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# FROM TRADITION TO REGULATION: A LEGAL ANALYSIS OF AYURVEDA IN CONTEMPORARY HEALTHCARE

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## ABSTRACT

Ayurveda, one of the world's ancient medical systems, has evolved from a community-based healing practice to a regulated part of India's healthcare system. This article examines the legal aspects of Ayurveda, including its governance under national health programs, constitutional requirements, judicial interpretations, and the regulatory function of statutory authorities. It also takes into account intellectual property rights, medico-legal consequences, and international problems that affect Ayurveda's global standing. By positioning Ayurveda within the larger discourse of complementary and alternative medicine, the study underscores ongoing obstacles in standardization, safety, and worldwide recognition, while also emphasizing prospects for integrative healthcare and comparative legal perspectives. The analysis indicates that Ayurveda's long-term integration into modern healthcare systems and global recognition require a balanced regulatory strategy based on transparency, scientific validation, and respect for indigenous epistemologies.

**Keywords:** Ayurveda, Law, Regulation, Constitutional Law, Medico-Legal Issues, Policy Reform.

## **Introduction**

Ayurveda, also known as the "science of life," is one of the most enduring healthcare systems throughout history. It has its foundation on ancient Indian philosophy and has historically served as a community-based healing system, emphasizing holistic well-being, preventive care, and mental, physical, and spiritual balance. Over centuries, Ayurveda has shaped cultural identity as well as global discourses on traditional and complementary medicine. However, the move from a cultural practice to a regulated component of modern healthcare involves difficult legal and policy issues. This article situates Ayurveda within the broader discourse on complementary and alternative medicine, analyzing its legal dimensions at both national and international levels. It explores constitutional provisions, regulatory statutes, judicial precedents, and global disputes that shape Ayurveda's contemporary status. By examining the intersection of law and Ayurveda, the study highlights the tension between safeguarding public health and preserving cultural heritage, while also identifying opportunities for integrative healthcare and comparative legal insights. Ultimately, the paper argues that a balanced regulatory approach - anchored in transparency, scientific validation, and respect for indigenous epistemologies - is essential for Ayurveda's sustainable integration into global healthcare systems.

## **Background of the study**

Ayurveda, the ancient Indian system of medicine, is rooted in the philosophy of maintaining harmony within the body and mind. At its core lies the concept of doshas - Vata, Pitta, and Kapha, three fundamentals that govern physiological and psychological functions. Health, in Ayurvedic thought, is achieved when these doshas remain in balance, while imbalance leads to disease. In practice, Ayurveda employs a wide range of methods to restore and sustain equilibrium. Herbal formulations are tailored to individual constitutions, while Panchakarma therapies provide detoxification and rejuvenation based on personalized considerations. Equally important are dietary guidelines and lifestyle regulation, which emphasize seasonal adaptation, mindful eating, and daily routines aligned with natural rhythms. The Ayurvedic approach is inherently preventive, personalized, and holistic. Rather than focusing solely on curing illness, it seeks to strengthen resilience, promote longevity, and nurture the interconnectedness of body, mind, and spirit. This makes Ayurveda not just a medical system, but a philosophy of living in tune with nature.

Finally, as Ayurveda continues to gain global recognition, its legal importance becomes essential. Establishing clear regulatory frameworks ensures authenticity, safety, and ethical practice, while protecting both practitioners and patients.

### **Evolution of Ayurveda Legal Recognition**

While Ayurveda is strongly grounded in history, it continues to operate within a modern regulatory and legal framework that protects its safety and ethics. As the global demand for Ayurvedic medicine rises, clear frameworks must be established to ensure legitimacy, safety, and integration into healthcare systems.

Ayurveda has long been acknowledged as part of India's legitimate healthcare system, alongside Siddha, Unani, and other traditional techniques. Internationally, Ayurveda has become more recognized under complementary and alternative medicine legislation, while legal acceptance differs by jurisdiction. In India, the Ministry of AYUSH (Ayurveda, Yoga & Naturopathy, Unani, Siddha, and Homeopathy) is accountable for policy, education, and practice standards, whereas in countries such as the United States and the European Union, Ayurveda is frequently classified as a herbal supplement or alternative medicine, subject to local health authority oversight.

