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A Review of Medicolegal Aspects in Ayurvedic Practice

Bhute R.[1], Chavan K.[2]

1. PG student, Department of Agadtantra, Govt. Ayurved College Nagpur
2. Associate professor, Department of Agadtantra, Govt. Ayurved College Nagpur

ABSTRACT:

The integration of law into medical practice is crucial to ensure the healthcare system functions effectively and avoids issues such as malpractice, inadequacies, and regulatory gaps. This includes practices like obtaining consent, preventing adulteration, and regulating marketing and advertising. While these legal aspects are well-established in conventional medical fields, their application in Ayurveda remains underdeveloped in many areas. This presents a significant challenge, especially given the existing gaps in the current system. Key issues include the absence of informed consent for procedures like *Panchakarma, Agnikarma*, and *Ksharakarma*, as well as misleading advertisements about Ayurvedic treatments. Furthermore, false claims regarding the efficacy and longevity of Ayurvedic medicines, and the marketing of herbal products as "*Ayurvedic drugs*" exacerbate the problem. The lack of adequate medico-legal oversight contributes to a tarnished public image of Ayurveda, making it crucial for the community to address the need for stronger legal frameworks in Ayurveda practice. Such efforts will help improve the professional integrity of Ayurveda and protect both practitioners and patients.

KEYWORDS: Ayurveda, medico-legal issues, informed consent, legal regulations, healthcare, marketing practices.

CORRESPONDING AUTHOR:

Dr. Ruchita A. Bhute

PG student, Department of Agadtantra,

Govt. Ayurved College Nagpur

Email - ruchitabhute1995@gmail.com Mobile No.- 9405803010

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INTRODUCTION:

In medical practice, the application of law is essential for ensuring ethical conduct by practitioners worldwide. It helps prevent inadequacies, gaps, and malpractice that could harm patient care. Legal frameworks promote medical vigilance and uphold standards, ensuring safe and ethical practices across the globe. In Ayurvedic practice, medico-legal vigilance is often lacking, particularly in clinical procedures such as *Panchakarma, Raktamokshan*, and *Ksharsutra*. These procedures are frequently performed without proper informed consent or adequate explanation of potential risks and necessary precautions, as there is no standardized proforma or SOP in place[1]. In contrast, obtaining informed consent is a common and vital practice worldwide. Additionally, there is widespread misinformation being circulated through various advertising channels, many of which are illegal, misleading, and based on exaggerated claims. Unfortunately, these actions often go unnoticed by regulatory authorities, and when they are detected, strict measures are rarely enforced[2]. Another significant issue in Ayurvedic practice is the improper use of Ayurvedic drugs, including incorrect dosages, toxicity, and adulteration[3]. The standardization and safety of these drugs remain major concerns and are often overlooked due to widespread misconceptions about Ayurveda. For example, there is a belief that Ayurvedic drugs have no expiry date or that they are free from harmful effects. These misunderstandings contribute to the lack of proper regulation and oversight in the use of Ayurvedic medicines[4]. Lastly, it is important to note that biomedical waste management in Ayurveda practice only gained attention after the amendment of the Biomedical Waste Management Act in 2016, which included AYUSH hospitals. However, the implementation of this regulation remains a concern due to a lack of awareness and proper understanding within the Ayurveda community[5]. Several factors contribute to tarnishing the reputation of Ayurveda. As a community, it is the responsibility of every practitioner to work towards improving this situation. This study seeks to highlight these issues and aims to inspire further research focused on finding effective solutions[6].

Aim

To explore the medico-legal aspects in field of Ayurveda.

Objectives

1. To review the medico-legal aspects related to Ayurveda.
2. To provide comprehensive data for future research and development in Ayurvedic medico-legal oversight.

MATERIALS AND METHODS

Materials

Classical and modern textbooks, research articles, and online sources were reviewed for the research content.

Methods

The literature was reviewed, and the data was categorized into the following broad areas:

1. Consent
2. Drug-related issues
3. Advertising practices
4. Biomedical waste management

RESULT

1) Consent

The term "consent" refers to voluntary agreement, compliance, or permission (Section 13 of the Indian Contract Act). Legally, it is mandatory to provide reasonable information and allow the patient or their relatives to make an informed decision[7]. However, unlike in modern medical practice, obtaining informed consent for procedures such as *Agnikarma, Vaman, Virechan, Basti,* and *Raktamokshana* is not common or mandatory in Ayurveda. In the event of complications arising from any of these

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procedures, there is often no evidence of valid informed consent, as no standardized proforma or uniform protocol is in place[8].

