

Research on the Current Status, Challenges, and Improvement Paths of Legal Protection for Mongolian Medicine and Traditional Chinese Medicine

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Abstract: As vital components of traditional medicine in China, Mongolian Medicine and Traditional Chinese Medicine exhibit significant disparities in theoretical systems and medicinal characteristics. Currently, both practices share a common legal framework for protection, such as the *Traditional Chinese Medicine Law of the People's Republic of China*, while also facing unique challenges related to their respective legal protections. A thorough analysis of the distinctions between these two systems and a clear understanding of the current legal protections are of paramount importance for promoting the inheritance, innovation, and development of both Mongolian Medicine and Traditional Chinese Medicine. This paper will meticulously elaborate on the multifaceted differences between Mongolian Medicine and Traditional Chinese Medicine, while delving deeply into their legal protection status, with the intent to provide a reference for the inheritance and development of ethnic medicine.

Keywords: Mongolian Medicine; Traditional Chinese Medicine; Legal Protection; Current Status; Challenges; Improvement Paths

1. Introduction

Mongolian medicine and traditional Chinese medicine are both treasures of traditional medicine, each possessing its own distinctive characteristics. With a rich historical legacy, Traditional Chinese Medicine developed a theoretical framework centered around the concepts of Yin-Yang and the Five Elements during the Qin and Han dynasties. The *Huangdi Neijing (Inner Canon of the Yellow Emperor)*

laid the foundational principles, employing a comprehensive diagnostic approach of observation, listening and smelling, inquiry, and palpation, alongside differentiation and treatment methods using herbal medicine, acupuncture, and tuina, which include classic formulations such as Mahuang Decoction (ephedra decoction). Mongolian Medicine, on the other hand, has its roots deeply embedded in the production and lifestyle of the Mongolian people, closely intertwining with their cultural practices and natural environment. It is characterized by core theories such as the “Three Roots” and “Seven Essentials” and employs diagnostic techniques involving tongue observation, urine analysis, pulse diagnosis, and patient interviews, utilizing Mongolian herbal medicines (sourced from unique ecological environments and processed through distinct methods) along with practices such as bloodletting, acupuncture, and massage. Both traditions face challenges posed by the encroachment of modern medicine and the risk of certain knowledge and skills being lost. In terms of legal protection, while Traditional Chinese Medicine is safeguarded under the *Traditional Chinese Medicine Law*, Mongolian Medicine’s legal protections are comparatively inadequate. There is a pressing need to enhance legal mechanisms for the protection of intellectual property and the innovation and transmission of traditional knowledge.

A thorough exploration of the differences between these two medical systems can leverage their respective advantages. An analysis of the current state of legal protection can provide a basis for improving the relevant statutes, which is crucial for fostering inheritance and innovation, promoting the flourishing of ethnic

medicine, and maintaining the diversity of cultural heritage. In the context of globalization, the development and protection of these medical traditions are pivotal not only for the future of ethnic medicine but also for advancing human health.

2. Distinctions between Mongolian Medicine and Traditional Chinese Medicine

2.1 Further Comparison of Theoretical Systems and Practical Methods

Mongolian Medicine and Traditional Chinese Medicine exhibit significant differences in their theoretical frameworks and practical methodologies. The theoretical underpinnings of Mongolian Medicine are deeply rooted in Mongolian philosophy, centering around the “Five Elements” doctrine, which posits that all things are composed of earth, water, fire, air, and space. This framework gives rise to the theories of the “Three Roots” (Hii, Xira, Badagan) and the “Seven Essentials”, emphasizing that the balance of the Three Roots is fundamental to maintaining health. Diagnosis is achieved through the observation of facial complexion, tongue coating, urine analysis, and patient interviews, along with palpation to assess the state of the Three Roots [1]. In contrast, Traditional Chinese Medicine is anchored in the concepts of “Yin-Yang” and the “Five Elements”, viewing the balance of Yin and Yang as a prerequisite for health. It employs the interactions of the Five Elements to elucidate the relationships among the internal organs, diagnosing through the comprehensive techniques of observation, auscultation, interrogation, and palpation—collectively referred to as the “Four Diagnostic Methods”—and adhering to the principle of differentiation for treatment [2]. Practically, Mongolian Medicine showcases distinctive regional and cultural attributes, with acupuncture focusing on the combination of pressure points and the depth of needle insertion, as well as therapeutic baths utilizing specific herbs and minerals in immersion treatments. Conversely, the practices of Traditional Chinese Medicine are varied and encompass acupuncture, tuina, and herbal decoctions, with a core emphasis on individualized treatment plans formulated according to the patient’s condition through the lens of differentiation.