### **Regulatory Bodies in the Ayurveda Sector**

#### **In India:**

- **Ministry of AYUSH** - Central authority responsible for policy, promotion, and regulation of Ayurveda, Yoga, Naturopathy, Unani, Siddha, and Homeopathy.
- **Central Council of Indian Medicine (CCIM)** - Governs education standards, practitioner registration, and professional ethics in Ayurveda.
- **Pharmacopoeia Commission for Indian Medicine & Homoeopathy (PCIM&H)** - Develops standards for Ayurvedic drugs, formulations, and quality control.
- **Drug Control Authorities (State & National)** - Monitor manufacturing, licensing, and compliance with Good Manufacturing Practices (GMP).

## **Globally:**

- **World Health Organization (WHO)** - Provides guidelines for traditional medicine integration, safety, and quality assurance.
- **Regional Health Authorities (e.g., FDA in the US, EMA in Europe)** - Regulate Ayurvedic products under herbal medicine or dietary supplement categories.
- **National Complementary Medicine Boards** - In countries like Australia, UK, and Canada, Ayurveda is regulated under complementary and alternative medicine frameworks.

**Licensing and Registration** - Licensing and registration form the backbone of Ayurveda's regulatory framework, ensuring that practitioners and manufacturers meet defined standards of safety, quality, and professionalism. These mechanisms safeguard patients while preserving the integrity of traditional knowledge.

### **1. Practitioner Licensing in Ayurveda**

The licensing of Ayurvedic practitioners is a vital regulatory mechanism that ensures that only qualified individuals can practice. In India, practitioners must register with State Medical Councils under the Central Council of Indian Medicine (CCIM) and graduate from the National Commission for Indian System of Medicine (NCISM). Registration requires the completion of a recognized degree, such as the Bachelor of Ayurvedic Medicine and Surgery (BAMS) or further postgraduate qualifications (MD/MS in Ayurveda). This procedure verifies the practitioner's academic training and clinical competence, giving them the legal authorization to diagnose, prescribe Ayurvedic medicines, and execute specialist therapies like Panchakarma.

The authorization structure also makes professionals accountable. Registered practitioners are required to follow ethical rules and may face disciplinary action if they commit misconduct. This protects patients and increases the legitimacy of Ayurveda as a regulated medical field.

Globally, the terrain is more diversified. In many countries, Ayurveda falls under the category of complementary and alternative medicine (CAM). Requirements vary greatly: some jurisdictions allow practice under general wellness regulations without formal authorization,

whereas others need certification from recognized boards or groups. For example, in the United States, Ayurvedic practitioners are frequently employed as wellness consultants rather than licensed medical professionals, although in other parts of Europe, Ayurveda may be regulated under herbal medicine or CAM frameworks. This discrepancy emphasizes the need for more harmonization and international recognition to establish consistent standards of practice around the world.

Ultimately, practitioner authorization is the foundation of Ayurveda's incorporation into modern healthcare systems. It strikes a compromise between ancient wisdom and modern regulations, ensuring that patients receive authentic, safe, and effective therapy.

## **2. Manufacturer Licensing in Ayurveda**

Traditional Ayurvedic drug manufacturing is highly monitored to guarantee that the products reaching consumers are safe, consistent, and genuine. Manufacturers must seek permits from India's State Drug Control Authorities, which operate under the broader framework of the Drugs and Cosmetics Act and Ministry of AYUSH guidelines. Licensing is an organized procedure that requires precise requirements to be met at every stage of production, rather than a one-time clearance.

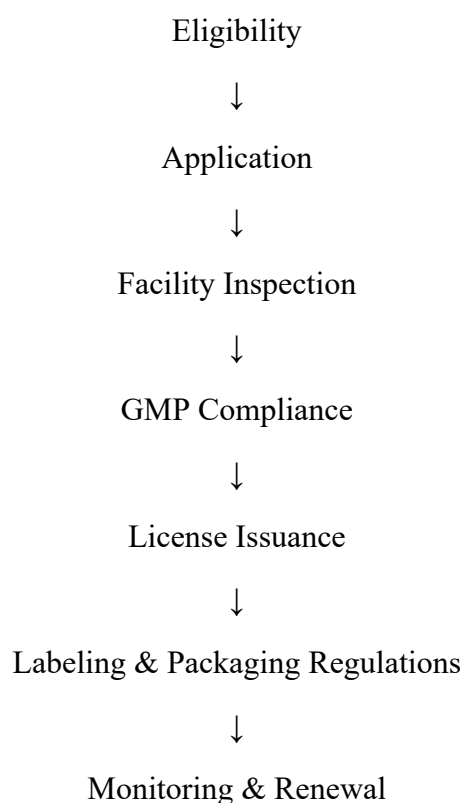
Compliance with Good Manufacturing Practices (GMP) is a key component of this process. GMP guarantees that Ayurvedic medicines are manufactured in sanitary conditions, following standardized procedures, and with correct documentation of raw ingredients, formulations, and quality checks. This reduces the chance of contamination, adulteration, or inconsistency, ensuring patient safety and maintaining Ayurveda's credibility.

