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ETHICS, REGULATION, AND RESEARCH IN AYURVEDA: A COMPREHENSIVE REVIEW OF CURRENT GUIDELINES AND CHALLENGES

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ABSTRACT

Introduction: Ayurveda, one of the world's oldest healthcare systems, is rooted in ethical conduct and holistic well-being. With its global resurgence, there is an increasing need to align *Ayurvedic* practices with contemporary ethical and legal standards to ensure patient safety, treatment efficacy, and professional accountability. **Methods:** A comprehensive literature and policy review was undertaken using sources including scientific journals, government websites, and official AYUSH portals. National and international frameworks were reviewed to analyze ethical principles, regulatory mechanisms, and recent updates in the field. **Results:** A wide array of national regulations, such as the GCP-ASU guidelines, *Ayurveda Ahara* regulations, and NCISM Acts, now govern clinical practice, product safety, and professional conduct. Internationally, WHO has issued detailed frameworks supporting the standardization and global integration of traditional medicine. Digital initiatives like A-HMIS and the AYUSH Suraksha Portal have strengthened pharmacovigilance, patient data management, and transparency. However, disparities in

implementation, limited awareness of ethical obligations among practitioners, and gaps in enforcement remain significant concerns. **Discussion:** The ethical and legal landscape of *ayurveda* is evolving to accommodate modern expectations without compromising traditional values. Strengthening practitioner education, improving regulatory compliance, and fostering integrative research will be pivotal in advancing *Ayurveda's* role in global healthcare while maintaining safety and trust.

KEYWORDS: Medicine, Ayurvedic, Ethics, Research, Code of Ethics, Government Regulations, National Health programs, Health planning guidelines.

Abbreviations

AYUSH – *Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homeopathy*

ADR – Adverse Drug Reaction

AI – Artificial Intelligence

GCP-ASU – Good Clinical Practices guidelines for Clinical trials in *Ayurveda, Siddha and Unani* Medicine

GHPP –Good Herbal Processing Practices

NCISM – National Commission for Indian System of Medicine

A-HMIS – AYUSH Hospital Management Information System

EHR – Electronic Health Records

ICD – International Classification of Diseases

ICMR – Indian Council for Medical Research

IM – Integrative medicine

CCRAS – Central Council for Research in *Ayurvedic* Sciences

CCPA – Central Consumer Protection Authority

CHCs – Community Health Centres

DHs – District Hospitals

ECs – Ethics Committees

PHCs – Primary Health Centres

NAMSTP – National AYUSH Morbidity and Standardized Terminology Portal

NHP – National Health Policy

TM – Traditional medicine

RIM – Research in Integrative Medicine

ASU – Ayurvedic, Siddha, and Unani

GOI – Government of India

GMP – Good Manufacturing Practices

NABH – National Accreditation Board for Hospital and Healthcare

NAMSTP –National AYUSH Morbidity and Standardized Terminology Portal

FSSAI – Food Safety and Standards Authority of India

ICH – International Council for Harmonization

TCIM – Traditional, Complementary, and Integrative Medicine

UHC – Universal Health Coverage

WHO – World Health Organization

1. INTRODUCTION

Ayurveda is traditional holistic approach to healthcare and being practiced since thousands of years. Its vast knowledge regarding the *Ayurveda* principles of treatment, its code of ethics have paved way to channelizing its treatment procedures with respect to legal boundaries and standardization of medicine. *Ayurveda* with its emergence in the developing world has spread its wings to various countries with its various treatment protocols and modification of its traditional medications as well. Its philosophical underpinning is based on the principles of *Tridosha, Panchamahabhuta,* and ethical codes of conduct such as *Sadvritta* and *Vaidyavritti*, which influence not only clinical practice but also practitioner's personal conduct.[1] From evidence-based medicine to evidence-informed medicine is the need of the hour. Globalization of *Ayurveda* is the forefront goal for betterment of medical education and society with appropriate treatment protocols and safety of patients being the utmost concern. A major factor in the globalization of *ayurveda* is the World Health Organization's recent improvement of the International Classification of Diseases [ICD-11], which included the adoption of the eleventh updated suggestions for the first time to classify traditional medicine. By including AYUSH terminology in ICD-11, medical conditions can be counted and compared, facilitating research and assessment to confirm the safety and effectiveness of traditional medicine.[2-3]

The important Concerns about ethical behavior, product safety, regulatory oversight, and evidence-based authentication have increased as a result of *ayurveda's* rapid expansion and commercialization. The necessity of comprehensive medico-legal and ethical controls has been highlighted by issues with unregulated promotion, lack of form standardization, inconsistent clinical records, and insufficient ethical training for practitioners. The article

aims to examine how current *Ayurvedic* governance and practice are shaped by ethical standards, legal frameworks, and policy developments. *Ayurveda* can advance towards safer, more responsible, and internationally integrated healthcare delivery by bringing traditional values into line with modern bioethical norms and bolstering regulatory compliance.

