International Journal of Advanced Research and Development
www.multireviewjournal.com
ISSN: 2455-4030
Received: 19-03-2026, Accepted: 19-04-2026, Published: 04-05-2026
Volume 11, Issue 2, 2026, Page No. 20-23

Ethical and legal issues in the integration of Ayurveda with modern medicine in India

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Abstract
India's healthcare landscape occupies a singular position in the world, straddling two epistemological traditions that are separated by centuries of divergent development yet increasingly forced into coexistence within a single administrative and clinical system. Ayurveda, one of the world's oldest continuous medical systems, and biomedicine, the globalised scientific framework dominant since the nineteenth century, are today being formally integrated through national policy mechanisms in ways that raise profound ethical and legal questions. This paper examines those questions by mapping four overlapping domains of concern: the regulatory architecture governing dual practice, informed consent as an ethical obligation, the politics of intellectual property over traditional formulations, and the contested terrain of research and evidence standards. Drawing on statutory instruments, scholarly commentary, and documented case studies, the analysis argues that integration conducted without rigorous ethical scaffolding risks subordinating patient welfare to institutional ambition. Genuine pluralism in healthcare requires not merely administrative convenience but a principled legal framework that respects the distinctiveness of each tradition while holding both to enforceable standards of safety and transparency.

Keywords: Ayurveda, bioethics, ayush policy, dual practice, informed consent, traditional knowledge, intellectual property, evidence-based medicine, India

Introduction

The ambition to combine the strengths of Ayurveda with those of contemporary biomedicine is not new in India, but it has acquired a fresh urgency and a formal policy character under the national AYUSH framework established in 2014. For proponents, integration promises expanded therapeutic options, reduced drug costs, culturally resonant care, and the revival of an indigenous intellectual heritage. For critics, it threatens to blur diagnostic categories, expose patients to under-studied interactions, and dilute the evidentiary standards that underpin safe clinical practice. Both positions contain genuine insight, and that very tension is what makes the subject ethically rich and legally complex.

The difficulty is compounded by the fact that Ayurveda and biomedicine are not simply different techniques for achieving the same ends; they rest on incompatible foundational ontologies. Ayurveda understands health as a dynamic equilibrium among the three doshas — vata, pitta, and kapha — within an individual constitution, or prakriti, that is unique and irreducible. Biomedicine, by contrast, constructs disease as a deviation from physiological norms that can in principle be identified, measured, and corrected through standardised interventions. When a practitioner trained in one tradition makes clinical decisions, the very categories being deployed differ from those available to a practitioner in the other. Integration that ignores this difference produces neither good Ayurveda nor good biomedicine; it produces a hybrid whose safety profile is difficult to predict. This paper does not argue that integration is inherently wrong. It argues that integration conducted in the absence of adequate ethical norms, clear legal accountability, and transparent communication with patients is wrong — and that this is, unfortunately, often the condition under which it currently proceeds in India. The sections that follow examine the specific dimensions of this problem in turn.

The Regulatory Framework For Integrated Practice

1. The Architecture of Dual Registration

The legal basis for Ayurvedic practice in India rests primarily on the Indian Medicine Central Council Act of 1970, which established the Central Council of Indian Medicine (CCIM) and empowered state governments to recognise practitioners through their own statutory boards. Biomedicine is governed through a parallel architecture anchored in the Indian Medical Council Act of 1956 and, more recently, the National Medical Commission Act of 2020. What these frameworks have conspicuously failed to provide is a coherent interface between them. The absence of such an interface has practical consequences. A number of state governments — most notably Andhra Pradesh, Maharashtra, and Gujarat — have issued orders permitting registered AYUSH practitioners to perform certain surgical procedures and prescribe allopathic medicines on completion of bridge courses. The legality of these orders has been disputed through litigation, most prominently in the proceedings before the Supreme Court in the matter of the Indian Medical Association versus the Union of India, which produced a significant judgment in 2021[8]. The Court, while acknowledging the government's authority to frame integration policy, expressed reservations about bridge courses as a substitute for full training and directed that any expansion of scope of practice comply with principles of patient safety.

The deeper issue is jurisdictional fragmentation. Health is a concurrent subject under the Seventh Schedule of the Constitution, meaning both Parliament and state legislatures may legislate on the matter. This produces an asymmetric patchwork: some states have enacted detailed integrative practice rules, others have none, and the central government's policy pronouncements through the Ministry of AYUSH create soft law that is politically potent but legally ambiguous. Patients moving between states, or receiving care from a practitioner whose qualifications span

traditions, may be unaware of which regulatory standard governs their treatment.