Licenses are issued for many types of medicines:

- Classical formulations are based on authentic Ayurvedic sources like the Charaka Samhita and Sushruta Samhita. Manufacturers must adhere to prescribed formulas and techniques without variation.
- Proprietary medications are unique combinations created by corporations that combine conventional expertise with modern innovation. Before they can be approved, they must undergo extra testing to assure their safety and effectiveness.

Regulations governing labelling and packaging are important in addition to licensing. Every product must clearly state its contents, dosage directions, route of administration, and potential negative effects. Labels must also include batch numbers, manufacturing and expiration dates, as well as the manufacturer's license number. This transparency increases customer trust and allows regulatory agencies to follow and monitor products on the market.

Drug control firms conduct periodic inspections and audits to verify continued compliance. Noncompliance with GMPs, false labeling, or harmful operations may result in license suspension or cancellation. Thus, manufacturer license is more than just a bureaucratic obligation; it is a precaution that strikes a balance between Ayurveda's ancient knowledge and modern regulatory accountability.



### **3. Registration of Medicines**

The registration of Ayurvedic medicines is a crucial phase towards assuring their validity, safety, and acceptance in modern healthcare systems. Before entering the market, any product must go through a structured approval process monitored by regulatory bodies. In India, the Pharmacopoeia Commission for Indian Medicine & Homoeopathy (PCIM&H) is primarily responsible for developing and enforcing pharmacopeia standards for both classical

formulations (those mentioned in authoritative Ayurvedic texts) and proprietary medicines (innovative combinations developed by manufacturers). Manufacturers must provide thorough paperwork outlining the formulation's composition, preparation procedures, medicinal claims, and supporting evidence. This method guarantees that medications are anchored in history while also meeting modern quality and efficacy standards. Labelling standards are equally crucial, including full disclosure of contents, recommended dosage, route of administration, and potential side effects. Such transparency protects consumers from misinformation and enables practitioners to prescribe ethically. To ensure accountability, labels must include batch numbers, manufacturing dates, and expiration dates.

Ayurvedic medicines are liable to different registration requirements in countries outside of India. In the United States, for example, they are frequently classed as dietary supplements and regulated by the Food and Drug Administration (FDA), whereas in the European Union, they may fall within herbal medicine categories governed by the European Medicines Agency. These frameworks prioritize safety, but they also underscore the difficulty of harmonizing worldwide standards for traditional medications.

#### **4. Renewal and Monitoring**

Ayurvedic practitioners' and manufacturers' licenses are not permanent; they must be renewed on a regular basis to ensure their legitimacy and responsibility. Renewal ensures that practitioners continue to meet professional requirements and that manufacturers maintain quality standards during production. During this procedure, regulatory entities such as state medical councils and drug control authorities check and audit to ensure that established norms, such as Good Manufacturing Practices (GMP) and ethical requirements, are followed. These inspections ensure patient safety, maintain the integrity of Ayurveda, and avoid malpractice. In cases of noncompliance, whether due to poor drugs, unethical conduct, or inability to meet infrastructural standards, authorities have the authority to suspend or terminate licenses. This renewal and monitoring systems establishes a dynamic regulatory framework that strikes a balance between tradition and modern accountability, ensuring that Ayurveda remains a trustworthy and legally recognized healthcare field.

#### **5. Advertising and Marketing Guidelines in Ayurveda**

Advertising and marketing in the Ayurvedic business are strictly regulated to safeguard

consumers and preserve the integrity of traditional knowledge. Unlike conventional medications, Ayurvedic products frequently draw on centuries-old formulas and cultural legacy, necessitating careful communication. First, statements must be evidence-based. Manufacturers and practitioners are forbidden from making exaggerated or deceptive claims about cures or assured results. Any therapeutic claims must be backed up by verifiable research, classical Ayurvedic texts, or clinical evidence. This ensures that consumers are not misled by unproven claims and that Ayurveda remains credible in modern healthcare systems.