2. AIM

To critically explore and analyze the ethical principles, regulatory frameworks, and recent legal advancements in *Ayurveda*, with a focus on aligning traditional practices with contemporary medico-legal standards to ensure patient safety, professional accountability, and global acceptance.

3. OBJECTIVES

1. To review the foundational ethical principles of *Ayurveda* and their alignment with modern biomedical ethics.
2. To identify key national and international legal frameworks governing *Ayurvedic* practice, product safety, and clinical research.
3. To highlight the challenges and gaps in the implementation of ethical and legal guidelines in *Ayurvedic* education, practice, and regulation.
4. To propose strategic recommendations for strengthening ethical compliance, practitioner training, and integrative frameworks in *Ayurveda*.

4. MATERIALS

The study utilized a wide range of sources to gather relevant data on the ethical and legal landscape of *Ayurveda*. These materials included.

- **Classical *Ayurvedic* texts** discussing ethical codes (e.g., *Sadvritta*, *Vaidyavritti*, *Chatuspada*).
- **Scientific journals and review articles** from databases such as PubMed, Google Scholar, ScienceDirect, and AYUSH Research Portals.
- **National regulations** including.
  - The Drugs and Cosmetics Act (1940)
  - GCP-ASU Guidelines (2013)
  - FSSAI *Ayurveda Ahara* Regulations (2022)
  - NCISM Acts and Codes of Conduct (2020–2023)
- **International guidelines** like.
  - WHO Traditional Medicine Strategy (2014-2023)

- WHO Guidelines on Safety, GMP and Pharmacovigilance
- **Digital initiatives** such as:
- AYUSH *Suraksha* Portal
- A-HMIS (AYUSH Hospital Management Information System)
- NAMSTP (National AYUSH Morbidity and Standardized Terminology Portal)
- **Policy reports, notifications, and circulars** from the Ministry of AYUSH, ICMR, CCRAS, and WHO.

5. METHODS

A comprehensive review methodology was adopted to collect, evaluate, and synthesize literature and official documents relevant to ethics and legal regulations in *Ayurveda*. The following steps were undertaken.

1. **Search Strategy:** A structured search was performed using combinations of keywords like *"Ayurveda ethics," "AYUSH legal regulations," "GCP-ASU," "FSSAI Ayurveda Ahara,"* and *"integrative medicine ethics."* Boolean operators (AND/OR) were applied to refine search results.
2. **Inclusion Criteria**
   - Articles, reports, or policies discussing ethics, legal frameworks, or regulatory updates in Ayurveda.
   - Publications from January 2000 to March 2025.
   - English language documents only.
3. **Exclusion Criteria**
   - Irrelevant editorials, duplicate studies, and commercial articles.
   - Studies lacking reference to ethical or regulatory components.
4. **Data Extraction and Thematic Synthesis**

Relevant content was extracted and categorized under:

- Ethical principles in classical and modern contexts.
- National regulatory acts and professional codes.
- Global guidelines on traditional medicine.
- Digital and policy advancements in AYUSH systems.

5. **Comparative Analysis**

Ayurvedic ethical principles were compared with the four universal principles of Western biomedical ethics—autonomy, beneficence, nonmaleficence, and justice—to highlight commonalities and contextual uniqueness. The details of which are enclosed in Table-01.

Table 01: Comparison between ethics mentioned in Western medicine and *Ayurveda*[1] [Tawalare, et al.]

Western Bioethics	***Ayurveda* Ethics**
Autonomy – Being respectful towards patient & profession	***Vaidyavritti* and *Chatuspada* –** Instructions given by the *acharyas* to the *shishyas.*
Beneficence – Providing care for benefit of others	***Sadvritta palana* –** Following good conduct of practices.
Non-maleficence – Doing no Harm	***Vaidyanimitta Vyapada*** – Avoiding carelessness and doing no harm.
Justice – All to be treated equally & Fairly	***Sadachara*** and ***Kalyanabhivyaharen* –** Following simple lifestyle.

