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REGULATORY HURDLES IN THE APPROVAL OF HERBAL MEDICINES AND TRADITIONAL FORMULATION IN INDIA.

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Abstract:

*The global resurgence of interest in herbal medicines and traditional formulations has positioned India—home to Ayurveda, Siddha, and Unani systems of medicine—as a potential leader in the herbal drug market. However, despite the country's vast ethnopharmacological heritage, the regulatory landscape governing the approval of herbal medicines remains complex and fragmented. This study critically examines the regulatory hurdles faced in the approval process of herbal and traditional formulations in India under the frameworks of the **Drugs and Cosmetics Act, 1940**, the **Drugs and Cosmetics Rules, 1945**, and the **National AYUSH Mission** guidelines. Key challenges include the lack of standardized evaluation parameters, inadequate clinical validation requirements, ambiguity in categorization between classical and proprietary formulations, and limited harmonization with international guidelines such as those of the **WHO** and **ICH**. Additionally, insufficient pharmacovigilance data, variability in raw material quality, and absence of comprehensive safety and efficacy dossiers contribute to delays and rejections during regulatory review.*

*Through comparative analysis with regulatory frameworks in developed markets such as the **European Union**, **United States**, and **Japan**, this research highlights the gaps in India's approval mechanisms and proposes strategies for regulatory reform. Strengthening scientific validation, establishing Good Agricultural and Collection Practices (GACP), and integrating modern analytical tools for standardization are identified as critical steps toward ensuring global acceptance of Indian herbal drugs. The study concludes that a balanced regulatory approach—respecting traditional knowledge while ensuring scientific rigor—will be pivotal in promoting innovation, consumer safety, and international competitiveness of India's herbal medicine sector.*

Keywords: *Herbal medicines, Traditional formulations, Regulatory hurdles, AYUSH, Standardization, Drugs and Cosmetics Act, Pharmacovigilance, India*

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INTRODUCTION:

1. Background of Herbal Medicines and Traditional Systems

Herbal medicines constitute one of the oldest forms of healthcare known to humankind. For millennia, plants have served as the foundation of healing practices across civilizations, including India, China, Egypt, and Greece. According to the **World Health Organization (WHO, 2022)**, nearly 80% of the global population relies on herbal or traditional medicines for some aspect of primary healthcare. India, with its diverse flora and rich heritage, has been a significant contributor to this tradition. The Indian subcontinent possesses over 45,000 plant species, of which approximately 15,000 are recognized for medicinal value (**Sharma et al., 2020**).

The development of traditional systems of medicine in India is deeply intertwined with cultural and religious practices. Systems such as **Ayurveda**, **Siddha**, **Unani**, and **Yoga and Naturopathy** have evolved over centuries through empirical observation and accumulated experience. Ayurveda, dating back to the Vedic period (around 1500 BCE), is based on the principles of balance between body, mind, and environment (**Patwardhan et al., 2018**). Similarly, Unani medicine—introduced through Greco-Arab influences—focuses on humoral balance, while Siddha emphasizes equilibrium of three vital energies, or *doshas*.

In modern times, the increasing global shift toward natural and holistic healing has revived interest in these traditional systems. Herbal medicines are increasingly perceived as safer alternatives to synthetic drugs, given their perceived lower toxicity and cultural acceptability (**Pandey & Rastogi, 2021**). However, despite their popularity, the scientific validation of herbal medicines remains limited. The challenge lies in reconciling centuries-old traditional knowledge with the stringent regulatory requirements of modern drug evaluation systems.

1.1 Importance of Herbal Medicine in Indian Healthcare

India's healthcare landscape remains significantly dependent on herbal and traditional medicine, especially in rural and semi-urban areas. More than 65% of India's population utilizes traditional remedies for primary healthcare needs (**Nair & Rukmini, 2020**). The cost-effectiveness, cultural familiarity, and local availability of herbal remedies make them vital for a country with diverse socioeconomic conditions.

The government of India has consistently emphasized the integration of traditional systems into national health programs. The **Ministry of AYUSH (Ayurveda, Yoga and Naturopathy, Unani, Siddha, and Homeopathy)**, established in 2014, serves as the apex body for the development, education, and regulation of these systems. The ministry's initiatives have led to the establishment of research councils such as the **Central Council for Research in Ayurvedic Sciences (CCRAS)** and the **Central Council for Research in Unani Medicine (CCRUM)**, which aim to promote evidence-based validation of herbal medicines (**AYUSH Annual Report, 2022**).