2)Drug-related Issues

Ayurvedic medicines are often misunderstood and are not regarded in the same way as other drugs, despite having their own pharmacopoeia and formulary. This misconception is fueled by beliefs such as "Ayurvedic drugs have no expiration date or side effects." However, specific definitions for ASU (Ayurveda, Siddha, and Unani) drugs clearly state that these medicines should be treated like any other pharmaceutical drugs, with due consideration for their safety, efficacy, and regulation[9].

The problems can be broadly categorised as

a) Adulteration.

b) Improper dosage and toxicity.

c) Lack of proper standardization.

a) **Adulteration**

Section 33EE addresses the adulteration of drugs. In summary, drugs that contain harmful or contaminated substances, are prepared in unsanitary conditions, or are mixed with other substances such as coloring agents (whether toxic or non-toxic), will be classified as adulterated drugs[10].

Today, numerous instances exist where herbal or herbo-mineral drugs are adulterated with artificial coloring, dust, and other harmful substances. In some cases, inexpensive powders are sold under the guise of costly and rare Ayurvedic raw materials. Additionally, there are cases where certain Ayurvedic proprietary medicines are adulterated with substances like steroids to produce quicker results, which is also considered an offense under Section 33EEC for misbranded drugs.

b) **Improper Dosage and Toxicity**

Every drug is meant to be administered in a specific dosage and for a defined duration. In modern medicine, these dosages are generally determined through clinical studies. However, under the Drugs and Cosmetics Act, ASU (Ayurveda, Siddha, and Unani) drugs are not required to undergo such safety trials, as classical texts are considered sufficient proof of their efficacy and safety. Ayurvedic drugs are usually described with guidelines on their dosage (*Matra*), method of administration (*Anupana*), and timing (*Kaal*), as well as indications and contraindications (*Arha-Anarha*) in the classics. Despite this, many Ayurvedic medicines are sold over the counter without a physician's recommendation. Some of these drugs contain substances listed under Schedule E(I), which includes poisonous or toxic substances.

These drugs are often consumed over extended periods in incorrect dosages, leading to adverse drug reactions (ADRs). For example, *Sanjeevani Vati,* which contains *Bhallataka*, or *Tribhuvan Kirti Ras*, can cause severe reactions in patients with a *Pitta* constitution. In some cases, acute or sub-acute toxicity may occur. For instance, the use of *Parada/Kajjali Kalpas* can lead to nephrotoxicity, while the prolonged use of *Taamra*-containing drugs like *Arogyavardhini*, without proper indications, can result in hepatotoxicity. Chronic use of *Garbhapal Rasa* may lead to neurotoxicity[11].

c) **Lack of Proper Standardization**

As per Sections 33EEB and 33EEC, ASU drugs must be manufactured only under a valid license issued by the Licensing Authority. Proprietary medicines can also be produced once they are approved by the competent authorities. While practitioners are permitted to compound and dispense medicines to their own patients, manufacturing, packaging, and distributing these drugs in the market require the proper license.

Despite these laws being clearly outlined, many small-scale pharmacies continue to operate, dispensing drugs without proper

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standardization or licenses. Many of these drugs lack appropriate labeling, resulting in substandard medicines being given to patients and leading to additional, avoidable complications.

