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LEGAL PROTECTION OF TRADITIONAL MEDICINE IN INDIA

In medicine, or the astronomy and metaphysics, the Hindus have kept pace with the most enlightened nations of the world: and that they attained as thorough a proficiency in medicine and surgery as any people whose acquisitions are recorded.

Horace Hayman Wilson[1]

1. Introduction

A famous specialist in the field of Indian medicine, French scholar Jean Filliozat, notes that ancient Indian science had a fundamental influence on the development of knowledge in Tibet, Indochina, Indonesia, Central Asia, and in certain Chinese and Japanese circles. The role of Indian medicine in Asian countries is comparable to the role of Greek medicine in the Western world. It is noteworthy that classical Indian medicine emerged as a system at the same time as Greek science had its golden age; similar intellectual transformations took place simultaneously in both regions of the world.[2] Both in theory and in the practice of treating diseases, local religions on the Indian subcontinent, especially Hinduism and Buddhism, have made their distinct mark. Religious norms that support and promote values such as kindness, charity, or compassion influence the practice of daily life, including care for health. From a religious perspective, a human being constitutes a material-spiritual unity, and his/her life is deeply embedded in the harmony of the entire

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DOI: 10.4467/23538724GS.24.011.19873

[1] Quot. Anonymous, *Eminent Orientalists Indian, European, American*, Asian Educational Services, New Delhi – Madras 1991, p. 77.

[2] J. Filliozat, *The Classical Doctrine of Indian Medicine. Its origins and its Greek Parallels*, trans. D.R. Chanana, Munshiram Manoharial, Delhi 1964, p. XVII.

universe. The appearance of disease is perceived here as a disruption of this balance; hence appropriate medical measures are taken to restore it.

Traditional Indian medicine is not a homogeneous system, but is divided into several subsystems, namely Ayurveda, Siddha (Tamil medicine), Unani (Persian-Arabic medicine), and Sowa-Rigpa (Tibetan medicine). While in ancient times, the medical knowledge of India as its intangible cultural heritage reached only neighbouring states and regions, nowadays it has global importance. The increasing use of natural healing methods, such as herbal medicine, cleansing, and diet, serves as an alternative to Western allopathic medicine. Yoga and homeopathy also find contemporary medical applications. Although the adaptation of traditional Indian practice in other cultures has caused them to lose some of their religious character, it nonetheless indicates their universal dimension. In this context, caring for one's health is perceived as a conscious effort of the individual, part of their lifestyle, and self-improvement. Modern Western medicine largely is based on a Cartesian, dualistic vision of humans as dual beings composed of mind (*res cogitans*) and matter (*res extensa*), causing the human body to lose its special ontological character and to be perceived as a complex mechanism operating according to fixed, predictable rules. However, analysis of the history of Western medical knowledge also makes it possible to advance the thesis that there were connections between Indian medicine and Western medicine (e.g., Hippocrates' theory of humours or the idea of the human microcosm formulated by Hildegard of Bingen).

Traditional Indian medicine is part of an intangible heritage that is subject to legal protection. According to art. 2 para. 1 of the UNESCO Convention for the Safeguarding of the Intangible Cultural Heritage adopted in Paris by the UNESCO General Conference on 17 October 2003 (hereinafter: the 2003 UNESCO Convention), intangible cultural heritage refers to the practices, representations, expressions, knowledge, and skills – as well as the instruments, objects, artefacts and cultural spaces associated with these – that communities, groups and, in some cases, individuals recognize as part of their cultural heritage. This heritage includes: oral traditions and expressions, including language as a vehicle for the intangible cultural heritage; performing arts; social practices, rituals and festive events; knowledge and practices concerning nature and the universe; and traditional craftsmanship (art. 2 para. 2 of the 2003 UNESCO Convention). The medical knowledge and traditional healing methods that have developed over several millennia in India, being an essential part of its national identity, can certainly be regarded as part of its intangible cultural heritage. The aim of this article is to analyze the instruments of legal protection for traditional Indian medicine, and to discuss whether the current model of legal protection is adequate in the context of the challenges posed by contemporary biomedicine. To achieve this goal, the author uses formal-dogmatic and comparative legal research methods, and resorts to the historical method as an auxiliary method.