Secondly, regulators actively scrutinize advertisements. In India, the Ministry of AYUSH and drug control agencies assess promotional materials to ensure they comply with the Drugs and Magic Remedies (Objectionable Advertisements) Act of 1954, which prohibits advertisements promoting miraculous treatments for serious diseases. This monitoring prevents the exploitation of traditional knowledge and safeguards vulnerable communities from deceptive or manipulative marketing.

Third, ethical marketing techniques are stressed. Advertisements must explicitly disclose product information, such as ingredients, dosage, and potential adverse effects, rather than relying entirely on cultural appeal or vague wellness promises. Transparency promotes customer trust and aligns Ayurveda with worldwide standards for responsible healthcare communication.

Finally, in the international setting, Ayurvedic medications are frequently sold as complementary or alternative medicines. Regulatory authorities such as the FDA (United States) and EMA (European Union) have rigorous requirements for labeling and health claims, requiring corporations to avoid making unjustified promises. This global inspection emphasizes the significance of unifying advertising norms to ensure that Ayurveda is promoted safely and ethically around the world.

### **Judicial Perspectives in Ayurveda:**

The judiciary has played a substantial part in establishing legal boundaries and regulatory clarity for Ayurveda in India. Courts have handled concerns ranging from scope of practice to licensing and advertising, bolstering Ayurveda's validity and enforcing accountability.

#### **1. Dr. Mukhtiar Chand v. State of Punjab (1998)**

This particular instance established the scope of practice for practitioners of Indian medicine. The Supreme Court ruled that Ayurvedic doctors registered under the Indian Medicine Central Council Act of 1970 could not prescribe allopathic drugs since their licenses were limited to Ayurveda and allied systems. The decision upheld the idea that practitioners must stay within the bounds of their approved system to ensure patient safety and professional integrity.

## **2. State of Kerala v. Kandath Distilleries (2013)**

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## **3. North Delhi Municipal Corporation v. Dr. Ram Naresh Sharma & Ors (2021)**

Here, the issue was parity and discrimination in the retirement age of Ayurvedic doctors compared to allopathic doctors. The Supreme Court recognized the need for equal treatment of practitioners across systems of medicine, reinforcing Ayurveda's status as a legitimate medical discipline within India's healthcare framework.

## **4. Advertising Case (2024)**

The Supreme Court came down heavily on misleading advertisements by a particular company, which claimed superior efficacy of its products compared to allopathic medicine. The Court emphasized that Ayurvedic companies must adhere to advertising laws and avoid unsubstantiated claims, thereby protecting consumers and preventing exploitation of traditional knowledge.

## **Constitutional Dimensions**

- **Article 21 – Right to Health:** The Supreme Court interprets the right to life as encompassing healthcare, legitimizing Ayurveda's role.
- **Article 25 – Cultural Rights:** Protects Ayurveda as part of India's cultural heritage.
- **Directive Principles (Articles 39, 47):** Mandate state responsibility for public health,

supporting Ayurveda's preventive focus.

- **Article 51A – Fundamental Duty:** Encourages preservation of heritage, including traditional medicine.

### **Comparative Legal Analysis**

- **India vs. China:** TCM enjoys stronger legal integration into mainstream healthcare.
- **India vs. EU:** Strict safety requirements limit Ayurveda's market penetration.
- **India vs. USA:** Ayurveda is regulated as complementary medicine under dietary supplement laws.

### **Medico-Legal Importance**

- **Consent and Liability:** Practitioners must obtain informed consent, especially when therapies differ from biomedical norms.
- **Malpractice:** Practicing outside recognized scope can lead to criminal liability.
- **Forensic Relevance:** Ayurvedic toxicology (*Agada Tantra*) intersects with forensic medicine.
- **Ethical Concerns:** Commercialization and exploitation of indigenous knowledge raise medico-legal disputes.

### **International Medico-Legal Disputes**

- **Biopiracy Cases:**

*Neem (Azadirachta indica):* Patents revoked after India demonstrated prior traditional use.

*Turmeric (Curcuma longa):* US patent overturned following evidence from Ayurvedic texts.

- **TRIPS and WTO:** India advocates for protection of traditional knowledge beyond conventional IP frameworks.

- **TKDL:** Prevents wrongful patents on Ayurvedic formulations.
- **Global Regulatory Challenges:** EU's strict safety laws, USA's dietary supplement classification, and China's stronger integration of TCM provide comparative lessons.