2.2 Sources and Applications of Medicinal Materials, and Preparation Methods

Both Mongolian Medicine and Traditional Chinese Medicine derive their medicinal materials from plant, animal, and mineral sources, yet they exhibit significant differences in their applications and preparation methods. In terms of application, Mongolian Medicine regards *Terminalia chebula* as the “King of Mongolian Medicines”, frequently combining it with *Aconitum* for toxicity reduction (whereas Chinese Medicine typically uses *Glycyrrhiza* for detoxification). Additionally, Mongolian Medicine employs the root, leaves, and buds of *Aconitum*, while Chinese Medicine restricts its use to the root. The pomegranate is utilized in its entirety within Mongolian Medicine (in contrast to Chinese Medicine, which uses only the rind), while Mongolian Medicine incorporates the flowers of both *Ligularia* and *Gentiana*, whereas Chinese Medicine relies on their roots. In the treatment of liver diseases, Mongolian Medicine frequently employs herbs such as “Digeda” and safflower (both of which benefit the liver), while Chinese Medicine more often selects *forsythia* and assigns safflower predominantly to the heart meridian. Nutmeg is considered a heart-clarifying medicine in Mongolian Medicine, whereas it is categorized under stomach remedies in Chinese Medicine. Additionally, Mongolian Medicine excels in utilizing drought-resistant plants such as *Cistanche*, along with unique materials like *fructus choerospondiatis* [3].

Regarding preparation, while both systems share a central goal of reducing toxicity, enhancing efficacy, and facilitating storage—rooted in similar theoretical underpinnings that emphasize the properties and synergistic combinations of the materials—their methodologies diverge significantly. Chinese Medicine encompasses a diverse array of preparation techniques, including water-based, fire-based, and auxiliary ingredient methods (such as the use of ginger juice for *Pinellia*). In contrast, Mongolian Medicine emphasizes specialized treatments, often involving calcination or soaking for mineral drugs, commonly using milk as an auxiliary ingredient, with methods such as boiling and steaming (for instance, using wolf poison with milk, whereas vinegar is favored in Chinese Medicine). The theoretical framework of Chinese Medicine elaborates on properties and meridian affinities (for example,

understanding that Gardenia fruit corresponds to the heart and lung meridians), while Mongolian Medicine focuses on the principles of the Five Origins and Six Flavors, along with Seventeen Effects (for instance, Gardenia is noted for dispelling “Bad-kan mKhris-pa (disorder of Phlegm and Bile)”) [4].

2.3 Characteristics of Medicinal Usage, Dosage Forms, and Administration Methods

In clinical practice, Mongolian Medicine predominantly employs fixed compound formulations, placing significant emphasis on synergistic effects. For instance, the “Four-Flavor Pomegranate Powder” is utilized for the treatment of cold-induced gastric sluggishness. The variety and dosage of medicinal types are relatively substantial, with patients typically consuming 3 to 6 different compound preparations divided throughout the day—morning, noon, and night. In cases of complications, medications may be layered; for example, in treating ischemic stroke, one might start with “Wuwei Qingzhuo San (Five Ingredients Turbidity-Clearing Powder)” in the morning, followed by “Zhenbao Wan (Precious Pill)” at noon, and “Zachong-13 (Puncturevine Thirteen)” in the evening, with additional preparations like “Ulan-13 Decoction” if hypertension is present [5]. Conversely, Traditional Chinese Medicine focuses on the principle of differentiation in treatment, allowing for flexible adjustments to formulas. For instance, in the early stages of spleen and stomach deficiency, the primary approach is to tonify the spleen and augment qi, with the addition of damp-dispersing and digestive herbs as the condition evolves.

Regarding dosage forms and administration, Mongolian Medicine offers preparations such as decoctions and powders. Decoctions are crafted from coarsely ground mixtures, with a small administration dosage (3 to 5 grams), which may be taken with sugar or butter, typically decocted once using solvents like milk or bone broth. Traditional Chinese Medicine, on the other hand, encompasses a variety of forms including pills, decoctions, and pastes. Decoctions are composed of herbal slices that are temporarily combined, requiring larger dosages (often exceeding several tens of grams per serving). The volume of the water decoction is typically substantial, with the customary procedure involving decocting 2 to 3 times and adhering to specific methods such as

initial and subsequent boiling stages [6].