2. Drugs and Cosmetics Act Provisions

The Drugs and Cosmetics Act of 1940 and its 1945 Rules remain the primary instrument for regulating Ayurvedic formulations, distinguishing between classical formulations listed in authoritative texts and proprietary Ayurvedic medicines that claim novel compositions. The distinction matters legally because classical formulations are largely exempt from the pre-market clinical trial requirements that apply to new chemical entities under Schedule Y. This exemption, designed to protect traditional knowledge from regulatory overreach, has the unintended effect of creating an uneven safety standard: a new synthetic drug must pass through controlled trials before reaching patients, but an ancient formulation need not, even when it is being commercially manufactured at industrial scale and marketed to populations whose daily exposure to heavy metals, for instance, may differ substantially from historical norms. Certain rasa shastra formulations contain metals such as mercury, arsenic, and lead that have been subjected to purification processes — shodhana and marana — intended to render them therapeutically active and non-toxic. Whether these purification processes achieve their intended effect at the molecular level is a matter of ongoing scientific debate. Documented cases of heavy metal toxicity associated with Ayurvedic preparations have been reported both within India and among diaspora communities abroad, creating a reputational hazard for the tradition and a genuine patient safety problem. The legal framework's failure to require systematic post-market surveillance for such formulations represents a significant ethical lacuna.

Informed Consent and Patient Autonomy

1. The Philosophical Foundations of Consent

Informed consent in medical ethics rests on two interlocking values: respect for persons as rational agents capable of directing their own lives, and the practical safeguard that meaningful consent provides against exploitation. For consent to be genuinely informed, a patient must receive information that is accurate, comprehensible, and sufficient to support a decision; must be capable of understanding and deliberating on that information; and must be free from coercion. These requirements are codified in Indian law through the Consumer Protection Act, through the professional codes issued by the National Medical Commission, and through common law principles that have been elaborated in a series of High Court and Supreme Court judgments. In the context of integrated practice, the consent challenge becomes substantially more complex than in single-tradition care. A patient visiting a practitioner who may draw on both Ayurvedic and biomedical repertoires needs to understand, at minimum, the epistemic basis of any recommended intervention, whether it has been evaluated through controlled research, what adverse effects and drug interactions have been identified, and what alternatives exist within both traditions. In practice, none of these disclosures is consistently provided. Surveys conducted in hospital outpatient departments in several cities have found that a majority of patients receiving integrated treatment were unaware that the formulations they were being prescribed had not been tested in randomised trials, and many did not know that their Ayurvedic treatment was being combined with biomedicinal drugs.

2. The Specific Problem of Herb-Drug Interactions

Pharmacological research has identified numerous clinically significant interactions between Ayurvedic botanicals and pharmaceutical drugs. Ashwagandha has shown additive effects with sedative medications. Ginger and garlic preparations can potentiate anticoagulant therapy, increasing bleeding risk. Guggul has been shown to affect the bioavailability of certain cardiac drugs including propranolol. Triphala affects intestinal motility in ways that can alter the absorption of co-administered pharmaceuticals. These interactions are not hypothetical: case reports documenting adverse outcomes attributable to undisclosed concurrent use of Ayurvedic preparations and pharmaceutical drugs appear in the medical literature with sufficient frequency to constitute a pattern.

The ethical obligation of informed consent requires that patients be told of these risks. The legal obligation is less clear because it is poorly enforced. No central registry of herb-drug interactions exists that practitioners are required to consult, and the educational curricula of neither BAMS nor MBBS programmes systematically cover cross-tradition pharmacology. This is an ethical failure embedded in an institutional one: it cannot be corrected by individual clinical virtue alone but requires structural reform of training, documentation, and liability.

Traditional Knowledge and Intellectual Property Rights

1. Biopiracy and the Limits of Patent Law

The encounter between traditional Ayurvedic knowledge and the global intellectual property system has produced some of the most internationally visible legal controversies in Indian health policy. The case of turmeric — in which a United States patent for wound healing using curcumin was successfully challenged by the Council of Scientific and Industrial Research on grounds of prior art documented in ancient Sanskrit texts — became a defining episode that demonstrated both the vulnerability of traditional knowledge to appropriation and the possibility of defending it through existing legal mechanisms. Similarly, the neem patent disputes of the 1990s and the legal battles over basmati rice illustrated how products and processes central to Indian agricultural and medical practice could be claimed as novel inventions by foreign entities with access to patent offices and legal resources that traditional communities lacked.