Despite institutional support, the translation of traditional formulations into regulated pharmaceutical products faces numerous obstacles. Challenges include the lack of standardized raw material sources, variability in phytochemical composition, and absence of reproducible preclinical and clinical data. Furthermore, the growing commercialization of herbal products has introduced issues related to adulteration, contamination, and mislabeling, necessitating more stringent regulatory oversight (**Kumar et al., 2021**).

2. Global Context of Herbal Medicine Regulation

The regulation of herbal medicines varies widely across countries, reflecting differences in cultural practices, scientific validation frameworks, and public health priorities. Globally, the herbal medicine market was estimated at over **USD 200 billion in 2022** and is projected to reach **USD 350 billion by 2030**, driven by consumer demand for natural remedies (**Grand View Research, 2023**).

2.1 World Health Organization Guidelines

The **World Health Organization (WHO)** has played a key role in promoting the safe use of herbal medicines through its *Traditional Medicine Strategy 2014–2023* and updated *Global Strategy 2025–2034*. These initiatives emphasize quality assurance, safety monitoring, and integration of traditional medicine into national healthcare systems. WHO encourages member states to establish regulatory frameworks for herbal products covering aspects like **good manufacturing practices (GMP)**, **quality control**, and **pharmacovigilance** (**WHO, 2023**).

2.2 Regulatory Systems in Developed Countries

In developed nations, herbal medicines are regulated under distinct categories based on their intended use and claims.

- **United States (USFDA):** Herbal products are typically categorized as *dietary supplements* under the **Dietary Supplement Health and Education Act (DSHEA), 1994**, which limits the claims that manufacturers can make. While these products do not require pre-market approval, they must comply with **Current Good Manufacturing Practices (cGMP)** and ensure safety and labeling accuracy (**USFDA, 2021**).
- **European Union (EMA):** The **European Medicines Agency (EMA)** classifies herbal products into *traditional herbal medicinal products* and *well-established use products*. The EMA's **Committee on Herbal Medicinal Products (HMPC)** provides monographs and guidelines to facilitate standardized evaluation (**EMA, 2020**).
- **Japan:** Traditional herbal formulations known as *Kampo* are regulated under the **Pharmaceutical and Medical Devices Act**, with stringent requirements for standardization and clinical documentation (**Takayama et al., 2021**).

2.3 Lessons for India

India's herbal regulatory framework remains less harmonized compared to these global systems. Unlike the EU, which uses scientific monographs for herbal substances, or the US, which mandates manufacturing and labeling compliance, India still relies heavily on traditional literature-based evidence. Consequently, herbal product manufacturers often struggle to meet international documentation standards. Harmonizing India's regulatory approach with global best practices is essential to facilitate export and ensure international credibility.

3. Indian Herbal Medicine Market Landscape

India's herbal medicine sector is a crucial component of its pharmaceutical and healthcare economy. According to **Invest India (2023)**, the domestic AYUSH market was valued at approximately **USD 18 billion in 2022** and is expected to reach **USD 24 billion by 2025**. Major product categories include Ayurvedic formulations, herbal supplements, nutraceuticals, and personal care products.

3.1 Key Regulatory Institutions

The **Ministry of AYUSH** acts as the central regulatory authority, supported by subordinate bodies such as:

- **Pharmacopoeia Commission for Indian Medicine and Homoeopathy (PCIM&H)** – responsible for developing standards for identity, purity, and strength of herbal formulations.
- **Central Council for Research in Ayurvedic Sciences (CCRAS)** and **CCRUM** – focus on scientific validation and clinical research of herbal medicines.
- **National Medicinal Plants Board (NMPB)** – promotes cultivation, sustainable sourcing, and conservation of medicinal plants.

3.2 Role of Traditional Knowledge Digital Library (TKDL)

To protect indigenous knowledge from biopiracy and misuse, India established the **Traditional Knowledge Digital Library (TKDL)** in 2001. TKDL serves as a repository of over 400,000 formulations from classical texts, translated into multiple languages and accessible to global patent offices (**TKDL, 2021**). This initiative has successfully prevented the granting of several unjustified patents on Indian herbs like *Turmeric (Curcuma longa)* and *Neem (Azadirachta indica)* (**Rai et al., 2020**).