6. Regulatory, Ethical, and Research Guidelines and Policies for Traditional Medicines: Importance and Need

Traditional medicine (TM), including *Ayurveda*, has served as the backbone of healthcare for millions globally, especially in Asia and Africa. With growing interest in integrative healthcare models and the global rise in the use of herbal and traditional systems, there is an urgent need to establish robust regulatory, ethical, and research frameworks. These frameworks help ensure safety, efficacy, standardization, and public trust.

6.1 Importance of Regulatory Guidelines

Regulatory guidelines are essential for the standardization and quality control of traditional medicines. Unregulated production and distribution can lead to adulteration, contamination, and misuse, posing significant health risks.

The Drugs and Cosmetics Act (1940) and its amendments provide legal definitions, manufacturing standards, and marketing regulations for *Ayurvedic, Siddha, and Unani (ASU*) drugs in India.

Such laws are pivotal in protecting consumers and ensuring the credibility of traditional healthcare systems in both domestic and international markets. The guidelines are enlisted in Table- 02.

6.2 Need for Ethical Guidelines

Ethical codes govern professional and research conduct of practitioners. *Ayurveda*, for instance, traditionally enforces ethics through *Sadvritta* (personal code of conduct) and *Chatuspada* (four pillars of treatment). Contemporary health care delivery requires the integration of bioethical concepts—autonomy, beneficence, non-maleficence, and justice.

These laws guarantee that patient rights are safeguarded and that professionals uphold professional integrity. Scientific confirmation of traditional medicine is crucial to its embracement in evidence-based care. Guidelines for structured research facilitate safe clinical trials and data integrity. These instruments play a vital role in closing the gap between conventional knowledge and contemporary biomedical research. Regulatory, ethical, and research guidelines development and enforcement are necessary to ensure the safety, scientific evaluation, and ethical practice of traditional medical systems. As *Ayurveda* and other indigenous systems accelerate global integration, such policies build public trust, facilitate interdisciplinary collaboration, and enhance the integrity of traditional medicine within contemporary healthcare.

Table- 02: Regulatory, ethical and research guidelines and policies for traditional medicines.[4]

Sr.No.	Name of Guidelines	Issuing agency
	National	
01	The Drugs and Cosmetics Act, 1940 and Rules 1945	Government of India (GOI)
02	The Drugs and Magic Remedies (Objectioable Advertsiement) Act 1954 and Rules	Government of India (GOI)
03	Practitioners of Indian Medicine (Standards of Professional conduct, Etiquette and Code of Ethics and Regulations,1982	Government of India (GOI)
04	Good Clinical Practices guidelines for Clinical trials in *Ayurveda, Siddha and Unani* Medicine (GCP-ASU), 2013	Department of AYUSH, Government of India
05	Guidelines for inspection of GMP compliance by *Ayurveda, Siddha and Unani* drug industry, Delhi Department of AYUSH, Ministry of Health and Family Welfare; 2014	Department of AYUSH, Government of India
06	Public notice to consumers and stake holders for promoting safe use of ASU Drugs, 2016	Ministry of AYUSH
07	Accreditation standards for Ayurveda Hospitals, 2nd edition. New Delhi: National Accreditation Board for Hospitals and Healthcare Providers; 2016	NABH
08	Accreditation standards for Panchakarma clinics, Delhi: National Accreditation Board for Hospitals and Healthcare Providers; 2017	NABH
09	National Ethical Guidelines for Biomedical and Health Research Involving Human Participation, 2017	Indian Council for Medical Research, India
10	National Ethical Guidelines for Biomedical Research Involving Children, 2017	Indian Council for Medical Research, India
11	General Guidelines for Drug Development of *Ayurvedic* Formulations, 2018	CCRAS, GOI
12	General Guidelines for Safety/Toxicity Evaluation of *Ayurvedic* Formulations, 2018	CCRAS, GOI
13	Patient rights and responsibility, New Delhi: All India Institute of *Ayurveda*	All India Institute of Ayurveda