### Regulatory Framework in India

- **Ministry of AYUSH & NCISM:** The National Commission for Indian System of Medicine (NCISM) prescribes curricula for *Agada Tantra* and *Vidhi Vaidyaka*, ensuring practitioners are trained in medico-legal responsibilities.
- **Professional Conduct Regulations (1982):** Ayurvedic practitioners are bound by codes of ethics and medico-legal obligations, especially in cases involving poisoning, malpractice, or negligence.

**Legal Dimensions of Agada Tantra** - *Agada Tantra*, one of Ayurveda's eight traditional branches, focuses on toxicology, forensic medicine, and medico-legal jurisprudence. Traditionally, it included the detection of poisons, their physiological effects, and antidotes. However, in the modern day, *Agada Tantra* has gained major legal importance, particularly in the fields of medical jurisprudence, forensic toxicology, and regulatory control of dangerous drugs.

**Toxicology in Ayurveda**, predominantly researched under *Agada Tantra*, has traditionally addressed poisons, antidotes, and medico-legal obligations. This branch of Ayurveda is currently governed by numerous layers of legislative regulation, reflecting concerns about patient safety, practitioner accountability, and global conformity. From a regulatory standpoint, the Drugs and Cosmetics Act of 1940 establishes the legal framework for the production, sale, and labeling of Ayurvedic medicines, including those derived from hazardous plants and minerals. The provisions of this Act demand that compositions containing toxic compounds be evaluated for safety and made in accordance with defined standards. The Ministry of AYUSH and the National Commission for Indian System of Medicine (NCISM) furthermore supervise toxicological education, licensure, and professional ethics, ensuring that practitioners trained in *Agada Tantra* are aware of their medico-legal obligations.

**Medico-legal implications** are particularly significant in toxicology. Ayurvedic practitioners may be called upon in forensic investigations involving poisoning, homicide, or accidental

ingestion. Courts have occasionally recognized the expertise of Ayurvedic toxicologists, though challenges remain in reconciling traditional diagnostic methods with modern forensic science. Liability concerns also arise when practitioners prescribe or administer formulations containing toxic ingredients such as *Dhatura* or *Vatsanabha*. In such cases, negligence laws and professional conduct regulations apply, making adherence to dosage, preparation standards, and informed consent a matter of legal accountability. In the modern legal context, the intersection of Ayurveda and crime is most visible in **medico-legal toxicology**. Ayurvedic practitioners trained in *Agada Tantra* may be consulted in cases of suspected poisoning, accidental ingestion, or homicide. Their responsibilities extend beyond treatment to medico-legal documentation, expert testimony, and compliance with statutory obligations. The **Indian Penal Code (IPC)** and the **Code of Criminal Procedure (CrPC)** recognize poisoning as a criminal act, and Ayurvedic toxicologists may contribute to investigations by identifying toxic substances or providing forensic insights.

Regulatory frameworks also shape the practice of **Forensic Psychiatry** in Ayurveda. The **National Commission for Indian System of Medicine (NCISM)** prescribes curricula that include medico-legal responsibilities, ensuring practitioners are aware of their role in psychiatric evaluation and legal testimony. The **Mental Healthcare Act, 2017**, though primarily biomedical in orientation, indirectly impacts Ayurvedic psychiatry by establishing patient rights, consent requirements, and standards for mental health care. Ayurvedic practitioners must align their psychiatric interventions with these legal safeguards, particularly in cases involving involuntary treatment or custodial care.

Intellectual property rights also intersect with **Ayurvedic psychiatry**. Traditional formulations for mental health, documented in classical texts, are now catalogued in the **Traditional Knowledge Digital Library (TKDL)** to prevent biopiracy. Protecting indigenous psychiatric knowledge ensures that Ayurvedic approaches to forensic psychiatry are not misappropriated or patented without recognition of their cultural origins. Globally, forensic psychiatry in Ayurveda faces challenges of recognition and integration. International law and medical standards demand rigorous validation of psychiatric therapies, particularly when used in forensic contexts such as criminal responsibility or custodial care. The **World Health Organization's Traditional Medicine Strategy** encourages integration of traditional psychiatric approaches, but epistemological differences between Ayurveda and biomedicine complicate acceptance in legal systems.