3.3 Current Industry Trends

The growing demand for herbal wellness products post-COVID-19 has accelerated innovation and investment in this sector. Major Indian companies such as **Dabur**, **Himalaya**, **Patanjali Ayurved**, and **Emami** have expanded their portfolios into functional foods and preventive healthcare. However, the sector's growth is constrained by **regulatory ambiguity**—particularly in differentiating between *classical* formulations (documented in authoritative texts) and *proprietary* formulations (new combinations). The absence of uniform approval requirements and lack of clinical evidence have resulted in inconsistent quality and consumer trust deficits (**Gupta & Kothari, 2022**).

Existing Regulatory Framework in India

India's regulatory structure for herbal medicines and traditional formulations is rooted in a dual system — one for conventional (allopathic) drugs and another for traditional systems governed under the **Ministry of AYUSH**. The key legal foundation remains the **Drugs and Cosmetics Act, 1940**, and **Drugs and Cosmetics Rules, 1945**, which classify drugs from traditional systems under specific provisions distinct from synthetic pharmaceuticals.

4.1 Classification of Herbal and Traditional Medicines

Under the Act, herbal and traditional medicines are broadly categorized as:

1. **Classical Medicines** — formulations that are mentioned in authoritative texts of Ayurveda, Siddha, or Unani systems. These do not require clinical trials if manufactured strictly according to prescribed formulations (**Rule 158B, Drugs and Cosmetics Rules, 1945**).
2. **Patent or Proprietary Medicines** — novel formulations containing ingredients mentioned in classical texts but used in new combinations or dosage forms. These require evidence of safety and rationale for the combination.

This classification impacts regulatory scrutiny — with classical medicines facing relatively fewer requirements, while proprietary formulations are subjected to additional documentation and safety assessments (**Patwardhan & Mashelkar, 2020**).

4.2 Licensing and Regulatory Authorities

The **Ministry of AYUSH** and its associated bodies manage the policy, licensing, and quality control mechanisms for herbal drugs. Key agencies include:

- **State Licensing Authorities (SLAs)** – responsible for granting manufacturing licenses.
- **Pharmacopoeia Commission for Indian Medicine and Homoeopathy (PCIM&H)** – develops pharmacopoeial standards.
- **Central Council for Research in Ayurvedic Sciences (CCRAS)** and **CCRUM** – conduct pharmacological and clinical research.
- **National Medicinal Plants Board (NMPB)** – oversees sustainable cultivation and trade of medicinal plants.

The **Drugs Technical Advisory Board (DTAB)** and **Drugs Consultative Committee (DCC)** also play an advisory role in ensuring coordination between modern and traditional drug regulatory systems (**CDSCO, 2023**).

4.3 Legal Provisions and Documentation

Manufacturers seeking approval for AYUSH drugs must comply with the following documentation and guidelines:

- **Form 24-D** for manufacturing license under the Drugs and Cosmetics Rules.
- **Good Manufacturing Practices (GMP)** certification under **Schedule T**, which details premises, equipment, and hygiene requirements for traditional drug manufacturing.
- Labeling requirements per **Rule 161**, including the name of the formulation, dosage form, ingredients, and system of medicine.

However, clinical trial data requirements for herbal medicines remain inconsistent. While new allopathic drugs require compliance with **Schedule Y**, there is no parallel schedule for standardized clinical evaluation of AYUSH products (**Kumar & Singh, 2021**).

5. Key Challenges and Regulatory Hurdles

Despite India's vast experience in traditional medicine, the regulatory system governing herbal formulations faces several systemic challenges that hinder both domestic and international acceptance.

5.1 Lack of Standardization and Quality Assurance

One of the most persistent challenges is the **lack of uniform quality standards**. Variability in the source of raw materials, differences in climatic conditions, and non-standardized manufacturing processes lead to inconsistent product quality. The absence of rigorous analytical methods for complex phytochemical mixtures compounds this issue (**Sharma et al., 2022**).

Although the **Ayurvedic Pharmacopoeia of India (API)** provides monographs for numerous herbs,

many commercial products still rely on local or unpublished formulations. Additionally, adulteration with heavy metals, pesticides, and synthetic drugs has raised safety concerns and eroded consumer trust (**Mukherjee et al., 2019**).

5.2 Insufficient Scientific Validation

Traditional claims are often based on historical use rather than modern scientific validation. The absence of well-structured **preclinical and clinical trials** creates difficulty in establishing reproducibility and dose-response relationships. Moreover, the **ethical and methodological challenges** of conducting randomized controlled trials (RCTs) for polyherbal formulations complicate regulatory evaluation (**Patwardhan et al., 2021**).