14	General Guidelines for Clinical Evaluation of *Ayurvedic* Interventions, 2018	CCRAS, GOI
15	Entry level standards for AYUSH Hospitals, New Delhi: National Accreditation Board for Hospital and Healthcare Providers; 2019.	NABH
16	Entry level standards for AYUSH Centre; New Delhi: National Accreditation Board for Hospitals and Healthcare Providers; 2019	NABH
17	Clinical Trials on AYUSH Interventions for COVID-19: Methodology and Protocol Development	Ministry of AYUSH, GOI
18	National Commission for Indian System of Medicine (NCISM)Act 2020	Central Government of India
19	*Ayurveda* and Conventional medicine medicine cross referral approach for selected disease conditions, New Delhi: Central Council for Research in *Ayurvedic* Sciences; 2021.	CCRAS
20	The Food Safety and Standards Authority of India (FSSAI; *Ayurveda Ahara*) Regulations Act 2022	Food Safety and Standards Authority of India
21	Board of Ethics and Registration Regulations 2022	National Commission for Indian System of Medicine (NCISM)
22	National Commission for Indian System of Medicine (Ethics and Regulation) Regulations, 2023.	National Commission for Indian System of Medicine (NCISM)
	International	
01	General guidelines for methodologies in research and evaluation of traditional medicine, 2000	World Health Organization
02	Guidelines for Regulation of Herbal Medicines in the South-East Asia Region, 2003	World Health Organization
03	WHO guidelines on safety monitoring of Herbal medicines in pharmacovigilance systems, 2004	World Health Organization
04	National policy on traditional medicines and regulation of Herbal medicines, 2005	World Health Organization
05	Operational guidance: Information needed to support Clinical trials, 2005	World Health Organization
06	Handbook for Good Clinical Research Practice (GCP): Guidance for Implementation, 2005	World Health Organization
07	WHO guidelines for assessing quality of herbal medicines with reference to contaminants and residues, 2007	World Health Organization
08	WHO guidelines on good manufacturing practices (GMP) for Herbal medicines, 2007	World Health Organization
09	Patient safety solutions, Geneva: World Health Organization; 2007	World Health Organization
10	Standards and operational guidance for ethics review of health related research with human participants, Geneva: World Health Organization; 2011	World Health Organization
11	Quality control methods for Herbal materials, Geneva: World Health Organization; 2011	World Health Organization
12	WHO Traditional Medicine Strategy 2014-2023	ICH

13	Guideline for good clinical practice: ICH Harmonized guideline (ICH GCP0 2016	ICH International Council for Harmonization
14	Medication errors; Technical series on safety after primary care. Geneva: World Health Organization, 2016	World Health Organization
15	WHO guidelines for marker substances of herbal origin for quality control of herbal medicines. Geneva: World Health Organization; 2017	World Health Organization
16	WHO Guidelines on good herbal processing practices (GHPP) for herbal medicines. Geneva World Health Organization; 2017	World Health Organization
17	WHO Global report on traditional and complementary medicine 2019, Geneva: World Health Organization; 2019	World Health Organization
18	Key technical issues of herbal medicines concerning interaction with other medicines, Geneva: World Health Organization; 2021	World Health Organization
19	WHO benchmarks for training of *Ayurveda*, Geneva: World Health Organization; 2022	World Health Organization
20	Global Strategy for Traditional Medicine 2025:2034	World Health Organization

7. Recent updates in AYUSH advancements

The AYUSH (*Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homeopathy*) system of medicine is in transition with digitalization, regulatory reforms, and integrative healthcare paradigms. Driven by renewed global interest in traditional and holistic health, recent developments have focused on standardizing care, enhancing public confidence, and mainstreaming AYUSH within public health systems. This note calls out important developments over the past few years capturing this forward progression. The recent cyber, regulative, and integrative transformations of AYUSH are a major step towards mainstreaming traditional medicine. These developments strengthen clinical leadership, research quality, and public health contribution, making AYUSH more resilient, internationally connected, and scientifically oriented. The recent updates have been discussed in detail in Table – 03.

Table - 03 Recent updates in AYUSH advancements.

Sr.No.	Name of updates	Highlights / Objectives	Benefits
01	National AYUSH Morbidity and Standardized Terminology Portal (NAMSTP)[5]	In the case of A-S-U systems, a dual coding system for reporting. The WHO's ICD-10/11 allows the homeopathic, yoga, and naturopathic medical systems to report using a single classification system.	By offering standardized diagnostic terminologies, it helps to regulate the health care delivery system in AYUSH systems and gets around the problem of the diagnosis being written in Sanskrit, Arabic, and Tamil in the case of A-S-U systems.