2. The heritage of traditional Indian medicine

India's cultural richness and diversity have made possible that culture's preservation and further development throughout the millennia until modern times. The origins of Ayurveda have disappeared in the darkness of the past, and it is now recognized as one of the oldest systems of medicine in the world. The word "Ayurveda" is the combination of two Sanskrit words: *ayur* (life) and *veda* (knowledge); this indicates that is the science of life and longevity. According to ancient beliefs, medical knowledge was transmitted by Brahma, the creator of the universe, and then passed through successive divine beings to the sage (*rishi*) Dhanvantari, who taught it to the physician Susruta and others.[3] Ayurvedic medicine is based on two complementary treatises of the Atharva Veda: the *Charaka Samhita*, mainly dealing with medicine, and the *Sushruta Samhita*, which focuses on surgery. Similar to Chinese medicine, various vital points on the human body, called *marmas*, were identified, which were important parts of Ayurvedic anatomy. Ancient Hindu physicians excelled in the field of surgery, performing tasks such as cauterization, suturing wounds, draining fluids, treating cataracts, removing bladder and kidney stones, and even performing rhinoplasty and earlobe reconstructions.[4]

The Ayurvedic system is holistic in nature. Its premise is that the human body constitutes an inseparable whole. Therefore, effective treatment should aim to restore harmony to the entire organism, not just its individual components. The human body consists of seven basic types of tissues: *rasa* (lymph, plasma), *rakta* (blood), *mamsa* (muscles), *meda* (fat), *asthi* (bones), *majja* (bone marrow), and *shukra* (egg cell, sperm). An important Ayurvedic principle is the concept of the five elements that make up everything in the world (ether, air, fire, water, and earth), and the three basic types of energy, the so-called doshas (*vata*, *pitta*, *kapha*). It is crucial for individuals to maintain the necessary balance between these elements and *doshas* to maintain their health. Various types of preparations, based on plant, animal products, minerals, and metals, are used in the treatment process.[5] Cleansing the body of toxic substances and enjoying a proper diet also play important roles. To achieve this, practices such as baths, enemas, and the use of essential oils are recommended. It is crucial to note that therapeutic activities should be tailored to the

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[3] H. Iyer, A.J. D'Ambrosio, "Web Representation and Interpretation of Culture: The Case of a Holistic Healing System" [in:] *Annual Review of Cultural Heritage Informatics 2012–2013*, ed. S.K. Hastings, Rowman&Littlefield, Lanham 2014, p. 47.

[4] N. Duin, J. Sutcliffe, *A History of Medicine: From Prehistory to The Year 2020*, Simon&Schuster, London 1992, p. 17.

[5] A. Máthé, I.A. Khan, "Introduction to Medicinal and Aromatic Plants in India" [in:] *Medicinal and Aromatic Plants of* India, vol. 1, eds. A. Máthé, I.A. Khan, Springer, Cham (Switzerland) 2022, p. 17.

specific patient, thus requiring a detailed interview beforehand, including gathering information about the patient's lifestyle and diet.

Similarly, the medical system of Indian Siddha, has an ancient origin. In it natural preparations are also commonly used. It developed mainly in the southern part of the India (Tamil Nadu), and it is a part of the local Tamil culture. The term *Siddha* means perfection or attainment, and it is associated with the practice of holy figures called Siddhars, who imparted medical knowledge. The medical concepts are very similar to those found in Ayurveda, namely the perception of the human body as a complementary whole and the need to maintain balance between the three types of energy. Furthermore, there are 96 main components of the human being, with physical, physiological, moral, and intellectual characteristics, which should be harmonized with each other, as otherwise the result may be disease. Siddha relates to iatrochemistry, utilizing minerals, metals, and herbal preparations for therapeutic purposes.[6] The fundamental difference between Siddha and Ayurveda seems to be that while the former recognizes the same influence of *vata*, *pitta*, and *kapha* in childhood, adulthood, and old age, the latter distinguishes this based on age: *kapha* predominates in childhood, *pitta* in adulthood, and *vata* in old age.[7]

On the other hand, the third medical system, known as Unani, referring to ancient medical knowledge from China, Egypt, India, Iraq, Persia, and Syria, originated in different historical circumstances. Its roots can be traced back to ancient Greece, and it was then developed by the Arabs; hence Unani is referred to as Greco-Arabic medicine. Medical practice focuses on the application of regimental therapy (venesection, cupping, diaphoresis, diuresis, Turkish bath, massage, cauterization, purgation, emesis, exercises, and leeches), dietary therapy, as well as pharmacotherapy (natural drugs of plant and animal origin, minerals). Diseases are treated as natural phenomena, and the symptoms of illness constitute the body's appropriate response; so the doctor's role is to support rather than replace the patient's natural forces. Significant importance is attached to the healing properties of nature itself (*vis medicatrix naturae*). Unani is based on the humoral theory, assuming that there are four elements in the human body – *Dam* (blood), *Balgham* (phlegm), *Safra* (yellow bile), and *Sauda* (black bile) – which should be balanced with each other.[8]

Cultural influences from India also penetrated neighboring Tibet, giving rise to the development of the Tibetan medical system known as Sowa-Rigpa. The fundamental medical treatise in the Sowa-Rigpa system is the "Four Tantras," which are divided into the following parts: root tantra, explanatory tantra, instructional tantra,

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[6] *Ibidem*, pp. 18–19.

