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Optimization Path of Legal Construction in Chinese Traditional Medicine

Wenze Cao

Faculty of Culture and Education, Jingdezhen Vocational University of Art, China

Abstract: Chinese traditional medicine, as an important component of China's medicine, has a long history and wide-ranging applications in China. Currently, with the development of modern technology and social progress, the traditional Chinese medicine industry is facing new challenges. Issues such as the loss of traditional Chinese medicine resources and the misappropriation of related industries urgently need to be addressed. Comparing the differences in legal protection of traditional Chinese medicine industry (such as intellectual property protection). Through comparative studies, it is important to clarify the significance of legal construction in traditional Chinese medicine, strengthen the protection of traditional Chinese medicine, and promote the internationalization of legal construction in traditional Chinese medicine.

Keywords: Traditional Chinese Medicine(TCM); Law; Medicine Resources; Pharmaceutical Intellectual Property Rights, Optimization Path

1 Introduction

As an important traditional medicine and cultural heritage, Traditional Chinese Medicine (TCM) has undeniable value and social status worldwide(Wanying Wang et al., 2020). Improving the legal framework of TCM is crucial for the protection, regulation, and development of this field, which is vital for promoting its healthy development(Yuqing Zhang et al., 2019).

On one hand, enhancing the legal framework of TCM ensures its safety and effectiveness. While the efficacy of TCM is widely recognized, the uniqueness of its treatment methods and the complexity of its ingredients entail certain uncertainties, necessitating legal regulations(Ting-Ye Wang et al., 2021). By establishing a scientific legal framework for TCM, it becomes possible to standardize its production, sales, and usage, reduce the irrational use and abuse of medications, and ensure the safety and effectiveness of TCM(R. Wei et al., 2021).

On the other hand, improving the legal framework of TCM contributes to the promotion of traditional Chinese culture(Yuqing Zhang et al., 2019). As a precious cultural

heritage of the Chinese nation, TCM has profound historical roots and cultural connotations(Wanying Wang et al., 2020). Protecting and regulating it through legal means can facilitate the inheritance and development of TCM culture, enabling more people to understand and recognize its value, and enhancing its international influence.

Furthermore, enhancing the legal framework of TCM also drives the development of the TCM industry. The TCM industry is one of China's important strategic emerging industries, with vast market prospects and economic value(Juncai Xu et al., 2019). By establishing a sound legal system, it becomes possible to protect the legitimate rights and interests of TCM enterprises, strengthen the management and supervision of the TCM industry, promote its innovative development, and enhance its market competitiveness(A. Lin et al., 2018)

2.Research Background

2.1 The Current Status of Traditional Chinese Medicine Legislation within China

Since the mid-20th century, China has developed and

implemented various policies and regulations to inherit and protect TCM, achieving some notable results(Wanying Wang et al., 2020). To protect herbal medicine resources, China successively implemented the "Regulations on the Protection and Management of Wild Medicinal Materials Resources" in 1987 and the "Regulations on the Protection of Chinese Medicinal Varieties" in 1993. In 2003, the State Council issued the "Law of the People's Republic of China on Traditional Chinese Medicine," further safeguarding and promoting the development of TCM(Ju Huang et al., 2022). In 2017, China formally enacted and implemented the "Law of the People's Republic of China on Traditional Chinese Medicine," marking the beginning of a new chapter in the legal construction of TCM in the country.

In addition to the aforementioned TCM laws and regulations, China's "Law of the People's Republic of China on Pharmaceutical Administration," "Practicing Physicians Law," and "Standardization Law of the People's Republic of China," among others, provide varying degrees of protection for the legal system of TCM. For instance, the "Price Law of the People's Republic of China" regulates the prices of TCM products, while the "Intangible Cultural Heritage Law" specifically lists traditional medicine as an intangible cultural heritage, offering protection. Furthermore, the "Trademark Law" and "Patent Law" provide some protection for TCM intellectual property rights. Based on these, China's legal construction of TCM has shown initial effectiveness.

Firstly, China's legal framework for TCM plays an important role in the regulation and standardization of TCM clinical practice(Lu Zhao-li et al., 2008). According to Chinese law, TCM practitioners must possess corresponding qualifications and practice certificates to engage in TCM diagnosis and treatment(S. Mist et al., 2009). This requirement ensures that the professional competence and treatment levels of TCM practitioners are trustworthy, thereby protecting the rights of patients. Moreover, the management of TCM clinical practice in China is becoming increasingly standardized(Juan Wang et al., 2016). Chinese herbal prescriptions must be issued according to specified procedures, with strict control over the dosage and duration of herbal medicine use to ensure the safety and efficacy of patient treatments.