		For safe access, registered institutions have been assigned unique user IDs and passwords.	It is useful in determining the various systems' strong points under AYUSH.
		Through the site, users can access the standardized terminologies of their respective systems.	The Morbidity codes are linked into electronic health record systems. Future policy decisions can be aided by the volume of services offered by AYUSH systems.
		This gateway provides access to the WHO's ICD-10 and ICD-11 coding for ASU medications.	It helps in collecting morbidity data in real time.
02	The Food Safety and Standards Authority of India (FSSAI; *Ayurveda Ahara*) Regulations Act 2022[6]	It enforces guidelines for the safety, quality, and labeling of *Ayurvedic* food products, excluding medicines and proprietary drugs.	It represents a significant milestone in ensuring the safety, quality, and authenticity of *Ayurvedic* food products in India.
		It mandates compliance with Good Manufacturing Practices, contains food additives, and restricts health claims to those substantiated by authoritative Ayurvedic texts.	By enforcing stringent standards for safety, quality, and labeling, the Act seeks to address the growing concerns about *Ayurvedic* products available in the market
		This act aims to enhance consumer trust and product authenticity, impacting *Ayurvedic* doctors' recommendations and practices.	The rules mark a substantial improvement in India's laws governing *Ayurvedic* food items.
		The laws emphasize the significance of upholding traditional dietary practices in *Ayurvedic* treatment by defining "*Ayurveda Aahara*" as food made in accordance with recipes, ingredients, or procedures detailed in authorized *Ayurvedic* literatures.	The regulations introduce critical standards for the safety, quality, and labeling of *Ayurvedic* food products in India distinct from *Ayurvedic* medicines and proprietary drugs.
		Labels must include warnings and usage instructions. Noncompliance results in fines, license suspension/cancelation.	It promotes uniform production procedures and product formulas.
03	Central Consumer Protection Authority (CCPA)[7]	To prevent unfair trade practices and make sure that no one participates in them; safeguard, advance, and defend the rights of consumers as a class; and stop violations of consumers' rights under this Act;	E-commerce platforms are advised that they can only sell or facilitate the sale of *Ayurvedic, Siddha, and Unani* medications that contain ingredients listed in Schedule E (1) of the Drugs and Cosmetics Rules, 1945, once a user uploads a valid prescription from a registered *Ayurvedic,*

			Siddha, or Unani practitioner, respectively.
		To guarantee that no products or services are advertised in a way that is deceptive or untrue and that does not violate the requirements of this Act or the rules or regulations established under it;	The CCPA has the authority to prevent consumer rights violations and to defend, advance, and enforce the rights of consumers as a class.
		Make sure that no one participates in the publication of any deceptive or fraudulent advertisements.	Additionally, the CCPA has the authority to stop unfair commercial practices and make sure that no one participates in them.
04	AYUSH-*Suraksha* Portal[8]	An *Ayurvedic, Siddha, Unani, and Homeopathic* (ASU and H) medication adverse drug reaction (ADR) monitoring program at the national level	It will support the creation of evidence for medications, clinical safety, and the monitoring of deceptive advertising.
		AYUSH-*Suraksha's* primary goals are to track deceptive advertising and gather, compile, and evaluate clinical safety data on ASU & H medications.	On the basis of the generated Adverse Drug Reaction (ADR) data and offensive ads, it will suggest regulatory actions.
05	AYUSH Hospital Management Information System A-HMIS (portal) 2018[8]	AYUSH Electronic Health Records (EHR) dedicated portal To enhance patient care, productivity, research, hospital administration, documentation, and morbidity code collection.	This application offers automated administrative and patient care in a hassle-free manner. Each user of the site has the option to create a unique AYUSH ID.
		To preserve the distinctiveness of each system, the five distinct modules of A-HMIS have been given the following names: *DHANVANTARI* for *Ayurveda, PATANJALI* for *Yoga & Naturopathy, HAKKIM AJMAL KHAN* for *Unani*, *THERAN* for *Siddha,* and *BABU RAJENDRA LAL* for *Homoeopathy*.	All of the A-HMIS data is kept in a centralized database that is part of this web application. It is applicable to all medical systems and throughout India.
06	National AYUSH Mission[9]	i. Strengthening and enhancing Ayush health care services in order to offer them across the nation.	**Infrastructure Development Integrated AYUSH Hospitals:** Established 137 units to provide holistic healthcare services.
		ii. To lessen the burden of sickness and out-of-pocket expenses by implementing a comprehensive wellness model through Ayush Health and Wellness Centers that emphasize	**Upgradation of Facilities:** Enhanced infrastructure and amenities in 315 AYUSH hospitals and 5,023 dispensaries.
			Co-location in Public Health Facilities

