of their implementation — particularly across the large number of MSMEs that dominate the sector.[12,17]

The standardization challenge is fundamentally linked to the biological nature of herbal raw materials. As Prajapati and Pandey demonstrate, herbal medicines vary based on plant species, growth conditions, harvesting practices, and extraction methods — making validated analytical methods and internationally recognized marker compounds essential foundations of quality assurance.[18] Despite advances in HPLC, TLC, NMR, and DNA barcoding techniques, the absence of universal standards continues to be the principal barrier to global harmonization.[18]+

The clinical evidence gap has particularly consequential implications for international recognition. The traditional use paradigm underlying Indian regulatory philosophy is not accepted by US and EU regulatory frameworks as a substitute for controlled clinical trial data.[20,21] The reverse pharmacology approach offers a scientifically valid pathway to bridging this gap without compromising Ayurvedic epistemological principles.[16]

The labelling findings are particularly concerning from a public health perspective. The absence of Schedule E1 caution warnings from 45% of proprietary formulation labels represents a direct patient safety failure with serious regulatory implications.[13] This is compounded by widespread advertising making unsubstantiated claims — documented through 1,434 regulatory notices in Maharashtra alone in a single year.[16]

The pharmacovigilance gap reflects both a global challenge and a specifically Indian regulatory deficit. Calixto's foundational review establishes that the belief that natural equates to safe is empirically unfounded, and the adverse effects of phytotherapeutic agents are confirmed by controlled clinical studies.[9] Heinrich further emphasizes that quality assurance along the entire supply chain is a prerequisite for meaningful pharmacovigilance.[19]

The comparative analysis reveals that the EMA's THMPD model — which accepts traditional use as the basis for limited marketing authorization while requiring rigorous quality

documentation — may offer a more accessible international template for Indian Ayurvedic exporters than the full clinical evidence requirements of the FDA.[21] However, even this pathway demands quality documentation standards that most Indian manufacturers are currently ill-equipped to provide.[22] Sharma and Pundarikakshudu further emphasize that the success of herbal products in international markets depends on compliance with established documentation standards and Standard Operating Procedures, following guidelines published by the FDA, WHO, ICH, and CDSCO.[22]

6. FUTURE PERSPECTIVES AND RECOMMENDATIONS

6.1 Strengthening Standardization

Development and validation of standardized analytical methods for identification, quality testing, and marker compound quantification specific to Ayurvedic drug categories is a priority.[18] Good Agricultural Practices (GAP) training for medicinal plant cultivators and collectors should be institutionalized to address upstream quality determinants.[17]

6.2 GMP Compliance Support for MSMEs

Targeted GMP compliance support for MSMEs — including subsidized infrastructure upgrades, mobile quality testing units, and shared analytical laboratory facilities — would address resource constraints impeding Schedule T compliance.[17] Regular GMP and GAP training programmes, developed in partnership with academic institutions, are essential for workforce capacity building.[17]

6.3 Clinical Evidence Generation

Investment in dedicated clinical research programmes for Ayurvedic medicines is necessary to bridge the evidence gap.[8] The reverse pharmacology approach — translating clinical experiences from Ayurvedic practice into systematic drug development — offers a scientifically valid and culturally appropriate evidence-generation pathway.[16] Collaborative networks between AYUSH institutions, Indian universities, and international research partners would accelerate evidence generation.

6.4 Pharmacovigilance Strengthening

The National Pharmacovigilance Programme for ASU drugs requires expansion in reach, reporting infrastructure, and analytical capacity.[17] Digital pharmacovigilance platforms adapted for Ayurvedic practice settings and integration of ASU adverse event reporting into the national pharmacovigilance network should be prioritized.[19]

6.5 Labelling and Advertising Reform

Strict enforcement of Rule 161 and Rule 161A provisions, supported by systematic market surveillance and proportionate penalties for non-compliance, is urgently needed.[13] Amendment of the Drugs and Magic Remedies Act to cover digital and social media advertising channels is essential to address the contemporary advertising landscape.[16]

6.6 International Regulatory Harmonization

India should engage with the WHO and international regulatory networks to advocate for internationally recognized standards for Ayurvedic medicines that respect traditional knowledge while meeting global quality and safety expectations.[7,19] The TKDL provides a valuable foundation for documentation standards that could facilitate international regulatory recognition.[12] Bilateral mutual recognition agreements for GMP inspection and quality testing between India and key export markets would reduce regulatory duplication and trade barriers.

7. CONCLUSION

This narrative review has provided a comprehensive examination of the regulatory landscape governing Ayurvedic medicines in India, drawing on 21 source documents. India possesses an established framework anchored in the D&C Act 1940, Schedule T GMP, Ministry of AYUSH policies, and official Pharmacopoeial standards — but significant implementation gaps persist across all domains of quality assurance.

The principal challenges — standardization deficits, quality control insufficiencies, GMP compliance gaps among MSMEs, absence of mandatory clinical evidence, widespread labelling non-compliance[13], rudimentary pharmacovigilance infrastructure, and international regulatory barriers — are interrelated and mutually reinforcing. Comparative analysis with USFDA[20] and EMA[21] frameworks confirms that Indian regulatory provisions currently lack the evidential rigor required for international regulatory recognition.

The coordinated recommendations put forward — spanning standardization, GMP compliance support, adapted clinical research, pharmacovigilance strengthening, labelling enforcement, advertising reform, and international harmonization — provide a practical roadmap for policymakers, manufacturers, researchers, and healthcare professionals. Fulfilling Ayurveda's potential in the global healthcare landscape of the 21st century requires

a regulatory framework equal to its more than 5,000-year heritage of service to human health.[1,3]

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AUTHOR CONTRIBUTIONS

Sumit Chaudhary: Conceptualization of the review, literature search and synthesis, manuscript drafting, Vancouver-style citation compilation, and correspondence with the journal. Prerna Bhalla: Assisted in literature collection, review of regulatory documents, and critical revision of the manuscript for intellectual content. Dr. Anil Kumar Sharma: Provided senior academic guidance, critical review of the regulatory framework sections, validation of content related to Traditional Indian Medicines regulation, and final approval of the version to be submitted. All authors read and approved the final manuscript.

CONFLICT OF INTEREST

The authors declare no conflict of interest. All three authors are associated with M/s Aimil Pharmaceuticals India Ltd., an Ayurvedic pharmaceutical manufacturer. This review presents an independent academic analysis of the regulatory landscape for Ayurvedic medicines in India and does not represent the official views or positions of the employing organization.

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