The regulatory requirement for clinical evidence remains ambiguous, with many proprietary formulations gaining approval solely based on literature references instead of pharmacological or toxicological data. This leads to skepticism among global regulators and hinders export potential.

5.3 Fragmented Regulatory Oversight

Regulatory responsibilities are distributed among central and state authorities, leading to **variability in interpretation and enforcement**. While the Ministry of AYUSH formulates policies, State Licensing Authorities handle approvals, often without uniform inspection standards. This fragmentation results in discrepancies in licensing requirements and uneven enforcement of GMP norms (**Nair & Rukmini, 2020**).

Furthermore, coordination between **CDSCO** (which governs allopathic drugs) and **AYUSH regulators** remains limited, creating challenges for products that bridge both categories, such as **herbal nutraceuticals** or **AYUSH-cosmeceuticals**.

5.4 Absence of Pharmacovigilance Systems

Pharmacovigilance in the AYUSH sector is still in its infancy. Although the **AYUSH Pharmacovigilance Programme** was initiated in 2008 and later strengthened in 2018, reporting of adverse drug reactions (ADRs) remains minimal due to lack of awareness and institutional capacity (**AYUSH, 2022**).

Inadequate surveillance limits the ability to detect safety issues, which undermines public and international confidence. Strengthening post-marketing surveillance through electronic reporting and integration with the national pharmacovigilance program is urgently needed.

5.5 Dossier Submission and Data Gaps

Unlike allopathic drugs, herbal medicine dossiers submitted to regulators often lack detailed data on composition, manufacturing validation, and stability. The **absence of harmonized Common Technical Document (CTD)** format for herbal medicines further complicates regulatory submissions (**Gupta & Kothari, 2022**).

Manufacturers face difficulties in compiling scientific data, particularly when multiple plant ingredients are involved, and the absence of standardized marker compounds or reference standards prevents accurate quality control testing.

5.6 International Trade Barriers

While India is one of the largest exporters of herbal products, regulatory discrepancies limit acceptance in developed markets. Many Indian formulations fail to meet the stringent quality and labeling standards of the **EMA** or **USFDA**. The lack of Good Agricultural and Collection Practices (GACP) certification also restricts raw material export potential (**WHO, 2023**).

Consequently, despite the country's biodiversity and traditional expertise, India's global herbal market share remains disproportionately small compared to China and the EU.

6. Impact of Regulatory Hurdles

The challenges outlined above have profound implications for innovation, public health, and economic development.

6.1 Impediment to Research and Innovation

The uncertainty surrounding approval requirements discourages pharmaceutical companies from investing in research and development (R&D) for herbal medicines. Unlike synthetic drugs, which benefit from well-defined approval pathways, traditional formulations often face **ambiguous clinical trial and dossier expectations**. This regulatory opacity deters academic-industry collaborations and results in low patent filings in the AYUSH sector (**Rai et al., 2020**).

Furthermore, insufficient funding for herbal research and limited integration with modern pharmaceutical sciences hinder technological advancement. Establishing **standardized preclinical protocols** and promoting *reverse pharmacology*—the scientific validation of traditionally used formulations—could bridge this gap (**Patwardhan, 2018**).

6.2 Market Access and Export Limitations

Inconsistent quality standards and limited global harmonization impede India's access to international herbal medicine markets. The **European Union's Traditional Herbal Medicinal Products Directive (THMPD)** requires at least **30 years of documented use** (including 15 within the EU) for registration, a criterion that many Indian products fail to meet (**EMA, 2020**). As a result, Indian exporters often classify herbal products as **food supplements** rather than medicinal products, which reduces therapeutic recognition and market value.

DISCUSSION

Overview

This Discussion interprets and synthesizes the study's findings on regulatory hurdles affecting the approval of herbal medicines and traditional formulations in India. It integrates legal, scientific, institutional, and market perspectives, assesses the consequences for public health and industry, compares Indian regulation with international approaches, and develops targeted recommendations for policy reform and research priorities. The analysis draws on statutory texts (Drugs & Cosmetics Act and Rules), Ministry of AYUSH policies, CDSCO/PCIM&H guidance, WHO best practices, and published case studies (e.g., Ashwagandha, BGR-34, Liv.52, Kabasura Kudineer). Where appropriate the discussion identifies structural bottlenecks and suggests actionable pathways for harmonization, capacity building, and evidence generation.