Secondly, China's legal framework for TCM has also played a positive role in protecting herbal medicine resources and ensuring the quality of TCM(Xiaoyi Zhang et al., 2021). With the growing international influence of TCM, the Chinese herbal medicine market has seen some illegal activities, such as the sale of counterfeit drugs and the excessive exploitation of herbal medicine resources. In order to ensure the sustainable utilization of herbal medicine resources, China has enacted a series of laws and regulations to regulate the collection, processing, circulation, and use of herbal materials, strengthening the protection of herbal medicine resources(Ran-Ran Gao et al., 2019).

Furthermore, China's legal framework for TCM has achieved some success in protecting TCM intellectual property rights(Jinguo Wang et al., 2017). Protection of TCM intellectual property includes patent protection for TCM prescriptions and geographical indication protection for Chinese herbal medicines(Wang Saina et al., 2014). Although China's current legal system still has many shortcomings in protecting TCM intellectual property rights, with the continuous improvement of the legal construction of TCM, more and more issues are being resolved, and China's legal system for protecting TCM intellectual property rights is expected to achieve better results.

2.2 The Current Status of Traditional Chinese Medicine Legislation outside of China

The legal systems for Traditional Chinese Medicine (TCM) in countries outside of China have their own characteristics, but overall, they are dedicated to protecting the legitimate rights and promoting the development of TCM(Wanying Wang et al., 2020).

The Current Status of Traditional Chinese Medicine Legislation in the United Kingdom:

The United Kingdom is a culturally diverse country where the cultural heritage of TCM, originating from China, also holds a significant position(X. Ye et al., 2016). TCM has a wide influence in the UK. The legislative body of the UK has passed laws regarding TCM, clarifying the status of TCM and recognizing its legality within the UK(M. Oravecz et al., 2014). Additionally, they have established a TCM Regulatory Authority responsible for the registration and management of TCM practitioners and pharmacists. Furthermore, the UK encourages the development of TCM education by establishing multiple TCM colleges, cultivating a large number of TCM professionals(Yi Chen et al., 2019). China can learn from the UK's practices to strengthen the registration and management of TCM practitioners and actively promote the development of TCM education.

The Current Status of Traditional Chinese Medicine Legislation in France:

France not only passed laws regarding TCM but also incorporated TCM into its national healthcare system(Haixia Dang et al., 2016). The French government has also established a TCM research institution responsible for scientific research and clinical practice of TCM. Additionally, France has implemented a series of policy measures that promote the development and application of TCM within its borders. China can learn from France's practices to intensify scientific research and clinical practice of TCM.

The Current Status of Traditional Chinese Medicine Legislation in the United States:

The United States is a country of immigrants, and immigrants from East Asian countries such as China, Japan, and Korea have brought TCM to the US. TCM has a wide dissemination and application in the United States(Yulian Ke et al., 2023). The US government has included TCM in its national healthcare system through legislation and established a TCM regulatory body responsible for the registration and management of TCM practitioners and pharmacists(Y. Park et al., 2019). Moreover, the US allows collaboration between TCM practitioners and Western medicine practitioners, promoting the development of integrative medicine. China can learn from the US experience to strengthen the registration and management of TCM practitioners and pharmacists and actively promote the development of integrative medicine. The US's legal system for TCM is relatively comprehensive, with a dedicated federal agency for TCM management overseeing aspects such as education, clinical practice, and drug registration.

In addition, Japan's legal system for TCM focuses more on the protection and development of traditional medicine through the establishment of specialized institutions for TCM research and application.

