

## A Summary Of Literature Research On The Current Status Of Quality Supervision Of Traditional Chinese Medicine Decoction Pieces

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**Abstract:** Since the 18th National Congress of CPC, traditional Chinese medicine(TCM) has become increasingly prominent. Inheriting innovative development of TCM is an important part of the cause of socialism with Chinese characteristics in the new era and a major event for the great rejuvenation of the Chinese nation. The quality of TCM decoction pieces affects the effectiveness of TCM clinical treatment and is the basis for ensuring the safety of people's livelihood. The state has always attached great importance to the supervision of the quality of TCM decoction pieces, but there are always certain problems with the effectiveness of supervision. This article is based on a research review of the literature on the quality supervision of TCM decoction pieces, and analyzes the current status and related problems of quality supervision of TCM decoction pieces, and provides some help for improving the efficiency of quality supervision of TCM decoction pieces.

### 1. Overview Of TCM Decoction Pieces And Its Quality Supervision

The origin of the TCM decoction pieces can be traced back to the "Wulin Old Events" of Mi Zhou in the Southern Song Dynasty: "The Workshop" sells "Crude Medicine that called 'Yuansan', Raw Medicine that called 'Decoction Pieces'". According to the "Chinese Pharmacopoeia" records, decoctions refer to processed Chinese herbal medicines, which can be directly used for preparation or preparation. Modern Chinese medicine circles generally believe that Chinese herbal medicines are Chinese herbal medicines that have been processed and processed according to Chinese medicine theories and Chinese medicine processing methods, and can be used directly in Chinese medicine. From the perspective of management, the concept of Chinese herbal decoction can be interpreted as: according to the needs of blending or preparation, the finished products processed and processed by the net medicinal materials processed by the origin are called Chinese herbal decoction<sup>[1]</sup> On August 18, 2009, the former Ministry of Health and other 9 ministries and commissions included traditional Chinese medicine decoction pieces for the first time in the National Essential Medicines Directory and retained them until the current 2012 edition of the Essential Medicines Directory, bringing unprecedented new opportunities to the Chinese medicine industry<sup>[2]</sup>. As one of the three pillars of the Chinese medicine industry in China, it plays an important role in the industry chain. Its quality problems will seriously hinder the pace of modernization of the Chinese medicine industry and affect the inheritance and innovation of the Chinese medicine industry. Han Xue (2015) and others proposed that the adulteration of traditional Chinese medicine decoctions and related phenomena such as excessive metal standards and pesticide residues, the safety of the use of drugs has been severely restricted, and at the same time, it has seriously affected the healthy development of the application and operation of traditional Chinese medicine<sup>[3]</sup>. The Drug Administration Law of the People's Republic of China and other relevant laws and regulations stipulate that the administrative authority for drug supervision and management shall, in accordance with the authorization of the laws and regulations and in accordance with the provisions of the relevant laws and regulations, manage the development, production, circulation and use of drugs. Moreover, it can be clearly found that there is a typical interest asymmetry phenomenon in the Chinese herbal medicine market. Consumers are at a relative disadvantage of information and it is difficult to distinguish between the advantages and

disadvantages of Chinese herbal medicine. The book "Western Economics" once emphasized that government supervision in the asymmetric information market the important role of government intervention can effectively avoid the vicious consequences of market failure caused by asymmetric information between the two parties. Therefore, it is particularly important to supervise and control the quality of Chinese herbal medicines from production to circulation.