		preventative and promotional healthcare based on Ayush principles and practices.	Annual Support: On average each year, 306 District Hospitals (DHs), 713 Community Health Centres (CHCs), and 2,375 Primary Health Centres (PHCs) received assistance for integrating AYUSH services, including medicine supply and contingency support.
			Essential Medicine Supply Annual Provision: Approximately 895 AYUSH hospitals and 12,194 dispensaries were supplied with essential AYUSH medicines each year.
			AYUSH Grams: Developed 692 villages as AYUSH Grams to integrate traditional healthcare practices at the grassroots level.
			Upgradation of Existing Institutes: Enhanced infrastructure and libraries in 77 undergraduate and 35 postgraduate AYUSH educational institutes.
		iii. To promote medical pluralism by co-locating Ayush facilities at PHCs, CHCs, and DHs in order to give the underprivileged public an informed option.	**Health & Wellness Centres *Ayushman Arogya Mandirs*:** Operationalised 12,500 centres to provide comprehensive AYUSH healthcare services, aiming to reduce disease burden and promote self-care.
		iv. To highlight Ayush's contribution to public health in accordance with NHP 2017.	**Educational Advancements** New Institutions: Supported the establishment of 13 new AYUSH educational institutions.
		v. To improve and fortify Ayush educational institutions' infrastructure	**Community Wellness Initiatives Yoga Wellness Centres:** Supported 2,813 centres to promote yoga and holistic health practices.
07	Artificial Intelligence (AI) for global health and advancing traditional medicine[10]	• To discuss experiences pertaining to AI's use in TM, emphasizing the lessons discovered through data collecting and analysis and the conversion of these discoveries into useful applications.	It facilitates transdisciplinary dialogue and global consensus on AI integration in TM. Enhances diagnostic precision, personalization of treatment, and system efficiency in TM. Ensures responsible AI deployment, minimizing risks and maximizing public trust.
		• To clarify the educational requirements of TM stakeholders	

		utilizing AI and promote cooperation among global stakeholders to share best practices and information;	
		• To improve comprehension by providing a thorough overview of AI applications in the TM sector.	Promotes coherent and scalable AI integration across Traditional Medicine sectors.
		• To give stakeholders the abilities and information needed to integrate AI technologies into their TM practices.	It sustains global cooperation, accelerates research, and nurtures innovation in AI for Traditional Medicine.
08	Global Strategy for Traditional Medicine 2025:2034[11]	1.Reviewing and establishing the regional research priorities; conducting regional consultations to obtain insightful feedback and ideas for creating a more suitable and successful strategy	It provides thorough information on international laws, rules, and customs pertaining to complementary and alternative medicine (T&CM). Through emphasis on the health and welfare of Indigenous Peoples, biodiversity protection, and regulatory procedures, it evaluates the advancements and difficulties in incorporating T&CM into national health systems.
		2. Through dialogue and comments, member states' participants will provide their thoughts and suggestions for the following: Vision, Goals, Principles, Objectives, Strategic Directions, and Action Items.	In order to enhance health and wellbeing, this approach places a strong emphasis on providing everyone with safe, efficient, and people-centered Traditional, Complementary, and Integrative Medicine (TCIM).
		3. To assess, establish, and improve regional research priorities	Optimizing TCIM's cross-sector value, bolstering the evidence base, promoting safe and high-quality TCIM through regulatory mechanisms, and incorporating TCIM into health systems for universal health coverage (UHC) are among the strategic goals.
		4. To set up a stakeholders' group and an online dashboard for quarterly virtual meetings to monitor regional research priorities and the global TRM plan.	Evidence-based decision-making, sustainability, holism, Indigenous Peoples' rights, and health equity are important areas of focus.

8. Era of Integration of Traditional Medicine with Modern system

The Indian Council of Medical Research (ICMR) has come up with a path-breaking framework to bring in conventional healing traditions such as *Ayurveda* and *Homeopathy* alongside conventional medicine. This innovation strategy encourages a more integrated model of health care, encouraging interdisciplinary collaboration between various medical disciplines for better patient care and outcomes.