[7] *Cf.* S. Amruthesh, "Dentistry and Ayurveda – IV: Classification and management of common oral diseases", *Indian Journal of Dental Research* 2008, vol. 19, no. 1, pp. 52–61.

[8] *Cf.* P.K. Mukherjee, A. Wahile, "Integrated approaches towards drug development from Ayurveda and other Indian system of medicines", *Journal of Ethnopharmacology* 2006, vol. 103, no. 1, p. 25–35.

and subsequent tantra. The medical recommendations described here are associated with traditional Tibetan knowledge as well as Indian, Chinese, and Greco-Arabic influences. Although the foundations of this medical system are recorded in the "Four Tantras," oral transmission of knowledge about health still plays a significant role. During a patient's treatment, various techniques are used, such as pulse analysis, urine analysis, dietary changes, and natural remedies. Key emphasis is placed on nutrition and dietary therapy, where the diet is considered the most important method of treatment. Proper nutrition, dietary restrictions, and appropriate food intake have a significant impact on our health.[9]

3. Basic legal regulations regarding traditional Indian medicine

The Indian pharmaceutical industry is the third largest in the world, primarily focusing on the production of generic drugs.[10] The primary legal framework regulating the import, production, and distribution of drugs in India is the 1940 Drugs and Cosmetics Act, enacted by the Central Legislative Assembly[11]. In 1945, the Drugs and Cosmetics Rules[12] were adopted, containing provisions regarding the classification of drugs according to specific schedules, as well as guidelines for storage, sale, dispensing, and prescribing of each schedule. In 1964, amendments were made to the 1940 Drugs and Cosmetics Act, introducing provisions for the first time regarding Ayurvedic, Siddha, and Unani drugs.

In order to ensure optimal development and promotion of traditional medical knowledge, the Ministry of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy (AYUSH) was established in 2014. Previously, it operated as the Department of Indian Systems of Medicine and Homeopathy, created in 1995, and later renamed in 2003 as the Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy. The ministry collaborates with the Indian Council of Medical Research (ICMR) and the Council of Scientific and Industrial Research (CSIR) in the development of safe and effective medical products. AYUSH is responsible for quality control of drugs and setting pharmacopeial standards, and

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9 *Nomination form Asia/Pacific Memory of the World Register (revised October 2016)*, MOWCAP UNESCO Memory of the World Regional Committee for Asia/Pacific, p. 13, www.mowcapunesco.org (accessed: 9.04.2024).

10 "India produces over 60,000 generic drugs, highlights MoS Bhagwant Khuba", *The Economic Times*, 25.07.2023, https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/india-produces-over-60000-generic-drugs-highlights-mos-bhagwant-khuba/articleshow/102106352.cms (accessed: 13.04.2024).

11 The 1940 The Drugs Bill was passed by the Central Legislative Assembly of India on 5 April, and received the assent of the Governor General on 10 April 1940.

12 The Drugs Comsetics Rules were published in the Official Gazette in 21 December 1945.

oversees the operation of the Indian Pharmacopoeial Drugs Laboratory (in conjunction with the Quality Council of India) and the functioning of the Indian Medicines Pharmaceutical Corporation Limited (IMPCL).[13]

The attempt to standardize traditional medicine drugs does not have a simple solution due to the complex nature of such drugs.[14] According to Indian regulations, Ayurvedic, Siddha, or Unani medicine includes all drugs intended for internal or external use for or in the diagnosis, treatment, mitigation, or prevention of disease or disorder in human beings or animals, and manufactured exclusively in accordance with the formulae described in the authoritative books of Ayurvedic, Siddha, and Unani Tibb systems of medicine (s. 3A of the 1940 Drugs and Cosmetics Act). Ayurvedic drugs are divided into two groups: traditional and patentable. The former are manufactured according to classical formulae described in fifty-six Ayurvedic texts, while the latter contain combinations of ingredients listed in any formula in any official Ayurvedic text. In the case of patented drugs, the method of their production is reserved for a specific manufacturer; however, these medicines do not need to be standardized or tested for efficacy or toxicity.[15] It can be assumed that such an approach complicates procedures and the specificity of assessing the quality of herbal products, but, on the other hand, it avoids administrative rigors and additional costs. Ayurvedic, Siddha, or Unani drugs certainly have a longer history than conventional medicines, but this does not mean that they should not be analyzed according to production quality guidelines.