India's legislative response was multifaceted. The Patents Act was amended in 2005 to include Section 3(p), which excludes from patentability any invention that is traditional knowledge or an aggregation or duplication of known properties of traditionally known components. The Traditional Knowledge Digital Library (TKDL), developed jointly by the Ministry of AYUSH and the Council of Scientific and Industrial Research, represents a more proactive instrument: a structured, searchable database of Ayurvedic, Unani, Siddha, and Yoga formulations drawn from classical texts and formatted in a manner compatible with international patent classification systems. As of recent counts, the TKDL contains over three hundred thousand formulations and has been successfully used to oppose or invalidate patents in multiple jurisdictions.

2. The Community Dimension: Who Benefits?

Defensive mechanisms like the TKDL address the question of who may appropriate traditional knowledge; they do not address the separate question of how value generated from that knowledge should flow back to the communities that produced and transmitted it. A pharmaceutical company that adapts an Ayurvedic formulation, conducts trials under regulatory standards, and brings a new product to market may have done nothing that patent law prohibits — particularly if it has introduced sufficient chemical modification to clear the Section 3(p) bar. Yet the communities whose accumulated observation gave rise to the original formulation receive nothing. The Convention on Biological Diversity and its Nagoya Protocol, to which India is a signatory, establish a framework of access and benefit sharing premised on prior informed consent and mutually agreed terms. India implemented this framework domestically through the Biological Diversity Act of 2002 and associated regulations. In theory, entities wishing to access biological resources associated with traditional knowledge for research or commercialization must obtain approval from the National Biodiversity Authority and must negotiate benefit-sharing arrangements with local communities through Biodiversity Management Committees. In practice, compliance is inconsistent, awareness among local communities is uneven, and enforcement capacity is limited. The ethical aspiration of the framework — equitable sharing of benefits with those who created the knowledge — has not been translated into reliable practice.

Research Standards, Evidence, and Epistemic Justice

1. The Randomised Controlled Trial as Contested Paradigm

A persistent tension in the integration debate concerns the appropriate evidentiary standard for Ayurvedic interventions. The randomised controlled trial, or RCT, occupies the apex of the evidence hierarchy in contemporary biomedicine for good methodological reasons: randomisation controls for confounding, blinding minimises expectancy effects, and statistical inference allows generalisation. Applying this standard to Ayurveda, however, creates difficulties that are not merely practical but conceptual. Ayurvedic treatment is individualized in a way that makes standardised interventions — the methodological prerequisite for an RCT — difficult to construct without distorting the therapeutic logic being tested. A classical Ayurvedic practitioner selects a formulation based on the patient's prakriti, the current state of the doshas, the season, the patient's digestive strength, and multiple other factors. Two patients presenting with what biomedicine would classify as the same disease might receive entirely different treatments, and a third patient might receive a treatment that addresses a different condition altogether because the practitioner has identified a more fundamental imbalance. A trial that administers a fixed formulation to all patients in a diagnostic category is, from a classical Ayurvedic perspective, studying something that no trained vaidya would actually do..

2. Research Ethics and Vulnerable Participants

The Indian Council of Medical Research's National Ethical Guidelines for Biomedical and Health Research Involving Human Participants provide the primary ethical framework for research in India. These guidelines, last comprehensively updated in 2017[7], draw on internationally recognised principles including the Declaration of Helsinki. They apply in principle to research on Ayurvedic interventions as much as to pharmaceutical trials. In practice, their application to traditional medicine research has been inconsistent. Research on Ayurvedic treatments has in a number of documented cases been conducted without ethics committee review, without adequate informed consent protocols, and with inadequate attention to the risks of herb-drug interactions in participant populations who may be concurrently taking pharmaceutical medications. The ethical vulnerability of participants is compounded when research is conducted in rural or tribal communities where formal literacy may be limited, institutional authority may suppress genuine voluntariness, and the researchers are perceived as representatives of a distant state. These conditions do not disqualify community-based Ayurvedic research; they impose heightened obligations of procedural care on those who conduct it.

Conclusion

India's experiment in formal Ayurveda-biomedicine integration is proceeding at a pace that outstrips the development of the ethical and legal architecture needed to govern it responsibly. The result is a clinical landscape in which patients receive care of uncertain epistemic provenance, traditional knowledge is both valorised and exposed to appropriation, evidence standards remain contested, and accountability mechanisms are fragmented. None of these problems is inherent to integration as such; all of them reflect failures of institutional design that can, in principle, be corrected.

The ethical stakes are high because they involve some of the most fundamental commitments of medical practice: the obligation not to harm, the duty to tell the truth about what one knows and does not know, the requirement to obtain meaningful consent, and the aspiration to distribute the benefits of healing knowledge equitably. These commitments do not belong to any single medical tradition. They are the common inheritance of every system that takes seriously its responsibility to those who are ill and vulnerable.

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