In Ayurveda, the legal implications of **Sexual offenses** are understood using both ethical ideas from classical literature and modern law frameworks. Ancient Ayurvedic literature, such as the Charaka Samhita and Sushruta Samhita, emphasizes moral responsibility, consent, and the control of sexual behavior as essential components of sustaining social order and individual health. Sexual crimes, such as rape, exploitation, and abuse, are defined as violations of both physical integrity and dharma (ethical obligation), rendering them punishable acts within society's larger moral-legal framework. In contemporary practice, Ayurvedic specialists are subject to the same medico-legal requirements as biomedical practitioners, which means that offenses such as sexual misconduct are prosecuted under general criminal law rules in India (e.g., the Indian Penal Code) and professional ethics codes. Furthermore, forensic medicine in Ayurveda (Agadatantra) has always addressed medico-legal responsibilities, including physicians' obligations to patients and the state, which now extend to protecting patients against exploitation. Thus, the Ayurvedic perspective combines old ethical teachings with current legal safeguards, emphasizing that sexual assaults are both a violation of medical ethics and a criminal crime under statute law.

**Legal Dimensions of Quackery in Ayurveda** - The issue of quackery - unqualified individuals posing as medical practitioners - has long been a concern in Ayurveda. While Ayurveda is recognized as a regulated medical system under the Ministry of AYUSH, the persistence of unlicensed practitioners raises serious legal, ethical, and public health challenges.

- Under the **Indian Penal Code (IPC)**, quacks may be prosecuted for:
- **Section 304A**: Causing death by negligence.
- **Sections 336–338**: Acts endangering life or personal safety.
- **Sections 420 & 468**: Cheating and forgery, often applicable when fake degrees or fraudulent claims are made.

Courts have often ruled that unqualified practitioners cannot seek protection under statutes that govern recognized medical systems. Patients victimized by quacks may seek redress under the Consumer Protection Act of 2019, which recognizes medical services as part of consumer rights. Compensation suits against fraudulent practitioners are becoming more widespread. Indian courts have consistently criticized quackery in Ayurveda. In various cases, the judiciary

has highlighted that only registered practitioners can legally prescribe or execute Ayurvedic remedies. The Supreme Court has clarified that cross-practice (Ayurvedic practitioners giving allopathic medications and vice versa) is prohibited unless specifically allowed. Enforcement remains difficult due to the prevalence of quacks in remote regions with limited access to certified practitioners. Public awareness initiatives and stricter monitoring by state medical councils are critical for combating quackery. Ayurvedic quackery is a source of worry on a global scale. In areas where Ayurveda is not strictly regulated, unqualified practitioners may take advantage of cultural interest in traditional medicine. This raises liability concerns under local health and consumer regulations.

### **Legal dimensions of Ayurveda Researches:**

The significance of legal considerations in Ayurveda research cannot be emphasized, as they lay the groundwork for assuring ethical integrity, scientific credibility, and international legitimacy of traditional knowledge. Ayurveda research frequently includes clinical trials, pharmacological studies, and the investigation of formulations produced from plants, minerals, and animal products, all of which necessitate rigorous respect to legal and ethical guidelines. Legal monitoring ensures that participants' rights are respected through informed consent, that safety standards are followed throughout testing and product development, and that intellectual property rights preserve indigenous knowledge from exploitation or biopiracy. In India, compliance with the Drugs and Cosmetics Act, 1940, guidelines from the Indian Council of Medical Research (ICMR), and directives from the Ministry of AYUSH ensures that Ayurvedic research is conducted responsibly and transparently. Globally, adherence to international drug safety laws and the World Health Organization's Traditional Medicine Strategy is essential for Ayurveda's acceptance in mainstream healthcare. Without these legal dimensions, Ayurveda research risks being dismissed as unscientific or unsafe, undermining its credibility and potential contributions to integrative medicine. Thus, law acts as both a protective shield and a legitimizing force, enabling Ayurveda to evolve from a traditional knowledge system into a globally recognized scientific discipline.