Three aspects of the risks of widespread use of traditional Indian medicine can be identified. The first is that although many herbal drugs are not harmful, especially where the absorption of active substances is low, potential side effects of their use are not well known. The second is that positive associations with Ayurvedic medicine should not result in an uncritical approach by consumers towards such products available on the market. The third is that the commercial use of Ayurvedic drugs, containing natural ingredients, is often criticized for "commodifying" patients' health, in ways that are similar to conventional, allopathic medicine.[16] On the other hand, the global significance of the Indian pharmaceutical market prompts the government to make efforts towards standardizing traditional medicine products. This would promote indigenous medicine while effectively competing with conventional medicine products. Research on drugs containing natural substances follows

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[13] T.A. Oyedepo, S. Palai, "Herbal remedies, toxicity and regulations" [in:] *Preparation of Phytopharmaceuticals for the Management of Disorders: The Development of Nutraceuticals and Traditional Medicine*, eds. A.P. Mishra, Ch. Egbuna, M.R. Goyal, Elsevier, London 2021, pp. 115–116.

[14] Mr. Mahajan, A.V. Dasture, "Standarisation of Ayurveda Drugs" [in:] *Compendia Of Ayurveda (Ayurveda Samhita)*, vol. 9, ed. P.H. Kulkarni, Deerghayu International 2022, p. 36.

[15] M. Nichter, M. Nichter, *Anthropology and International Health: Asian Case Studies*, Routledge, London – New York 2003, p. 315.

[16] *Ibidem*, p. 297.

a different methodology compared to that involved in the production of synthetic drugs, and there are no uniform research methods applicable to all traditional medicine drugs.

To prevent negative market practices concerning the export, production, and distribution of Ayurvedic, Siddha, and Unani drugs, the Indian legislature introduced the following three categories: misbranded drugs, adulterated drugs, and spurious drugs. The label and packaging of the drug should display a list of all herbal ingredients used to manufacture the preparation, along with the quantity of each ingredient contained in it and a reference to the method of its preparation (s. 161 subs. 1 of the 1945 Drugs and Cosmetics Rules). The legislature specifies detailed information that should be included on the label and packaging: the name of the drug, a correct statement of net content in terms of weight and measure in the metric system, the name and address of the manufacturer, a license number, a distinct batch number, date of manufacture, the designations "Ayurvedic medicine," "Siddha medicine," or "Unani medicine," depending on the type of medicine (s. 161 subs. 3 of the 1945 Drugs and Cosmetics Rules). Ayurvedic, Siddha, or Unani drugs are deemed to be misbranded: if colored, coated, powdered, or polished to conceal damage or made to appear have a better therapeutic value than the medicine really has; if it is not labeled in the specified manner; if it is not labeled in the prescribed manner; or if the label or container or anything accompanying the drug bears any statement, design, or device which may make a false claim for the drug, or which is false or misleading in any particular (s. 33E of the 1940 Drugs and Cosmetics Act). The external characteristics of the medicine and the information describing the medicine should be consistent with reality and should not suggest therapeutic action other than that resulting from the typical properties of the drugs.

An Ayurvedic, Siddha, or Unani drug available on the market is deemed to be adulterated: if it consists, in whole or in part, of any filthy, putrid, or decomposed material; if prepared, packed, or stored under insanitary conditions; if its container contains any poisonous or if its container is composed of any poisonous or deleterious substance which may render the contents injurious to health; if it bears or contains, for purpose of colouring, a colour other than the prescribed one; if it contains any harmful or toxic substance which may render it injurious to health; if any substance is mixed with it to reduce its quality or strength (s. 33EE of the 1940 Drugs and Cosmetics Act). In this case, the internal characteristics of the medicinal product (apart from the packaging) are of primary importance, that is, defects inherent in the drug itself. A different situation occurs when a drug has been spurious: if it is sold or offered or exhibited under another name; if it is an imitation of, or is a substitute for, another drug or resembles another drug in a manner likely to deceive, or bears upon it or upon its label or container the name of another drug, unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with the other such drug; if the label or container bears the name of

an individual or company which is fictitious or does not exist; if it has been replaced wholly or in part by any other drug or substance; if it purports to be the product of a manufacturer of whom it is not truly a product (s. 33EEA of the 1940 Drugs and Cosmetics Act). The action of spurious drugs is limited, negligible, or has no health effect; so the verification of original traditional medicine drugs is important, especially since standardization in their case still has limited scope.