To provide a clear ethical framework for research in integrative medicine (RIM), the Indian Council of Medical Research (ICMR) published an update to the ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017). Through ethical rigor and regulatory sufficiency in research examining the merger of traditional and conventional medical practices, the move represents a significant milestone in the development of the scientific underpinning of Ayush-based integrative healthcare. Integrative medicine (IM) is a multimodal approach that combines modern/conventional medicine with Ayush techniques to optimize patient care and health benefits. Since holistic and individualized treatment is becoming more and more important to people worldwide, ethics and laws must be clear to guarantee the validity, safety, and efficacy of integrative therapies.

Patient safety and scientific integrity are always of the highest concern, and this addendum serves as a reminder to researchers, institutions, Ethics Committees (ECs), and regulatory organizations involved in Integrative Medicine research.

Moreover, Ayush-approved drugs utilized in integrative studies won't need preclinical research or extra safety testing. However, the full regulatory approval process will be required for common medications that are not identified. Thw New Drugs & Clinical Trials Rules (2019), the Drugs & Cosmetics Act (1940), and the Good Clinical Practice (GCP) guidelines for AYUSH systems must all be followed in order to guarantee the compliance.[12]

9. Challenges in Ayurveda and Scope Ahead

According to WHO estimates, over 25% of newly found medications or pharmacological compounds are naturally occurring. The use of medicinal plants in India's mainstream healthcare system is still in its infancy, despite these advantages, and there are still a number of issues that need to be resolved. Natural resources are now under stress due to industrialization and pharmaceutical industry profits, and one of the main problems is the

growing need for genuine and high-quality raw materials. The bio-piracy and bio-prospection; as natural products become more commercialized and in high demand, the idea of distant woods has evolved into natural resources that can be used to make money. Clinical trials, pharmacovigilance (safety, toxicity, and adverse drug response), and quality control are the most difficult problems in herbal medications.[13]

The future scope lies where *Ayurvedic* medications must meet all current licensing, registration, and approval standards set forth by the relevant regulatory bodies in the Member State. Member states should adhere to the regulations they have set up to guarantee the quality of *Ayurvedic* medicines in order to guarantee their safety, efficacy, and quality. It is crucial to make sure that individuals receiving treatments and medications are safe.[14] The important safety regulations are briefed in Fig – 01.

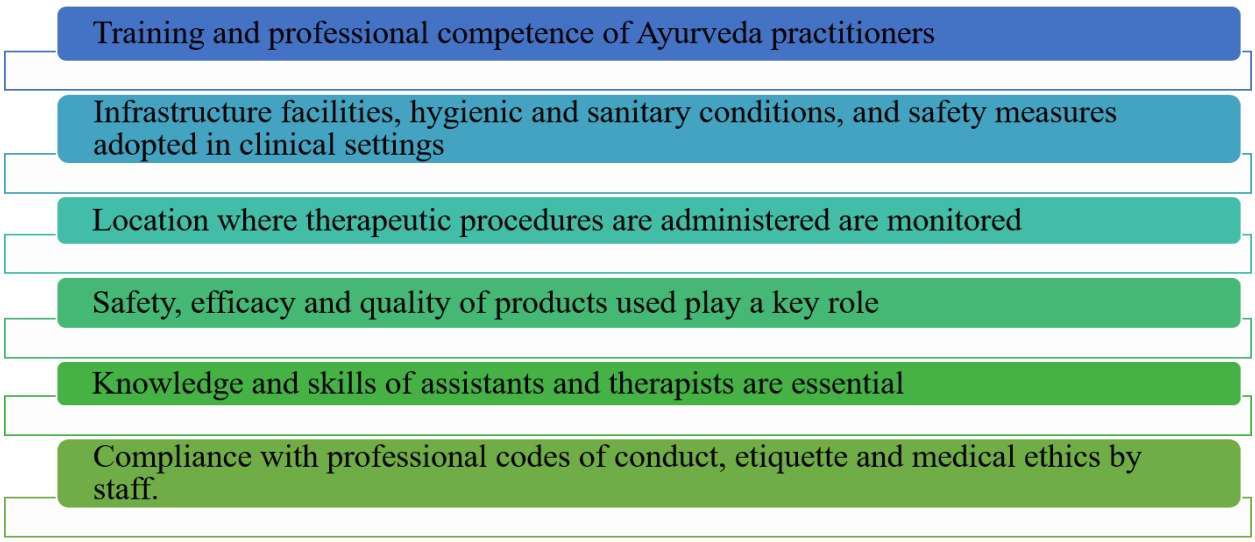

Fig. 01: Important safety standards for regulating *Ayurveda* Interventions.[14]

10. DISCUSSION

The evolving landscape of *Ayurveda* in the 21st century demands a dynamic interplay between its classical ethical doctrines and modern legal and regulatory frameworks. While the foundation of *Ayurvedic* ethics emphasizes personal discipline, patient respect, and professional integrity, aligning these ancient tenets with bioethical principles like autonomy, beneficence, nonmaleficence, and justice enhances the credibility and global relevance of the system (Tawalare et al., 2014).