3.Problem Analysis

3.1 Loss of Traditional Chinese Medicine Resources

In the current context, the loss of Traditional Chinese Medicine (TCM) resources has become increasingly severe, posing a series of challenges to the development of TCM(Fengqing Wei et al., 2016). Firstly, the loss of TCM resources primarily manifests as over-harvesting and indiscriminate digging of herbal resources. Due to the increasing demand for medicinal herbs, illegal and destructive collection activities frequently occur, endangering some important medicinal herbs with extinction(Soo-Rang Lee et al., 2018). This not only threatens the valuable resources of global TCM but also damages the ecological environment. Additionally, excessive mining of mineral medicinal materials and illegal acquisition of animal-based medicinal materials also cause irreversible loss to TCM resources and the natural environment(Mao-Hong Tang et., 2023). Secondly, due to the imperfect legal regulations and inadequate management mechanisms for protecting TCM resources, illegal loss of some TCM resources also occurs. Illegal activities such as resource collection, transportation, and sales have had a significant negative impact on the TCM industry chain, damaging the reputation of the TCM industry and posing serious challenges to the sustainable development of China's TCM industry. Furthermore, the protection of TCM resources in China also faces issues regarding cultural inheritance. With the acceleration of the modernization process, many traditional TCM resources and knowledge are gradually being forgotten and diluted, negatively affecting the development of traditional TCM culture and the inheritance of China's intangible cultural heritage.

3.2 Market Regulation of Chinese Herbal Medicine

Chinese herbal medicine is an important component of traditional Chinese medicine with a long history and profound cultural heritage. However, in recent years, the Chinese herbal medicine industry has faced a serious problem: foreign companies control a portion of the Chinese herbal medicine market through trademark or patent grabbing and the acquisition of Chinese herbal medicine enterprises.

In 2023, Zi Guang Chen Ji was acquired by a Japanese company. In recent years, some Chinese herbal medicine enterprises have been acquired by Japanese companies, allowing Japan to control a considerable share of the global Chinese herbal medicine market. Additionally, many patents related to Chinese herbal medicine have been obtained or registered by foreign countries. Furthermore, due to the lack of awareness of trademarks among some Chinese herbal medicine enterprises, instances of their trademarks being registered by foreign pharmaceutical companies are not uncommon. Overall, due to foreign companies controlling the Chinese herbal medicine market through various means in recent years, although China is the birthplace of TCM, it does not have an advantage in the global Chinese herbal medicine market(X. Han et al., 2022). The situation is not optimistic in

some aspects. How to prevent Chinese herbal medicine enterprises from being legally acquired by foreign companies and how to prevent foreign companies from grabbing trademarks related to TCM have become issues that China's legal system for TCM must consider and address.

3.3 Biopiracy and Protection of Traditional Chinese Medicine Intellectual Property Rights

In the enhancement of the legal framework for Traditional Chinese Medicine (TCM), combating biopiracy and protecting the intellectual property rights (IPR) of TCM are crucial topics(Jinguo Wang et al., 2017). With the increasing demand for TCM both domestically and internationally, some unscrupulous individuals have started to exploit TCM resources and infringe upon TCM intellectual property rights, posing a serious threat to the development of TCM.

Biopiracy refers to the act of multinational corporations extracting genes from biological genetic resources existing in other countries' communities, especially indigenous communities, without permission(Y. Imran et al., 2021). They then proceed to develop, utilize, and commercially control these resources. With the advancement of technology, transgenic technology has been widely used in pharmaceuticals. In this context, some foreign companies, in order to profit in the global Chinese herbal medicine market, have begun to use biopiracy to steal China's TCM resources. They extract genes from Chinese medicinal materials and use technologies such as transgenic methods to produce effective components of Chinese medicinal materials. This undoubtedly brings about significant losses to China's TCM resources

Furthermore, the protection of TCM intellectual property rights is a critical aspect of improving the legal framework for TCM. Due to the uniqueness and traditionality of TCM knowledge, protecting its intellectual property rights presents certain challenges. Unlawful businesses engage in activities such as piracy and counterfeiting, infringing upon the legitimate rights of TCM inheritors. They even seize trademarks and patents related to the TCM industry on the international market, causing serious damage to China's TCM intellectual property rights.

3.4 Insufficient Protection Efforts for Traditional Medicine of Ethnic Minorities

The "Law of the People's Republic of China on Traditional Chinese Medicine" defines TCM as "the

collective name for the traditional medicines of all ethnic groups in China, including the Han ethnic group and ethnic minorities." However, in reality, TCM is often understood mainly as traditional medicine of the Han ethnic group. Even in the research process of constructing the legal framework for TCM, scholars tend to focus more on the legal development of traditional medicine of the Han ethnic group. However, traditional medicine of ethnic minorities is also an integral part of TCM.