Legal frameworks safeguard Ayurveda research by enforcing standards of informed consent, patient safety, and ethical review. They also protect indigenous formulations through intellectual property rights and initiatives like the Traditional Knowledge Digital Library (TKDL), preventing biopiracy and unauthorized patents. Internationally, compliance with drug

safety laws and the World Health Organization's Traditional Medicine Strategy ensures Ayurveda research is recognized and respected beyond India. The benefits of strong legal dimensions in Ayurveda research are substantial. They enhance credibility and trust, ensuring that research outcomes are scientifically validated and ethically sound. Legal protections encourage innovation, allowing researchers to explore new formulations while safeguarding traditional knowledge. They also facilitate global recognition, enabling Ayurveda to participate in international healthcare systems and integrative medicine initiatives. Ultimately, law acts as both a protective shield against exploitation and a legitimizing force that elevates Ayurveda from a cultural tradition to a globally respected scientific discipline. Despite these safeguards, Ayurveda research faces significant challenges. One major issue is the lack of standardized protocols for clinical trials and toxicity evaluation, which hampers global acceptance. Another challenge lies in epistemological differences between Ayurveda and biomedicine, making it difficult to align traditional methodologies with evidence-based standards demanded by international regulators. Legal disputes over intellectual property and cross-border trade further complicate the landscape, while enforcement gaps allow unethical practices or unregulated research to persist.

### **Challenges**

- **Standardization vs. Diversity:** Regional variations complicate codification.
- **Safety and Efficacy:** Limited clinical validation raises medico-legal concerns.
- **Integration with Biomedicine:** Liability issues in integrative models.
- **Ethical Concerns:** Protecting indigenous knowledge while enabling commercialization.

### **Roadmap for various Opportunities**

#### **Short-Term:**

- **Regulatory Standardization:** Draft clear legal guidelines for Ayurvedic drug approval, labeling, and advertising.
- **Consumer Protection:** Enforce laws against misleading claims and unethical

advertisements.

- **Medico-Legal Training:** Introduce training modules for AYUSH practitioners on patient rights and consent.
- **Insurance Integration (Pilot):** Begin pilot projects with insurers to cover select Ayurvedic treatments.

#### **Medium-Term:**

- **Intellectual Property Rights:** Expand TKDL to include regional practices and unpublished manuscripts.
- **Public Health Law:** Embed Ayurveda into national health legislation for integrative healthcare.
- **Specialized Legal Boards:** Establish medico-legal boards for AYUSH disputes and malpractice claims.
- **International Trade Law:** Negotiate agreements to harmonize Ayurvedic product standards globally.

#### **Long-Term:**

- **Constitutional Backing:** Advocate for explicit recognition of Ayurveda under Article 21 (Right to Health).
- **Global Harmonization:** Secure mutual recognition agreements with EU, USA, and other countries.
- **Universal Insurance Integration:** Ensure comprehensive coverage of Ayurvedic treatments under insurance schemes.
- **Global Diplomacy:** Position Ayurveda as a soft-power tool in India's international relations.

## **Policy Recommendations**

- 1. Strengthen Evidence-Based Research** - To strengthen evidence-based research in Ayurveda, dedicated clinical trial frameworks tailored to its unique formulations and therapeutic approaches must be established, ensuring that traditional remedies are validated through rigorous, standardized protocols that adhere to both AYUSH and international regulatory standards. This entails developing specific trial designs that take into account multi-herbal combinations, individualized treatments, and holistic outcomes, all while being backed by a strong infrastructure and ongoing safety monitoring. At the same time, fostering collaboration between AYUSH and biomedical institutions is critical because it allows interdisciplinary teams to combine traditional knowledge with modern scientific tools, share resources like laboratories and patient networks, and co-author research that boosts credibility in the global medical literature. Such partnerships not only validate Ayurvedic principles through molecular and clinical evidence but also build capacity by training researchers across disciplines, ultimately positioning Ayurveda as a credible and integrative component of modern healthcare.
- 2. Global Harmonization of Standards** - Universal unification of Ayurvedic product standards entails matching safety, quality, and efficacy norms with internationally recognized frameworks developed by the World Health Organization (WHO) and leading pharmacopoeias. This necessitates standardized testing techniques, labeling, and production practices to meet global standards, maintaining customer confidence and promoting greater acceptance. At the same time, obtaining mutual recognition agreements with regions such as the European Union, the United States, and other countries is critical, since this permits Ayurvedic medicines certified in India to enter these markets with less regulatory friction. Such partnerships decrease testing duplication, speed approvals, and create confidence among regulatory organizations, allowing Ayurveda to extend its global footprint while adhering to strict safety and quality guidelines.
- 3. Legal Protection of Traditional Knowledge** - To protect Ayurvedic traditional knowledge from misappropriation and biopiracy, the Traditional Knowledge Digital Library (TKDL) must be expanded to include regional practices, oral traditions, and

unpublished manuscripts that are not part of formal documentation. India's intellectual property defenses against illegitimate patents on Ayurvedic treatments can be strengthened by systematically collecting and integrating varied local knowledge systems into TKDL. At the same time, pushing for revisions to the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement that expressly recognize traditional medicine is vital because it ensures global recognition of indigenous knowledge systems under international law. Such reforms will not only conserve the originality and cultural history of Ayurveda, but also empower communities by offering them genuine ownership.