## **2. Research on the status quo of quality control of TCM decoction pieces in China**

Since the original Ministry of Health issued the first Chinese Pharmacopoeia in 1963, which contains quality standards for Chinese herbal medicines, the quality control and supervision of Chinese herbal medicines have been continuously improved regardless of the improvement and improvement of the quality of Chinese herbal medicines. . With the continuous development of Chinese medicine, it is currently widely used in the treatment and prevention of various diseases. Some studies have found that at present, the commodities circulating in the Chinese herbal medicine market have problems in packaging, storage and production irregularities that affect the quality of the herbal medicine<sup>[4]</sup> According to the data of the drug inspection report released by the State Drug Administration: 29 of the 38 Chinese medicine manufacturing enterprises that were inspected in the 2017 annual drug inspection report did not meet the relevant requirements, and 21 of them were withdrawn the drug GMP certificate<sup>[5]</sup>. Relevant data show that only 75% of the Chinese herbal medicines currently sampled on the market can meet the pharmacopoeial standards, and the remaining 25% are unqualified Chinese medicines. Through reading the literature, it is found that all experts and scholars believe that the current status of the quality supervision of traditional Chinese medicine decoctions is not optimistic. There are still many problems in the current situation of the quality supervision of traditional Chinese medicine decoctions. Comprehensive research by scholars can be divided into regulatory standards, regulatory forces, regulatory measures and the object of supervision itself. Through reading the literature, it is found that all experts and scholars believe that the current status of the quality supervision of traditional Chinese medicine decoction pieces is not optimistic. There are still many problems in the current situation of the quality supervision of traditional Chinese medicine decoction pieces.

### **2.1 Supervising standard**

Modern academia generally believes that the inconsistent basis for the supervision of Chinese herbal medicines in various parts of the country is the main reason for the low efficiency of traditional Chinese medicine decoction pieces quality supervision. There are conflicting supervisory intentions, unclear powers, and mutual blame between supervisory authorities. The name, equipment and process of the same Chinese herbal is different in the different place, which is what we often say "one place, one method". The laws and regulations related to the quality supervision of traditional Chinese medicine decoction pieces mainly include "Drug Administration Law", " Drug Administration Law Implementation Regulations ", " Measures for the administration of drug Trade Licenses", " Measures for supervision and administration of drug production ", " Good Manufacturing Practice " (GMP), " Good Supply Practice " (GSP), " Chinese medicinal materials production quality management standard (Trial)", "Pharmaceutical and Medical Device Flight Inspection Measures", etc. Some scholars believe that the current laws and regulations in China are biased towards Western medical theory, and lack of consideration of the characteristics of traditional Chinese medicine. For example, Zhu Zhongrui et al. (2019) " Study on legal issues of quality supervision in the process of processing Chinese herbal pieces" mentioned: The Drug Administration Law of the People's Republic of China has more detailed regulations on drug management, but its content is more for Western medicines, less for Chinese medicines, and the regulations on the processing process are also insufficient<sup>[6]</sup>. Because the definite boundaries of TCM decoction pieces are unclear and because of the great differences in the characteristics and quality of the original medicinal materials in different local environments and climates, as well as the collision between ancient methods and modern crafts, some scholars believe that they exist All the laws and regulations on the quality supervision of Chinese herbal medicines include incomplete

Chinese herbal medicines, inaccurate processing standards, and some specifications only stipulate the quality standards of the original medicinal materials, which is prone to regulatory confusion. The standards for the implementation of TCM decoction pieces are firstly the Chinese Pharmacopoeia, followed by the national standards for the preparation of TCM decoction pieces and the local standards for the preparation of TCM decoction pieces. However, due to the inconsistency of standards at all levels, it has brought certain difficulties to supervision. Taking yam as an example, the clinical use of Chinese herbal decoctions is not included in the provincial-level Chinese herbal decoction preparation specifications. The inspection items included in the Chinese Pharmacopoeia are only the standard of the original medicines. Description of the quality standard of decoction pieces<sup>[7]</sup>. Some scholars have conducted research from the perspective of legal publicity, and concluded that it can be understood that since the establishment of the drug regulatory department, a lot of work has indeed been done in the promotion of drug laws and regulations. However, due to the special nature of Chinese herbal medicine, All kinds of enterprises do not have enough knowledge about the production rules of Chinese herbal medicines prescribed by the state. The production and processing of Chinese herbal medicines are based on the experience of the predecessors. For example, Zhang Xueliang (2007) believes that the quality managers of Chinese herbal medicines, especially some old Chinese doctors, hold the traditional concept that "decay of decayed medicine is not decayed", and quarrels and funnels are common phenomena. It is a small problem that Chinese medicine labels do not have correct names.<sup>[8]</sup>