Currently, China's legal framework for TCM needs to pay more attention to the protection of traditional medicine of ethnic minorities. Taking Tibetan medicine as an example, there are very few universities in China that offer Tibetan medicine majors, and they are mainly concentrated in western regions. The number of Tibetan medicine talents that can be delivered to society each year is very limited, resulting in a relatively small number of Tibetan medicine professionals in China. Secondly, the distribution of Tibetan medical institutions in China is limited and mainly concentrated in areas inhabited by Tibetan people. Most other areas do not have Tibetan medical institutions, and hospitals lack Tibetan medical departments. Finally, there are not many people in China who truly understand Tibetan medicine. Currently, the situation of traditional medicine of other ethnic minorities is similar to that of Tibetan medicine, facing challenges such as a shortage of talents, limited distribution, and limited dissemination.

4.Suggestion

4.1 Strengthening the Protection of Traditional Chinese Medicine Resources

Currently, the loss and protection of Traditional Chinese Medicine (TCM) resources require urgent attention, thus necessitating the strengthening and implementation of relevant legal protection measures. Firstly, a sound legal framework for the protection of TCM resources should be established. This includes refining relevant laws and regulations, clarifying the definition, classification, and protection scope of TCM resources, establishing clear protection and punitive measures, and intensifying efforts to combat illegal activities that damage TCM resources. Additionally, it is necessary to establish a robust registration system for authentic TCM resources, registering and recording important TCM resources to ensure their lawful use and protection. Secondly, efforts should be made to enhance the supervision of TCM resources. Establish specialized institutions to strengthen supervision and management throughout the process of TCM resource development and utilization, strictly prohibit illegal collection, abuse, and destruction of TCM resources. Implement corresponding punitive measures to rigorously crack down on unlawful activities, providing effective legal safeguards for the protection of TCM resources.

Moreover, there should be increased advocacy and education on the protection of TCM resources. Through various forms of promotional activities, raise public awareness of the importance of protecting TCM resources and enhance the public's consciousness regarding the protection of TCM resources. Simultaneously, strengthen training and education for relevant professionals to improve their understanding and awareness of TCM resource protection, thereby enhancing the level of rational utilization and protection of TCM resources.

Finally, efforts should be made to enhance international cooperation and actively promote the internationalization of TCM resource protection. Strengthen cooperation with various countries to jointly protect and develop the utilization of TCM resources, share knowledge and technologies related to TCM, and make positive contributions to the development of TCM.

4.2 Strengthening the Protection of Traditional Chinese Medicine Intellectual Property Rights

Enhancing the protection of Traditional Chinese Medicine (TCM) intellectual property rights is a crucial aspect of improving the legal framework for TCM. As an integral part of China's traditional medicine, TCM boasts a rich history and profound cultural heritage. However, due to the lack of effective intellectual property protection measures, TCM knowledge faces issues such as piracy, infringement, and misuse.

To strengthen the protection of TCM intellectual property rights, improvements should be made in several aspects. Firstly, enhance the protection of TCM knowledge, including ancient TCM texts, formulations, herbal knowledge, and more. This can be achieved by refining relevant laws and regulations, increasing the crackdown on infringement, and ensuring the lawful use of TCM knowledge. Secondly, establish a robust system for the registration, application, and protection of TCM intellectual property rights. This may involve setting up specialized institutions responsible for the management and maintenance of TCM intellectual property, providing related services, strengthening the review and supervision of TCM intellectual property, and ensuring the protection of the lawful rights of TCM and its inheritors.

Additionally, there should be increased international cooperation in the protection of TCM intellectual property. By joining international intellectual property organizations and collaborating with other countries, efforts can be made to jointly protect and develop TCM intellectual property rights, ensuring the international dissemination and lawful use of TCM knowledge. Lastly, there needs to be enhanced advocacy and education on the protection of TCM intellectual property rights. Through specialized promotional activities and training programs, raise awareness among medical professionals and TCM practitioners about the importance of intellectual property protection, increase their level of attention to TCM intellectual property rights, and promote the implementation of TCM intellectual property protection efforts.

4.3 Enhancing the Recognition of Traditional Medicine of Ethnic Minorities

The traditional medicine of various ethnic minorities is an integral part of TCM. TCM does not solely belong to the Han ethnic group but is the medicine of the entire Chinese nation. China has fifty-six ethnic groups, all of which belong to the Chinese nation, and the traditional medicine of each ethnic group is part of the TCM family. In the process of improving the legal framework for TCM, China should enhance the recognition of traditional medicine of ethnic minorities.