- 4. Medico-Legal Safeguards** - Medico-legal safeguards for Ayurveda are critical to ensuring patient rights and practitioner accountability within the larger healthcare system. Mandating informed consent guidelines for Ayurvedic treatments will ensure that patients are fully aware of the nature, potential benefits, and hazards of the therapies they receive, bringing traditional practices in line with current medical ethics. In tandem, the establishment of specialist medico-legal boards for AYUSH practitioners would provide a structured system for resolving disputes, malpractice claims, and professional conduct issues in a fair and transparent way. These boards will not only safeguard patients, but also maintain the integrity of Ayurvedic experts by providing a forum for due process. Collectively, these approaches build trust in Ayurveda, integrate it more fluidly into healthcare's legal and ethical frameworks, and ensure that traditional medicine functions with the same rigor and responsibility as modern medical systems.
- 5. Constitutional Backing for Integrative Healthcare** - Constitutional support for integrative healthcare would entail formally recognizing Ayurveda under Article 21 jurisprudence, which ensures the fundamental right to health, thereby establishing that access to traditional medical systems is part of the larger right to life and well-being. Such recognition would elevate Ayurveda from an optional alternative to a constitutionally protected healthcare option, securing its credibility within the legal framework. Furthermore, expanding the Directive Principles of State Policy to require integrative healthcare policies will direct governments to actively foster collaboration between Ayurveda and modern biomedicine, therefore incorporating holistic approaches into public health plans. Together, these measures would provide a

constitutional foundation for integrative healthcare, ensuring that traditional knowledge systems are not only preserved but also systematically incorporated into national health strategies, thereby enhancing accessibility, equity, and cultural relevance in medical care.

## **Conclusion**

The transition of Ayurveda from tradition to regulation illustrates India's efforts to conserve cultural legacy while also assuring healthcare safety and efficacy. Legal frameworks legitimate Ayurveda, safeguard traditional knowledge, and encourage global acceptance. Constitutional protections strengthen Ayurveda's contribution to public health, while medico-legal factors ensure accountability and patient safety. International challenges over biopiracy and trade law emphasize Ayurveda's worldwide importance, emphasizing the necessity for strong legal safeguards and consistent regulatory norms. Policy changes can boost Ayurveda's global visibility, establishing it as an essential component of integrative treatment.

## Bibliography

1. Achal R, Anamika K. The need for greater representation of AYUSH in the National Health Policy. *Eastern Scientist Journal*. 2025;3(32):45–56.
2. Government of India. *The Drugs and Cosmetics Act, 1940*. New Delhi: Government of India; 1940.
3. Government of India. *Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954*. New Delhi: Government of India; 1954.
4. Government of India. *Indian Medicine Central Council Act, 1970*. New Delhi: Government of India; 1970.
5. Government of India. *Consumer Protection Act, 2019*. New Delhi: Government of India; 2019.
6. Ministry of AYUSH. *AYUSH Research Portal: Evidence Based Research Data of AYUSH Systems at Global Level*. New Delhi: Government of India; 2025.
7. National Commission for Indian System of Medicine. *NCISM regulations and educational standards*. New Delhi: Government of India; 2020.
8. Nesari T, et al. India's journey in mainstreaming AYUSH in primary health care—from tradition to integration. *Frontiers in Medicine*. 2025; 12:1629515.
9. World Health Organization. *Global report on traditional and complementary medicine*. Geneva: WHO Press; 2023.
10. Mukhtiar Chand v. State of Punjab. (1998) 7 SCC 579.
11. State of Kerala v. Kandath Distilleries. (2013) 6 SCC 573.
12. North Delhi Municipal Corporation v. Dr. Ram Naresh Sharma and Others. Supreme Court of India; 2021.
13. Traditional Knowledge Digital Library (TKDL). Government of India initiative for protection of traditional medicinal knowledge. New Delhi: Government of India.
14. World Trade Organization. *Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)*. Geneva: WTO; 1994.