3) Advertising practices

a) Generalizing term “Ayurvedic”

b) Misleading hoardings

c) Unauthorized TV commercial/newspaper advertisement

Various laws govern the advertisement of ASU (Ayurveda, Siddha, and Unani) drugs. Section 33EEC of the Drugs and Cosmetics Act specifically addresses misbranded drugs, stating that making false claims about the efficacy or activity of a drug is considered a form of misbranding.

a. **Generalizing the Term "Ayurvedic"**

An Ayurvedic drug is one that is referenced in Ayurvedic classics. Any other preparation should be classified as herbal, proprietary, or patent. According to the Drugs and Cosmetics Rules, 1945, Chapter XIX, there are a total of 56 Ayurvedic classics listed under the Drugs and Cosmetics Act. However, this protocol is often not followed, and the term "Ayurvedic" has become a generic label applied to any preparation containing even minimal herbal ingredients. This practice tarnishes the image of Ayurveda, as many of these products have no scientific basis or references from any of the scheduled classics. However, this protocol is often not followed, and the term "Ayurvedic" has become a generic label applied to any preparation containing even minimal herbal ingredients. This practice tarnishes the image of Ayurveda, as many of these products have no scientific basis or references from any of the scheduled classics.

b. **Misleading Hoardings/Pamphlets**

It is common to see large hoardings or flashy pamphlets making exaggerated claims, such as "100% results" or complete recovery from otherwise incurable disorders. These practices are often carried out by practitioners or even unqualified individuals. Soliciting patients with false promises of permanent cures is not only unethical but also highly misleading and harmful to the reputation of Ayurveda.

c. **Misleading TV Commercials/Newspaper Advertisements**

Under various sections of the Drug and Magic Remedies (Objectionable Advertisements) Act, 1955, it is an offense to advertise drugs and remedies based on false claims and without scientific evidence. Misleading advertisements in TV commercials or newspapers that make unsubstantiated promises violate this law[12]. Many products, including proprietary herbal medicines and herbal extracts, are falsely advertised as "Ayurvedic" treatments for curing diseases, enhancing sexual power, avoiding surgery, or acting as tonics. Influential personalities and sometimes fabricated patient testimonials are used to mislead the public and manipulate the judgment of unsuspecting viewers[13]. For instance, *Punsavan Vidhi,* which is a procedure described in Ayurveda to ensure the birth of a healthy and well-developed infant (regardless of gender), is misrepresented as a method for sex selection and promoting female foeticide, which tarnishes the image of Ayurveda[14]. Additionally, remedies like gemstones, amulets, and other unrelated products are unnecessarily linked to Ayurveda. This misrepresentation is concerning, as such media has a vast reach and is easily believed by impressionable audiences[15].

IV) **Biomedical Waste**

The Biomedical Waste Management Rules, 1998, were amended in 2016 to include AYUSH hospitals. Any waste generated in Ayurvedic practice can be categorized according to Schedule I of the BMW management rules. However, there is still a need for proper segregation and implementation of these guidelines, as failure

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to do so could pose significant environmental and health risks[16].

Summary

As highlighted, the Ayurveda community faces several medico-lega l aspects, including the absence of standardized protocols for documentation, insufficient legal action against misleading advertisements, and a lack of stringent enforcement of the Drugs and Cosmetics Act and related regulations. These issues contribute to ongoing concerns within the practice of Ayurveda.

DISCUSSION:

As discussed in this study, the medico-legal aspects faced by the Ayurveda community are significant and require immediate attention. A thorough understanding of these issues is crucial to finding effective solutions. Further examination of existing laws, along with the introduction of new legislation that imposes stricter penalties for non-compliance with current regulations, is essential to improving the situation. Such measures will not only strengthen medico-legal oversight but also support the development of medical jurisprudence in Ayurveda.

CONCLUSION:

The medico-legal challenges in Ayurveda highlighted in this study reflect significant gaps in clinical practice, drug regulation, advertising ethics, and biomedical waste management. Despite the availability of legislative provisions such as the Drugs and Cosmetics Act, Drug and Magic Remedies Act, and Biomedical Waste Management Rules, inadequate implementation and poor awareness continue to affect the credibility of Ayurvedic practice. The absence of standardized informed consent processes, improper drug manufacturing and dispensing, misleading advertisements, and insufficient vigilance collectively weaken professional accountability. To safeguard both patients and practitioners, it is essential to strengthen medico-legal oversight through proper enforcement of existing laws, development of uniform clinical protocols, and improved regulatory monitoring. Increasing awareness among practitioners regarding legal obligations, ethical responsibilities, and safe clinical practices is equally important. Establishing robust legal frameworks and promoting evidence-based practice will ultimately enhance the integrity, reliability, and public trust in Ayurveda.

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Website: www.ijim.co.in **Email**: ijimjournal1@gmail.com