India has made significant strides in establishing regulatory structures for *Ayurveda* through acts such as the Drugs and Cosmetics Act (1940), GCP-ASU Guidelines (2013), and the NCISM Act (2020). These provide a robust legal framework to govern practitioner conduct, drug quality, and clinical research. Yet, despite this progress, challenges persist in ensuring uniform implementation across regions due to knowledge gaps, infrastructure limitations, and inconsistent enforcement (Nawab & Sherwani, 2024).

Internationally, the WHO Traditional Medicine Strategy 2014-2023 and the upcoming Global Strategy for Traditional Medicine 2025-2034 emphasize evidence-informed integration of traditional systems into national health frameworks. These efforts reinforce the importance of scientific validation, quality assurance, and ethical oversight for traditional medicine worldwide (WHO-SEARO, 2024).

Recent initiatives such as the AYUSH *Suraksha Portal* for pharmacovigilance (Muthappan et al., 2022), NAMSTP for standardized diagnostic coding (Lavaniya et al., 2017), and FSSAI *Ayurveda Ahara* Regulations (2022) for food-based formulations have significantly improved surveillance, standardization, and transparency. Additionally, the ICMR's Research in Integrative Medicine (RIM) addendum offers a crucial ethical framework for combining *Ayurveda* with conventional medicine while maintaining scientific integrity and patient safety [ICMR, 2023].

Despite these advancements, gaps remain. There is a lack of ethical awareness among a significant portion of practitioners, insufficient training on medico-legal responsibilities in *Ayurvedic* curricula, and limited public awareness about patient rights under AYUSH-based treatments. Furthermore, regulatory enforcement often varies across states, and digital platforms like A-HMIS and AYUSH e-portals, while promising, require stronger integration with mainstream health systems.

To ensure *Ayurveda's* responsible globalization, it is essential to.

- Institutionalize bioethics education within *Ayurvedic* academic programs.
- Strengthen regulatory implementation mechanisms at the grassroots.
- Foster cross-disciplinary collaboration between traditional and modern health sectors.
- Develop rapid diagnostic and quality-control technologies to prevent misbranding and adulteration.

In conclusion, the convergence of classical Ayurvedic ethics and modern medico-legal structures represents a critical juncture in the evolution of Ayurveda. Strategic alignment with global health policies, ethical rigour, and evidence-based practice will be key to establishing *Ayurveda* as a trusted and integrative system in contemporary healthcare.

11. CONCLUSION

The revitalization of *Ayurveda* as an essential part of integrative and holistic medicine requires a solid foundation in ethical practice and stringent regulatory adherence. This review highlights that although *Ayurveda's* original doctrines—such as *Sadvritta, Vaidyavritti, and Chatuspada*—naturally fall within contemporary biomedical ethical principles, their practical utilization entails situational adaptation and institutional support.

Substantial strides have been taken through the adoption of country-specific standards such as the GCP-ASU guidelines, FSSAI *Ayurveda Ahara* Regulations, and NCISM ethical codes, and global initiatives such as the WHO Traditional Medicine Strategy. Technological advancements in the form of the AYUSH Suraksha Portal and NAMSTP have propagated the standardization and safety of *Ayurvedic* practice.

Yet, gaps remain in the way of inconsistent application, insufficient ethical training among practitioners, and piecemeal integration with contemporary healthcare systems. Closing these gaps requires a multidimensional response—improving ethics education in *Ayurveda* programs, providing uniform application of legal provisions, and promoting cross-disciplinary coordination.

As traditional medicine finds itself increasingly recognized across the world, *Ayurveda* will undergo development within a scientifically proven, ethically based, and legally safe framework. Such an action will not only protect patient rights and increase clinical responsibility but also establish *Ayurveda* as a reliable and viable system of medicine in the international arena of health.

11.1 Ethical considerations

Not Applicable.

11.2 Conflict of Interest

The authors declare no conflict of interest.

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