2.4 Applications and Challenges in Modern Medicine

Mongolian Medicine has demonstrated significant efficacy in the treatment of chronic diseases such as diabetes and hypertension, aligning well with the preventive medicine philosophy of “treating before illness”. However, it faces challenges regarding the recognition of its scientific validity due to discrepancies between its theoretical framework and modern medical principles, as well as difficulties in succession owing to a shortage of qualified practitioners.

In contrast, Traditional Chinese Medicine boasts a broader scope of application, particularly in oncology, where it can modulate immune responses and alleviate the adverse effects of radiation and chemotherapy. It also holds advantages in addressing complex conditions such as rheumatoid arthritis. Nonetheless, the lag in standardization hampers its international competitiveness, and challenges persist in protecting intellectual property rights, particularly concerning the patenting of traditional formulations.

3. Legal Protection Status of Mongolian Medicine and Traditional Chinese Medicine

3.1 Legal Protection Status of Traditional Chinese Medicine

China has established a multi-tiered legal protection system for Traditional Chinese Medicine. At the national legal level, the *Traditional Chinese Medicine Law* serves as the cornerstone, laying a foundational framework for its inheritance and development, supporting scientific research and innovation, safeguarding intellectual property rights, and establishing a system for the evaluation of local medicinal materials [7]. The *Patent Law*, *Trademark Law*, and *Copyright Law* respectively protect patents for innovative results, trademarks for products, and copyrights for traditional knowledge literature. The *Anti-Unfair Competition Law* includes certain Chinese medicinal “secret formulas” under the protection of commercial secrets, allowing for the application of confidential patents [8]. On the level of administrative regulations, the *Regulations on the Protection of Chinese Medicinal Varieties* provides tiered protection for medicinal varieties

domestically [9]. The *Implementation Rules of the Patent Law* elaborate on the classification and application of new drug invention patents. At the departmental regulation level, the *Administrative Measures for Registration of Traditional Chinese Medicine Preparations in Medical Institutions (Trial)* stipulates requirements related to the preparations [10]. Additionally, the *Regulations on the Protection and Management of Wild Medicinal Material Resources* indirectly safeguard wild plants used for medicinal purposes [11]. Locally, provinces such as Liaoning, Shaanxi, and Sichuan have developed regulations tailored to their unique contexts, addressing aspects such as services, industry, intellectual property protection, surveys of medicinal resources, and support for development.

3.2 Legal Protection Status of Mongolian Medicine

The development of Mongolian Medicine is supported by various tiers of legal and policy safeguards. At the legal and policy level, the *Intangible Cultural Heritage Law of the People's Republic of China* encompasses the brewing techniques, formulation processes, related theories, and prescriptions of Mongolian Medicine, with several diagnostic techniques, such as the traditional Mongolian bone-setting, Ula moxibustion, and Zambala Dorji acupuncture, included in the national or provincial intangible cultural heritage lists [12]. The *Traditional Chinese Medicine Law* incorporates Mongolian Medicine into the broader category of Traditional Chinese Medicine, thereby providing a legal foundation for its practice. The pertinent opinions issued by Relevant authoritative departments explicitly encourage the development of the TCM industry, including Mongolian Medicine, ensuring multi-dimensional support for its inheritance and innovation [13].

On the front of local legislation, the Inner Mongolia Autonomous Region enacted the *Regulations on Mongolian Medicine and Traditional Chinese Medicine of the Inner Mongolia Autonomous Region* in 2001, marking the first legal recognition of the Mongolian Medicine sector. This was revised in 2010 to become the *Regulations on Mongolian Medicine and Traditional Chinese Medicine of the Inner Mongolia Autonomous Region*, which formalized Mongolian Medicine within the legal

framework [14]. Following the implementation of the *Traditional Chinese Medicine Law* in 2017, Inner Mongolia has advanced the standardization of Mongolian Medicine, completing multiple national Chinese medicinal standards and regional Mongolian Medicine standardization projects. This includes the issuance of standards related to clinical diagnosis and treatment as well as cultivation techniques, along with relevant implementation rules that clarify the principles, processes, and supervisory responsibilities regarding the registration of Mongolian medicinal preparations, thus achieving synergistic governance among the three medical systems [15].

Regarding intellectual property protection, Inner Mongolia initiated the country's first patent pool program for Mongolian Medicine in 2018, organizing and optimizing Mongolian Medicine technology patents while providing guidance on intellectual property protection. In 2024, the local procuratorate has prioritized the enforcement of intellectual property protection for "Mongolian Medicine" as a key annual task. Fuxin City has established a "1+8+8+9+N" intellectual property service system, employing organizations to conduct patent analysis and early warning, thereby strengthening the management of Mongolian Medicine's intellectual property throughout its lifecycle and offering multi-faceted services to facilitate innovation for market entities.