The trade in Indian traditional medicine drugs is subject to legal regulation, although there are still difficulties associated with the standardization of these medical products. No person shall manufacture for sale or distribution any ASU drug except in accordance with such standards, if any, as may be prescribed in relation to that drug (s. 33EEB of the 1940 Drugs and Cosmetics Act). The manufacture of misbranded drugs, adulterated drugs, spurious drugs, and unlicensed products for sale or distribution is prohibited and is punishable by appropriate legal sanctions. If the central government is satisfied, on the basis of any evidence or other material available to it, that the use of any Ayurvedic, Siddha, or Unani drug may involve any risk to humans or animals or that any such drug does not have therapeutic value, and if it is necessary or expedient in the public interest to do so, it may prohibit the manufacture, sale, or distribution of such a drug (s. 33EED of the 1940 Drugs and Cosmetics Act).

A license is not required for the sale of traditional drugs, but it is necessary for the production of such drugs, which is a licensed activity. The legislature provides for two main types of licenses for the manufacture of traditional drugs: an own manufacturing license and a loan license. In the first case, an application for the grant or renewal of a license to manufacture for sale of any Ayurvedic, Siddha, or Unani drugs is submitted on a prescribed form to the appropriate authority along with a fee of one thousand rupees (s. 153 of the 1945 Drugs and Cosmetics Rules). The license is issued by the authority after consultation with an expert in the field of traditional medicine systems, as is applicable, whose appointment may be approved on behalf of the state government (s. 154 subs. 2 of the 1945 Drugs and Cosmetics Rules). In the case of a loan license, the application is also submitted on a prescribed form to the appropriate authority, with a fee of six hundred rupees. The grant of the license requires consultation with a medical expert and verification that the manufacturing unit has adequate equipment, staff, and capacity for manufacture and facilities for testing (s. 154A subs. 3 of the 1945 Drugs and Cosmetics Rules).

The Indian government establishes the Ayurveda Siddha Unani Drugs Technical Advisory Board (ASUDTAB) to provide technical advice to the central government and state governments on technical matters related to traditional medicine drugs (s. 33C subs. 1 of the 1940 Drugs and Cosmetics Act). The Board consists of a total of twenty members, both *ex-officio* and nominated. The central government appoints a member of the Board as its chairman. Board members serve for three years but may be re-nominated (s. 33C subs. 3–4 of the 1940 Drugs and Cosmetics

Act). The central government may establish an advisory committee called the Ayurvedic, Siddha, and Unani Drugs Consultative Committee (ASUDCC) to advise the central government, state governments, and the Technical Advisory Board. Its task is to secure uniform application of the legal provisions concerning Ayurvedic, Siddha, or Unani drugs (s. 33D subs. 1 of the 1940 Drugs and Cosmetics Act). The committee consists of two persons appointed by the central government as representatives of that government and no more than one representative from each state appointed by the state government (s. 33D subs. 2 of the 1940 Drugs and Cosmetics Act).

The central government or state government can appoint individuals deemed appropriate and with the prescribed qualification as government analysts and inspectors for matters concerning the proper production of traditional medicine drugs. Samples for testing or analysis are sent by the inspector to the analyst, who then undertakes the appropriate procedures. The duty of the inspector authorized to control the production of Ayurvedic, Siddha, or Unani drugs includes conducting inspections no less than twice a year at all facilities licensed to manufacture drugs, sending a detailed report to the controlling authority after each inspection, collecting samples of drugs produced on the premises for testing or analysis, and initiating legal proceedings in connection with violations of the act and other regulations (s. 162 of the 1945 Drugs and Cosmetics Rules).