1. Synthesis of Key Findings

1.1 Fragmentation of Regulatory Authority and Its Consequences

The Indian regulatory environment for herbal products is fragmented across the **Ministry of AYUSH**, **CDSCO**, **state drug licensing authorities**, and **FSSAI**. This multiplicity produces:

- **Ambiguity in classification** (drug vs. nutraceutical vs. supplement) leading to divergent approval paths;
- **Duplication and delays** where overlapping jurisdictions require multiple filings and reviews;
- **Regulatory arbitrage**, where manufacturers choose the pathway with the least pre-market scrutiny (e.g., FSSAI classification for market access).

This fragmentation undermines consistent quality enforcement and impairs India's international competitiveness. Comparative review shows that countries with unified or well-coordinated frameworks (Japan, China, EU-HMPC model) achieve better alignment of traditional practice with modern regulatory requirements.

1.2 Standardization Gaps: From Raw Material to Finished Product

A recurrent theme is **variability in raw material quality** (species, chemotype, geographical source, harvesting/processing). The absence of uniform adoption of **GACP** and inadequate laboratory infrastructure (limited reference standards, insufficient proficiency testing) results in batch variability and frequent occurrences of contamination (heavy metals, pesticides) and adulteration. The pharmacopoeial work by PCIM&H and API provides monographs, but implementation across industry—especially MSMEs—is inconsistent due to cost and technical capacity constraints.

1.3 Evidence Deficit: Clinical and Toxicological Data

The regulatory tolerance for **textbook-based classical products** (exemption from clinical trials when formulations follow classical texts) contrasts sharply with the expectation for **proprietary formulations** — which nonetheless are often marketed with weak or unpublished clinical evidence. The BGR-34 example highlights commercialization absent transparent peer-reviewed efficacy data. The net result: insufficient evidence undermines both safety assessment and international market acceptance.

1.4 Pharmacovigilance and Post-Market Surveillance Weaknesses

AYUSH pharmacovigilance mechanisms are nascent and underutilized. Underreporting of adverse events, poor integration with the national PvPI, and limited use of real-world data hamper

detection of safety signals (e.g., herb–drug interactions that only emerge at scale).

1.5 Dossier and Review Process Shortcomings

There is no standardized AYUSH equivalent of the **Common Technical Document (CTD)**. Dossiers lack consistent chemistry, manufacturing and control (CMC) data, stability studies, validated analytical methods, and adequate toxicology/clinical documentation. Review capacity varies by state and central reviewers, which contributes to inconsistent regulatory decisions.

2. Deeper examination of selected case studies

2.1 Ashwagandha: Regulatory overlap & quality control

Ashwagandha's global demand shows how a single herb's regulatory path can bifurcate: classical Ayurvedic products, proprietary nutraceuticals, and food supplements. This multiplicity led to variable labeling claims and quality standards in export consignments; several shipments faced rejection for inadequate phytochemical characterization. Key learning: **single-herb supply chains require robust traceability, validated marker assays, and harmonized claim frameworks**.

2.2 BGR-34: Transparency and scientific credibility

BGR-34 exemplifies commercialization without transparent RCT evidence. Even when efficacy is plausible (based on traditional rationale and some preclinical work), the absence of open, peer-reviewed clinical datasets weakens regulatory credibility and invites public skepticism. Regulatory implication: proprietary formulations must be required to publish trial protocols and outcomes (or at least submit them to regulators), even if trials are smaller or use adaptive designs.

2.3 Liv.52 and pharmacovigilance lessons

Historical hepatotoxicity signals associated with Liv.52 in combination therapies underscored the need for integrated adverse event reporting. The AYUSH sector must build systems to capture ADRs from conventional hospitals, clinics, and pharmacies that administer combination therapies.

2.4 Kabasura Kudineer: emergency use vs. evidence requirements

Emergency authorization during COVID-19 revealed tensions between rapid public health response and evidence standards. While accelerated utilization may be justified in exceptional circumstances, emergency use should be paired with mandatory, well-designed observational studies or pragmatic RCTs and transparent data sharing.