3.3 International Aspects

The relevant treaties and agreements of the World Intellectual Property Organization (WIPO), such as the *Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)*, establish minimum standards for intellectual property protection, thereby laying the groundwork for the international safeguarding of Mongolian Medicine and Traditional Chinese Medicine. The European Union's regulations on the registration of herbal medicines also provide a reference for traditional herbal medicines, including TCM, seeking entry into international markets. China actively engages in international cooperation through initiatives like the "Belt and Road" Initiative, establishing overseas centers for Traditional Chinese Medicine and promoting activities related to medical services, educational training, and research collaboration to enhance the global influence of both Mongolian Medicine and TCM.

During these collaborations, emphasis is placed on the protection of intellectual property rights; comprehensive agreements are negotiated to clearly define the rights and obligations of both parties concerning the ownership and use of intellectual property, thereby minimizing the potential for disputes.

4. Issues in the Legal Protection of Mongolian Medicine and Traditional Chinese Medicine and Recommendations for Improvement

There exist numerous pressing issues in the legal protection of Mongolian Medicine and Traditional Chinese Medicine that significantly hinder their inheritance and development. It is imperative to adopt targeted measures in three key areas: the legal framework, intellectual property protection, and law enforcement and regulation.

4.1 Incomplete Legal Framework: The Necessity of a Robust Legal System

The development of Mongolian Medicine is beset by two major legal dilemmas. First, there is a lack of specialized legislation; at the national level, no distinct laws specifically addressing Mongolian Medicine exist. Reliance solely on the *Traditional Chinese Medicine Law* is inadequate for the precise protection of its unique theories and treatment methodologies. The standards and procedures for protecting traditional knowledge, the rights and responsibilities of inheritors, as well as guidelines governing prescriptions and therapeutic techniques remain ambiguous, complicating the integration of pharmaceutical management with modern medical practices. To address this, it is crucial to initiate specialized legislation for Mongolian Medicine promptly, clearly defining its scope and status while also refining existing legal provisions and establishing related identification methods and unique standards. Second, there is insufficient synergy among legal regulations; the interplay between the laws governing Mongolian Medicine and Traditional Chinese Medicine and those related to land, environment, and other sectors exhibit significant disconnections. Additionally, contradictions among regulations at different administrative levels hinder industrial development and generate enforcement confusion. Therefore, it is essential to establish a coordination and linking mechanism that takes into account the industrial

needs when formulating policies. Strengthening the consistency among regulatory hierarchies and establishing conflict resolution mechanisms will ensure that the industry can flourish within a clear legal framework.

4.2 Insufficient Intellectual Property Protection: The Need for Enhanced Safeguards

Mongolian Medicine and Traditional Chinese Medicine face numerous challenges in safeguarding intellectual property rights. In the realm of patent applications, the collective nature of traditional knowledge complicates the identification of individual inventors. Furthermore, the theories and mechanisms underlying diagnostic methods and formulations significantly deviate from those of modern medicine, making it difficult to provide sufficient experimental data according to current standards, leading to low approval rates. Even when patents are granted, determining infringement poses significant difficulties, rendering rights protection problematic. To address these issues, it is essential to adjust the examination standards to recognize collective inventions, lower the data validation thresholds, and establish dedicated criteria for determining infringement while imposing stringent penalties for violations. In terms of trademarks, there is a lack of awareness regarding the protection of time-honored brands, leaving them vulnerable to unauthorized registrations and infringements. Within the domain of trade secrets, core technologies and formulations are at risk of leakage, compounded by the difficulties of proving such breaches and the generally low compensation awarded. Therefore, it is crucial to bolster the protection of trademarks for time-honored brands by creating a registry, encouraging enterprises to enhance trademark management and brand development, and rigorously combating infringement. Moreover, it is necessary to refine mechanisms for the protection of trade secrets by enacting specialized regulations, strengthening internal controls within enterprises, and alleviating the burden of proof for rights holders in infringement cases, while also raising compensation standards.