4. Case law regarding traditional Indian medicine

Analysis of case law in India helps to demonstrate how legal protection is provided for traditional medicine, including Ayurveda, Siddha, and Unani medicine. The Indian judiciary system has a unified character and includes the Supreme Court, High Courts, state high courts, as well as administrative tribunals and special courts.[17] The Indian legal system is mixed, combining elements of civil law and common law. Interpretation of the law by the Supreme Court has a universally binding force and must be taken into account by all courts throughout India (art. 141 of the Constitution of India). High Courts are bound by the judgments of the Supreme Court, while the judgments of High Courts are binding for lower courts. The judgments of individual High Courts do not have a precedential effect on each other, although they may have persuasive significance in the adjudication of specific cases.[18] Analysis of court cases concerning legal issues related to the practice of traditional medicine reveals four main problematic issues: medical practice,

[17] Cf. art. 124, 214, 241 i 323A Constitution of India, adopted by the Constituent Assembly on 26 November 1949.

[18] Ch.S. Bagadi, *Jurisprudence (Legal Theory)*, Shashwat Publication, Ram das Nagar 2023, p. 118.

regulation and safety of traditional medicine drugs, advertising and marketing, and intellectual property rights.

In a sense, a milestone in the jurisprudential practice regarding Indian traditional medicine was the judgment of the Supreme Court dated 8 October 1998, in the case of *Dr. Mukhtiar Chand & Ors vs The State Of Punjab & Ors*. The subject of the case was to determine whether practitioners of Ayurveda, Unani, or Siddha medicine are authorized to prescribe allopathic drugs to patients. According to the position adopted, allopathic drugs may be sold or supplied by a pharmacist only on the basis of a prescription issued by a "registered medical practitioner," i.e., a person listed in the State Medical Register. A person listed in the State Register of Indian Medicine or the Central Register of Indian Medicine does not have the ability to practice modern scientific medicine. However, it is not excluded for individual state governments to issue permits for the prescription of allopathic drugs by practitioners of traditional medicine, applicable in the territory of a specific state.[19]

The High Court of Delhi's ruling on 8 April 2016 is of significant importance in interpreting the provisions concerning the healthcare system in India. It stated that practitioners of Ayurveda, Siddha, Unani medicine and Homeopathy generally do not have the authority to practice allopathic medicine. Even if a person holds qualifications in Indian medicine, such as a diploma in integrated medicine, they cannot be registered as allopathic medical practitioners based on those qualifications alone. "Indian medicine" as per the law governing the Central Council of Indian Medicine refers to the system of Indian medicine commonly known as Ashtang Ayurveda, Siddha, or Unani Tibb, supplemented or not with modern advances in the modern scientific system of medicine in all its branches, including surgery and obstetrics. On the other hand, "integrated medicine" refers to conjoint, concurrent study, training, and practice in Ayurved/Siddha/Unani Tibb and the Modern Scientific System of Medicine in all its branches including surgery and obstetrics. A person registered in the State Register of Indian Medicine or the Central Register of Indian Medicine does not have the right to practice modern scientific medicine unless they are also registered in the State Medical Register.[20] These definitions may *prima facie* suggest the existence of an integrated healthcare system in India, where the same practitioners have the right to practice both traditional and allopathic medicine. However, such an interpretation is not justified as both medical subsystems are distinct and employ different treatment methods.

The other issue considered by jurisprudence was the safety of drugs, including traditional medicine. In the case of *Laxmikant vs Union of India* in 1997, the question

[19] Supreme Court of India, *Dr. Mukhtiar Chand & Ors vs The State Of Punjab & Ors* on 8 October 1998, https://indiankanoon.org/doc/484509/ (accessed: 21.04.2024).

[20] Delhi High Court, *Delhi Medical Association vs Principal Secretary (Health) & Ors.* on 8 April 2016, No. 7865/2010, https://indiankanoon.org/doc/95645241/ (accessed: 18.04.2024); s. 2(b), (h) and (k) The Delhi Bharatiya Chikitsa Parishad Act, 1998 (Delhi Act No. 4 of 1999).

arose as to whether Ayurvedic drugs could contain tobacco. Several years earlier, the Central Government had issued a ban on using tobacco in the production and sale of all Ayurvedic drugs, including tooth powder and toothpaste. According to the petitioner, the use of at least 50% tobacco in the preparation of Ayurvedic drugs, including powders and toothpaste, was prohibited. If the petitioner used only 4% tobacco in the production of drugs, then his/her activity should not be subject to the ban. In the assessment of the Supreme Court, the position adopted by the Government of India regarding the total ban on the use of tobacco in the production of tooth powder and toothpaste is well justified, considering that scientific research shows the harmful effects of tobacco on human health, e.g. an increased susceptibility to cancer.[21] It is worth noting that Ayurvedic medicine is based on the use of plant, animal, and mineral ingredients, which does not mean that when used in excessive doses, they offer health benefits. In this case, the issue was not about the harmfulness of Ayurveda *per se*, but rather the use of tobacco in the production of drugs.