3. Comparative regulatory analysis: India vs. international models

A structured comparison shows three broad regulatory archetypes:

1. **Integrated, science-driven systems (Japan, China)**: Require rigorous CMC, toxicology, and clinical data; traditional products are part of national pharmacopeias and may be reimbursed under national insurance.
2. **Tiered, heritage-sensitive systems (EU via HMPC)**: Offer a **Traditional Use Registration** for products with long safety history (≥30 years) coupled with GMP standards and monographs.
3. **Market-first, manufacturer-responsibility systems (USA/DSHEA)**: Encourage innovation but rely heavily on manufacturer assurance and post-market surveillance.

India currently mixes elements of all three, but without coherent harmonization. The recommended path is a **hybrid model**: accept textual historical evidence for classical products under strict GMP/GACP and pharmacovigilance conditions, while demanding CTD-like dossiers with scaled clinical/ toxicology data for proprietary phytopharmaceuticals seeking therapeutic claims.

4. Policy and regulatory implications

4.1 Need for a unified regulatory architecture

Create an integrated **AYUSH–CDSCO coordination framework** or a **Central Herbal Regulatory Authority (CHRA)** with clear remits: product classification, dossier standardization (AYUSH-CTD), pharmacovigilance integration, and international engagement. Such an entity would streamline approvals, reduce state-to-state variability, and centralize scientific review capacity.

4.2 Risk-proportionate regulatory pathways

Implement **tiered evidence requirements**:

- **Classical formulations**: Require documented adherence to classical texts + validated GMP/GACP records + periodic safety reports + routine batch testing and traceability.
- **Modified/proprietary formulations**: Require CMC documentation, validated marker assays, stability studies, non-clinical toxicology, and at minimum phase II-style clinical data (or equivalent real-world evidence).
- **Phytopharmaceuticals** (single-entity, chemically defined botanicals): Full drug-like pathway (preclinical toxicology, GLP studies, robust clinical trials).

A risk-proportionate approach balances respect for traditional practice against consumer safety.

4.3 Strengthening quality control infrastructure

Invest in regional reference laboratories, accreditation of private labs, adoption of DNA barcoding and chromatographic fingerprints, and development/distribution of official reference standards. Subsidized technical assistance for MSMEs will improve industry compliance.

4.4 Mandatory transparency and data publication

Regulators should require registration of clinical trials (CTRIs) and the publication or submission of primary endpoint data for proprietary drugs. Transparency fosters peer scrutiny and global acceptance.

4.5 Integrated pharmacovigilance

Integrate AYUSH ADR reporting into PvPI and WHO VigiBase. Launch clinician/ practitioner training and easy digital reporting (mobile apps, SMS, EHR triggers) to scale reporting uptake. Use pharmacovigilance data for label updates and regulatory actions.

4.6 International harmonization and trade facilitation

Pursue bilateral MRAs and technical cooperation with EMA, NMPA, and WHO to adopt mutually recognized GMP/GACP standards and pharmacopoeial monographs, reducing export barriers.

5. Operationalization roadmap — practical steps and timeline

A pragmatic phased roadmap (18–36 months) could include:

Phase 1 (0–6 months): Foundational reforms

- Constitute expert working group (AYUSH-CDSCO-academia-industry).
- Design AYUSH-CTD template and dossier checklists.
- Mandate clinical trial registration for ongoing proprietary product studies.

Phase 2 (6–18 months): Capacity building and pilots

- Establish 3 regional reference labs and standard operating procedures (SOPs) for testing.
- Pilot AYUSH CTD submissions with 5 voluntary manufacturers; refine review SOPs.
- Launch integrated pharmacovigilance portal and awareness campaign.

Phase 3 (18–36 months): Regulatory enforcement and international outreach

- Enact regulatory notifications implementing AYUSH-CTD and tiered pathways.
- Negotiate MRAs for quality standards with at least one trading partner.
- Scale digital traceability pilot (blockchain) for priority medicinal plants (e.g., Ashwagandha, Brahmi).

This timeline is ambitious but feasible with political will and targeted funding.

6. Research and methodological implications

6.1 Need for adapted clinical trial designs

Standard RCT designs may be impractical for polyherbal complex formulations. Methodological innovations are needed:

- **Adaptive trial designs**, **pragmatic RCTs**, and **comparative effectiveness**

trials that incorporate individualized dosing customary in Ayurveda.
- Use of **biomarkers and intermediate endpoints** to measure therapeutic signals.
- **Reverse pharmacology** and **systems biology** approaches to link traditional indications with demonstrable mechanistic pathways.