4.3 Inadequate Enforcement and Regulation: A Call for Enhanced Enforcement and Oversight

The enforcement and regulation of Traditional Chinese Medicine and Mongolian Medicine are hindered by weak enforcement capabilities and outdated regulatory measures. In terms of enforcement power, the involvement of multiple departments leads to ineffective coordination and unclear delineation of responsibilities, resulting in both regulatory gaps and instances of duplicated oversight. Moreover, grassroots enforcement personnel often lack the requisite expertise to adequately identify unlawful practices, such as illegal medical practice. It is imperative to clarify departmental roles, establish coordination mechanisms alongside dedicated coordinating bodies to streamline operations and promote information sharing. Additionally, it is vital to enhance training for grassroots personnel and recruit specialized talent to optimize the workforce [16]. Regarding regulatory measures, the emergence of new market dynamics has outpaced existing oversight methods. Current platforms for monitoring online sales are inadequately developed, with timely access to information being a significant challenge. Quality regulation relies heavily on traditional sampling techniques, which are insufficient for comprehensive real-time oversight across the entire supply chain. Additionally, there is a lack of effective monitoring concerning the cultivation of medicinal herbs. Therefore, it is essential to leverage modern information technologies to create an integrated regulatory information platform, utilizing big data to monitor production, distribution, and usage processes. Collaboration with e-commerce platforms is crucial to establish a system for monitoring online pharmaceuticals to identify counterfeit and substandard products. Employing rapid testing and remote monitoring can enhance efficiency, while introducing sensors in the cultivation phase is necessary to ensure quality.

5. International Experience and Insights for the Legal Protection of Mongolian Medicine and Traditional Chinese Medicine

India has established specific legislation to protect the intellectual property of traditional medicine while creating a certification system. Meanwhile, South Korea utilizes the *Korean Medicine Act* to govern the practice, education, and pharmaceutical management of Korean medicine, actively engaging in international collaboration. The experiences of both nations

underscore the essential role of legal protection and international cooperation as pivotal factors for the sustainable development of traditional medical practices.

For the domains of Mongolian medicine and Traditional Chinese Medicine, drawing upon international experience holds profound significance. On one hand, it is essential to formulate dedicated legislation that clearly delineates their legal status and scope of protection, thereby addressing existing gaps in legal safeguards. On the other hand, enhancing international collaboration is vital; for instance, partnering with the World Health Organization to establish international standards and leveraging the TRIPS Agreement of the World Intellectual Property Organization to solidify the foundation for global protection. Furthermore, establishing overseas centers through initiatives such as the Belt and Road Initiative would promote cooperation in medicine, education, and research, thereby enhancing international influence while emphasizing the importance of intellectual property protection and negotiating clear rights and obligations to prevent disputes.

6. Conclusion

Both Mongolian medicine and Traditional Chinese Medicine are invaluable treasures of the Chinese nation's traditional medical heritage, yet they exhibit notable distinctions. Mongolian medicine is deeply rooted in Mongolian philosophical principles, guided by the theories of the "Five Elements" and "Three Roots and Seven Essentials". Distinctive practices such as acupuncture and medicinal baths are integral to its approach, utilizing herbal ingredients primarily sourced from areas inhabited by the Mongolian population, with an emphasis on complex prescriptions and larger dosages. In contrast, Traditional Chinese Medicine is based on ancient Chinese philosophy, incorporating the concepts of Yin and Yang and the Five Elements through a holistic diagnostic framework that includes observation, listening and smelling, inquiry, and palpation. This system benefits from a wide variety of medicinal materials and versatile formulations. Both medical traditions have successfully integrated with modern medicine, with Mongolian medicine particularly adept at treating chronic conditions like diabetes and enhancing general well-being. Traditional Chinese Medicine has demonstrated effectiveness in oncology and the management

of complex health issues, providing immune support and alleviating the side effects of chemotherapy and radiotherapy. However, each tradition faces significant challenges. Mongolian medicine struggles with low theoretical recognition and a shortage of qualified practitioners, while Traditional Chinese Medicine deals with slow standardization, insufficient international competitiveness, and significant difficulties in intellectual property protection. In terms of legal safeguards, Traditional Chinese Medicine benefits from the *Traditional Chinese Medicine Law* and other supportive regulations. In contrast, Mongolian medicine primarily relies on intangible cultural heritage laws, the laws governing Traditional Chinese Medicine, and local regulations. While international treaties and initiatives such as the “Belt and Road Initiative” promote collaboration, there remain substantial obstacles for Mongolian medicine, including the lack of specialized legislation for precise protection, inconsistencies in regulatory frameworks, challenges in safeguarding intellectual property, and weak enforcement mechanisms. Consequently, it is imperative to enhance the legal protection system through a multifaceted approach and draw from international experiences to foster the growth and sustainability of these traditional medical practices.

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