Moreover, Indian jurisprudence has also considered the issue of classifying a particular substance as a product of Ayurvedic medicine. In the case of *Sidi Pharmacy Pvt. Ltd. vs Union of India*, the Supreme Court examined whether the government could refuse a license for the production of Ayurvedic injection preparations. It was necessary to determine whether these injections could be classified as products of traditional medicine. According to the expert committee, Ayurvedic injections were not described in Ayurvedic texts, and there was no data confirming the efficacy and safety of these preparations; so they should be banned. Ultimately, the Court declined to decide whether to grant a license for Ayurvedic injections, leaning towards the view that it is a political decision requiring serious consideration and deliberation on public health and treatment methods. Adjudicating on such issues falls within the scope of judicial review and the jurisdiction of this Court, but it may be further addressed by the government of India.[22]

Products of traditional Indian medicine are promoted by their advocates as natural remedies with specific healing properties, based on ancient medical knowledge. This information often appears in advertisements for these drugs, which are presented as an alternative to conventional medicine. In the case of *Anand Mohan Chapparwal vs State of Maharashtra*, the Bombay High Court examined the compliance of one Ayurvedic medicine advertisement with advertising regulations. According to the regulations, advertising for a medicine is prohibited if it suggests that its use

[21] Supreme Court of India, *Laxmikant vs Union of India*, Appeal No. 3000 of 1997 on 11 April 1997, https://www.tobaccocontrollaws.org/litigation/decisions/laxmikant-v-union-of-india (accessed: 21.04.2024).

[22] Supreme Court of India, *Sidi Pharmacy Pvt. Ltd. vs Union of India* on 24 July 2004, (13) SCC 780, https://www.casemine.com/judgement/in/581180c92713e179479ce866 (accessed: 21.04.2024).

helps, among other things, to maintain or improve of the capacity human beings for sexual pleasure.[23] The disputed advertisement stated that the drug involved is intended exclusively for men to enhance their vigor and vitality. The Court noted that the regulation uses the phrase "the maintenance or improvement of the capacity human beings for sexual pleasure," while the advertisement refers to "improving vigor and vitality" without mentioning sexual aspects. Because of these differences, it is impossible to conclude that the advertiser intended to attribute properties other than those described in the content of the advertisement; so the case should be decided in favor of the defendant.[24]

The use of natural medical preparations in the market raises the issue of their patent protection. There are doubts about whether certain products containing herbal ingredients, known in Indian medicine for hundreds of years, have patentability at all. For example, turmeric root (*Curcuma longa*) has medicinal properties and is used in traditional Ayurvedic medicine to treat conditions such as anemia, asthma, conjunctivitis, dental problems, and diabetes. In 1995, two Indian scientists from the University of Mississippi Medical Center, Suma K. Das and Hari Har P. Choly, obtained a U.S. patent for a method of using turmeric to treat wounds. The Council of Scientific and Industrial Research (CSIR) based in New Delhi challenged the decision to grant the patent. Referring to Ayurvedic texts, CSIR pointed out that turmeric has been used for thousands of years to heal wounds and skin rashes; therefore, it lacks novelty and cannot be patented. Ultimately, the U.S. Patent Office considered the position of this Indian institution, and in 1997, invalidated the patent on turmeric. This story is considered the first known case of challenging biopiracy.[25]

5. Conclusions

Traditional Indian healing methods and medicinal preparations used in Ayurveda, Siddha, and Unani have gained popularity not only in India and Asia but also globally. Indian medicine is part of the intangible cultural heritage of the country; hence it is subject to special legal protection. The legal landscape regarding the protection of natural medicine is complex, accompanied by some tension between allopathic and traditional medicine. In this context, judicial decisions hold significant

[23] S. 3B of the Drugs and Magic Remedies (Objectionable Advertisements) Act, 30th April 1954 (21 OF 1954).

[24] Bombay High Court, *Anand Mohan Chapparwal vs State of Maharashtra* on 3 August 1995, 1996 CR LJ 596.