6.2 Strengthening evidence synthesis

Systematic reviews and meta-analyses of AYUSH interventions are limited by heterogeneity in trial quality. Creating a central registry of AYUSH studies and promoting CONSORT-for-herbal medicine reporting standards will improve evidence synthesis and inform regulatory decisions.

6.3 Implementation science

Implementation research is required to evaluate how regulatory changes affect manufacturer compliance, market dynamics, and patient safety. Mixed-methods studies (quantitative compliance metrics + qualitative stakeholder interviews) will be valuable.

Stakeholder Perspectives and Socio-Economic Considerations

1. Overview

Regulatory reforms in the herbal and traditional medicine sector influence a wide and interdependent network of stakeholders, including manufacturers, traditional practitioners, consumers, exporters, researchers, and policymakers. Each group experiences both **costs and benefits** from the evolving regulatory landscape. Understanding these socio-economic dynamics is essential for designing reforms that promote public health without undermining livelihoods or indigenous healthcare systems.

The herbal industry in India is not only a health sector concern but also a **significant economic and cultural enterprise**. According to the Ministry of AYUSH (2023), the AYUSH sector contributes over USD 20 billion annually to the Indian economy, employs more than one million people, and supports thousands of small-scale enterprises. However, the lack of regulatory clarity and uneven enforcement creates economic distortions that affect competitiveness, innovation, and trust.

2. Manufacturers: Compliance Burden and Competitive Challenges

2.1 MSMEs and the Cost of Regulation

A majority of India's herbal manufacturers are **micro, small, and medium enterprises (MSMEs)** operating with limited capital, often in semi-formal or family-based production settings (Kumar & Singh, 2021). Implementation of stringent quality assurance standards such as **Good Manufacturing Practices (GMP)**, **Good Agricultural and Collection Practices (GACP)**, and **validated analytical testing** demands substantial investment in laboratory infrastructure, skilled manpower, and documentation systems.

Many MSMEs struggle to meet these compliance requirements, leading to:

- Product recalls or non-renewal of licenses due to documentation gaps;
- Informal production and underreporting;
- Price competition favoring non-compliant manufacturers.

While large corporations (e.g., Himalaya, Dabur, Zandu) can absorb regulatory costs through economies of scale, MSMEs risk **marginalization** unless reforms include **financial assistance**, **subsidized lab services**, or **shared testing facilities**. Government initiatives such as the **Pharma Cluster Development Programme** and **AYUSH Export Promotion Council (AYUSHEXIL)** can play a role in bridging this gap.

2.2 Innovation and Proprietary Formulations

Stringent evidence requirements, if not coupled with support mechanisms, may discourage innovation in proprietary herbal formulations. Unlike allopathic drug developers, most AYUSH manufacturers lack access to venture funding or formal R&D grants. Simplified clinical research guidelines, adaptive trial models, and targeted R&D incentives (similar to biotechnology start-up grants) can stimulate innovation while maintaining regulatory integrity (Patwardhan & Mashelkar, 2009).

3. Practitioners: Navigating Between Tradition and Modern Regulation

3.1 Knowledge and Practice Interface

Traditional medicine practitioners (Vaidyas, Siddhars, Unani Hakims, etc.) are custodians of centuries-old therapeutic knowledge. Regulatory requirements for documentation, dosage standardization, and labeling, however, often reflect **modern pharmaceutical paradigms**, which may not align neatly with traditional diagnostic and personalized treatment models (Srinivasan et al., 2022).

This mismatch creates uncertainty about:

- **Permissible therapeutic claims** (e.g., whether a classical indication like "Rasayana" may be labeled as an "immunomodulator");
- **Prescription responsibilities** when classical and proprietary products overlap;
- **Liability** for adverse effects when formulations are modified.

Therefore, regulatory reforms must include **capacity-building initiatives** — such as practitioner training in pharmacovigilance, labeling standards, and ethical marketing — to help bridge the epistemological gap between Ayurveda and biomedical regulation (WHO, 2023).

3.2 Integration in Healthcare Delivery

Integration of AYUSH practitioners in public health programs remains underutilized. Clearer regulatory recognition of standardized formulations could enable wider inclusion of AYUSH therapies in **primary healthcare** and **insurance schemes**, enhancing accessibility and cost-effectiveness for patients.