In improving the legal framework for TCM, China should fully consider the issues faced by the traditional medicine of various ethnic minorities and work to solve these problems. For example, to address the scarcity of talent in ethnic minority medicine, China can improve relevant laws and regulations related to education to encourage medical schools to establish majors in ethnic minority medicine. Additionally, through strengthened promotion of ethnic minority medicine and the establishment of sound systems to support its development, progress can be made in promoting the development of traditional medicine is an important part of TCM, and enhancing its recognition should be an important aspect of improving the legal framework for TCM.

4.4 Promoting the Internationalization of the Legal Framework for Traditional Chinese Medicine

Promoting the internationalization of the legal framework for TCM is of significant importance for the development of the TCM industry. As the global demand for TCM continues to rise, promoting the internationalization of the legal framework for TCM can strengthen international exchanges and cooperation in TCM, enhance the international reputation and influence of TCM, and achieve the global development of TCM.

Key to promoting the internationalization of the legal framework for TCM is the strengthening of standardization efforts. Establishing unified TCM standards, including standards for the quality of drug production, clinical trials, and drug registration management, can guarantee the quality and safety of TCM and promote international cooperation and exchanges in TCM. Additionally, enhancing cooperation between the TCM field and international standardization organizations, actively participating in the formulation and revision of international TCM standards, is crucial for enhancing the international influence and competitiveness of TCM.

Strengthening the protection of TCM intellectual property rights is one of the important measures to promote the internationalization of the legal framework for TCM. TCM is a treasure of China's traditional medicine, with its unique medical theories and rich clinical experiences. Strengthening the protection of TCM intellectual property rights, including the naming of Chinese herbal medicines, clinical treatment plans, TCM patents, and more, is conducive to protecting the innovative achievements and intellectual property of TCM. promoting the internationalization of TCM, and establishing the international image of TCM.

Furthermore, cultivating and promoting talents in TCM and enhancing international exchanges are also important measures to promote the internationalization of the legal framework for TCM. Cultivating a group of TCM professionals with solid theoretical foundations, international perspectives, and cross-cultural communication abilities will help enhance the international competitiveness and influence of TCM. Meanwhile, strengthening international exchanges and cooperation in TCM talent will facilitate the absorption of excellent TCM theories and technologies from various countries, promoting the dissemination and application of TCM internationally.

Enhancing international promotion and publicity of TCM will help raise its international visibility and recognition. Through international promotion efforts, introducing the unique charm and effectiveness of TCM to countries worldwide, more nations and people can benefit from the therapeutic and health-promoting effects of TCM. Additionally, aligning the legal framework of TCM with those of other countries will promote the standardization and popularization of TCM internationally.

Promoting the internationalization of the legal framework for TCM is an inevitable choice for the development of the TCM industry. By strengthening TCM international standardization efforts, enhancing the protection of TCM intellectual property rights, promoting the cultivation and exchanges of TCM talents, and boosting international promotion and publicity efforts, the dissemination and application of TCM internationally can be achieved, promoting the prosperity and development of the TCM industry. The internationalization of the legal framework for TCM will not only bring health and well-being to people worldwide but also inject new vitality into the inheritance and development of TCM.

5.Conclusion

This article aims to explore the importance of the legal framework for Traditional Chinese Medicine (TCM) construction and its impact on the development of the TCM industry, as well as to propose relevant optimization suggestions. Firstly, the construction of the legal framework for TCM is of significant significance for the protection of TCM resources and the development of the Chinese herbal medicine-related industry. In the current social environment, issues such as the loss of TCM resources and the foreign hijacking of the Chinese herbal medicine-related industry are becoming increasingly prominent. Strengthening legal measures for the protection of TCM resources is an important direction for the construction of the legal framework for TCM. Secondly, establishing a sound system for the protection of TCM intellectual property rights is an important task in perfecting the legal framework for TCM construction. To address issues such as biopiracy and the current problems in the protection of TCM intellectual property rights, the implementation of specialized regulations for the protection of TCM intellectual property rights is an important step in perfecting the legal framework for TCM construction. Finally, in promoting the internationalization of the legal framework for TCM, efforts should be made to strengthen the external exchanges and cooperation of the legal framework for TCM, promote the influence and status of the legal framework for TCM internationally, and meet the development needs of the global TCM industry. The improvement of the legal framework for the development of the TCM industry. China should strengthen the protection of TCM resources, the protection of TCM intellectual property rights, optimize the system of TCM regulations, and promote the internationalization of the legal framework for TCM.

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