[25] P. Schuler, *Biopiracy and Commercialization of Ethnobotanical Knowledge* [in:] *Poor People's Knowledge Promoting Intellectual Property in Developing Countries*, eds. J. Finger, P. Schuler, World Bank & Oxford University Press, Washington 2004, pp. 166–167.

importance, as Supreme Court rulings set precedents within the Indian judicial system. Analysis of national legal regulations and judicial practices helps identify the basic principles of legal protection for traditional medicine in India. The production and distribution of traditional Indian drugs are regulated by regulatory bodies at both the national and state levels, with a special role played by the Ministry of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy (AYUSH). The production of Ayurveda, Siddha, and Unani drugs for sale requires prior license. Prohibited practices, such as the manufacture of misbranded drugs, adulterated drugs, and spurious drugs, or producing unlicensed products for sale or distribution are prohibited. Furthermore, legal mechanisms have been introduced to protect traditional Indian medicine from biopiracy.

Certainly, India's cultural richness has had a significant impact on various aspects of human life, including medical practice. One could metaphorically say that contemporary India has two lungs – traditional medicine and allopathic medicine – which, based on different assumptions, have the same goal of protecting human life and health. *De lege ferenda*, it is proposed to introduce legal solutions that would allow for better integration of traditional medicine with the allopathic medicine, for example, expanding the scope of services provided by qualified practitioners. It is also worth considering the regulation of scientific research programs on the safety and efficacy of Ayurveda, Siddha, and Unani drugs, including providing funding opportunities to research institutions, universities, and pharmaceutical companies. In order to prevent biopiracy, it is necessary to introduce adequate legal measures that would protect traditional Indian medical knowledge from appropriation by foreign corporations. A good solution would be to intensify international cooperation and establish a special international registry for natural medicine products.

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SUMMARY

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LEGAL PROTECTION OF TRADITIONAL MEDICINE IN INDIA

Specialized medical knowledge began to develop on the Indian subcontinent in ancient times. It is associated with information, skills, and practices based on theories, beliefs, and experiences of different generations. Traditional medicine in India is not a uniform system but is divided into several subsystems, i.e. Ayurveda, Siddha (Tamil medicine), Unani (Persian-Arabic medicine), and Sowa-Rigpa (Tibetan medicine). A wide range of natural healing methods is used, including herbal medicine, cleansing of toxins, and diet. This cultural heritage of medical thought requires the adoption of adequate legal protection nowadays. In the second half of the twentieth century India initiated efforts to introduce legal regulations concerning the use of natural medicine. Institutionalization of this issue was carried out by establishing the Central Council of Indian Medicine in the Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha Medicine, and Homeopathy (AYUSH). The government supports scientific research and undertakes educational initiatives in the field of traditional Indian medicine. The aim of this article is to reconstruct the model of regulation of natural medicine in India as part of its cultural heritage, in the context of the development of modern technologies.

Keywords: Ayurveda, drugs, Indian medicine, intangible cultural heritage, legal protection, traditional medicine

STRESZCZENIE

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OCHRONA PRAWNA TRADYCYJNEJ MEDYCYNY INDYJSKIEJ

Specjalistyczna wiedza medyczna zaczęła się rozwijać na obszarze subkontynentu indyjskiego już w czasach starożytnych. Obejmuje ona wiedzę, umiejętności i praktyki oparte na teoriach, przekonaniach i doświadczeniach kolejnych pokoleń, ukształtowanych w trakcie rozwoju historycznego. Tradycyjna medycyna indyjska nie jest jednolitym systemem, lecz dzieli się na kilka podsystemów, tj. Ayurveda, Siddha (medycyna tamilska), Unani (medycyna persko-arabska), Sowa-Rigpa (medycyna tybetańska). W tym przypadku wykorzystuje się w szerokim zakresie naturalne metody leczenia, takie jak m.in. ziołolecznictwo, oczyszczanie z toksyn i dietę. Ten szczególny dorobek dawnej myśli medycznej wymaga współcześnie przyjęcia adekwatnych instrumentów ochrony prawnej. Indie zainicjowały w drugiej połowie XX wieku działania mające na celu wprowadzenie regulacji prawnych dotyczących stosowania medycyny naturalnej. Dokonano instytucjonalizacji tej problematyki, powołując Centralną Radę Medycyny Indyjskiej w Departamencie ds. Ayurvedy, Jogi i Naturopatii, Unani, Siddha Medicine i Homeopatii (AYUSH). Rząd wspiera badania naukowe i podejmuje

inicjatywy edukacyjne w obszarze tradycyjnej medycyny indyjskiej. Celem artykułu jest zrekonstruowanie modelu regulacji medycyny naturalnej w Indiach jako jej niematerialnego dziedzictwa kultury w kontekście rozwoju nowoczesnych technologii.

Słowa kluczowe: Ayurveda, leki, medycyna indyjska, niematerialne dziedzictwo kultury, ochrona prawna, medycyna tradycyjna