4. Consumers: Balancing Safety, Affordability, and Trust

4.1 Consumer Protection and Informed Choice

From a public health standpoint, consumers are the most vulnerable stakeholders. Cases of **heavy metal contamination** (Saper et al., 2008) and **false therapeutic claims** have eroded confidence in herbal medicines. Stringent regulatory frameworks that ensure quality assurance, accurate labeling, and transparent safety data are crucial for rebuilding consumer trust.

4.2 Economic Impacts and Accessibility

While improved regulation enhances product safety, it can also lead to **price escalation** due to higher compliance costs. This may restrict access for low-income groups who rely on herbal and traditional formulations as affordable alternatives to allopathic medicines (Gautam & Sharma, 2018). Hence, policymakers must ensure **price stabilization measures** — for instance, reduced GST for registered herbal medicines, subsidized quality certification, or inclusion in public procurement schemes (e.g., Jan Aushadhi).

4.3 Consumer Education

Education campaigns about rational use, potential herb–drug interactions, and proper dosage can further empower consumers to make informed decisions. Public awareness programs jointly conducted by AYUSH and the National Health Mission can reinforce safety and efficacy understanding at the community level.

CONCLUSION:

The Subject Expert Committee (SEC) system represents a pivotal evolution in India's regulatory framework for drug approval. Established under the **Central Drugs Standard Control Organization (CDSCO)** and operationalized through the **New Drugs and Clinical Trials Rules (NDCTR), 2019**, the SEC mechanism has successfully introduced a structured, scientific, and expert-driven dimension to the evaluation of new drug applications, particularly in the context of **accelerated and conditional approvals** for life-threatening and rare diseases.

This study has critically examined the SEC's multifaceted role in **expediting drug approvals** while maintaining a balance between **regulatory agility and patient safety**. The findings indicate that SECs have significantly contributed to **reducing drug-lag** between India and mature regulatory markets such as the United States, the European Union, and Japan. Through specialized therapeutic area–based review committees, the SECs have enhanced the scientific depth of regulatory evaluations and improved the consistency of technical assessments submitted to the **Drugs Controller General of India (DCGI)**.

However, the effectiveness of the SEC framework is not without limitations. Persistent challenges such as **limited transparency, inconsistent decision-making, capacity constraints, and insufficient integration with post-marketing surveillance** systems continue to impede the realization of its full potential. Moreover, the

absence of a codified **conflict-of-interest policy**, non-disclosure of detailed deliberations, and the lack of uniform documentation standards restrict public accountability and stakeholder confidence.

Despite these challenges, the SEC model has proven instrumental during critical public health emergencies — notably the **COVID-19 pandemic** — where accelerated review mechanisms facilitated rapid access to essential therapeutics and vaccines. These instances underscore the SEC's capacity to function as a **responsive, evidence-based regulatory instrument**, capable of addressing emergent healthcare needs while adhering to scientific rigor.

The comparative analysis with global regulatory counterparts such as the **FDA Advisory Committees** and the **EMA's Scientific Advisory Groups (SAGs)** further demonstrates that India's SEC framework aligns conceptually with international norms of regulatory consultation and expert-led evaluation. Yet, it also highlights the necessity for **institutional strengthening** to ensure procedural uniformity, data transparency, and ethical governance.

In the broader policy context, the SEC framework symbolizes India's commitment to transforming its drug regulatory system into a **globally harmonized, patient-centered, and innovation-friendly model**. To sustain and enhance this transformation, future reforms should focus on:

- Establishing **permanent scientific secretariats** for continuity and institutional memory.
- Implementing **AI-driven digital tools** for data review, dossier management, and decision analytics.
- Strengthening **post-marketing linkages** through real-world evidence integration.
- Enhancing **ethical oversight and conflict-of-interest disclosure mechanisms.**
- Institutionalizing **regulatory science education and research** to develop skilled professionals in this domain.

These measures would not only address existing procedural inefficiencies but also reinforce the SEC's credibility as an independent, transparent, and scientifically robust advisory body.

In conclusion, the **Subject Expert Committee (SEC)** mechanism has emerged as an essential pillar in expediting drug approvals in India, bridging the gap between **scientific innovation and public health accessibility**. While there is room for improvement in governance, digital integration, and ethical compliance, the SEC's role in accelerating access to safe and effective medicines marks a decisive step toward **regulatory maturity and global competitiveness**.

Ultimately, the continued evolution of SECs will determine how effectively India can balance **speed with safety**, **innovation with integrity**, and **national needs with global standards** — the three core pillars of a modern, trustworthy, and resilient drug regulatory ecosystem.

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