## 2.2 Regulatory capacities

As far as the quality supervision of pharmaceuticals is concerned, research on the power of regulatory execution is indispensable. A comprehensive study based on the existing literature on HowNet shows that all scholars maintain an attitude towards the status quo of the quality supervision team of Chinese herbal medicines in China. Consistency-At present, the strength is still very weak, and there is a lack of professional inspection and supervision teams, especially the lack of a certain effective communication and joint mechanism between the various regulatory bodies of the grassroots units. The strength of the supervision team determines the strength of the supervision, which directly affects the quality supervision effect. According to the literature data, there are more than 880,000 Chinese herbal medicine production enterprises in China, but there are only 46259 food and drug supervision administrative personnel except the leadership team. The huge disparity highlights the extreme shortage of supervisory personnel in China. Some scholars analyzed the academic composition and professional composition of the quality supervision team of traditional Chinese medicine decoction pieces based on the professionalism of the supervision team. Traditional Chinese medicine professionals are very scarce, and few are devoted to the quality supervision system. Xu Yan (2019) learned through investigation and research that there are 7 persons in the 2 departments of the production and distribution supervision of pharmaceutical machinery in a city's Food and Drug Administration. Only one person is from a pharmacy-related profession, and only 3 persons have obtained the administrative enforcement power of drug regulation. The city's food and drug inspection center has 53 establishments and has 34 inspection and testing professionals, including less than 5 inspectors of Chinese medicinal materials and Chinese herbal medicines<sup>[9]</sup>. Due to the weak strength of the supervision team and the serious imbalance in the proportion of professional knowledge, some companies are aware of the loopholes and will not hesitate to seek benefits by "trying the law". In addition, some scholars analyzed the relationship between the stakeholders of the quality control of traditional Chinese medicine decoctions based on game theory, and believed that the interest game between the regulatory authorities at all levels and the communication and coordination mechanism issues will seriously affect the results of the quality supervision of traditional Chinese medicine decoctions. The quality supervision process should continue from the source of the cultivation of Chinese herbal medicines to the entire process of medical use, which will involve many departments such as agriculture, food and drug supervision, and health. In practice, these departments often lack certain communication and coordination The mechanism has not formed a good chain of custody.

## 2.3 Supervision measures

Experts and scholars have less research on the regulatory measures of traditional Chinese medicine decoction pieces than other aspects. It is generally believed that a single regulatory method is not an inevitable factor that affects the regulatory effect. China's drug supervision is dominated by government administrative supervision, but it is obviously not enough to rely on the power of the government for the huge drug market, and according to the opinions of experts, we believe that China's supervision mode is an "ex-post" model, that is, the media Exposure comes first, and the supervision team conducts the inspection later. This passive inspection method does not cure the symptoms, and cannot effectively solve the problem. Wu Yingxiong and others believe that the regulatory philosophy of my country's drug regulatory authority still bears the imprint of the planned economic system, such as "emphasis on power and power" and "emphasis on management and service". The authoritative regulatory concept is deeply ingrained<sup>[10]</sup>. Cui Yongming (2017) and others have studied that the law enforcement personnel of the drug supervision and administration department conduct regular and unscheduled supervision and random inspections on the production, circulation and use of Chinese herbal decoction pieces. The "Pharmaceutical Quality Bulletin" model cannot form a high-pressure situation for problem units<sup>[11]</sup>. Zhu Zhongrui and others proposed (2019) that the supervision of the processing of processed pieces in China is mainly the responsibility of the State Administration of Traditional Chinese Medicine, which overemphasizes the government as the main body of supervision, while ignoring the dynamics of supervision by other bodies and third parties and the diversified supervision methods that can be provided. It is conducive to the supervision of the broad consumer groups and the role of social supervision. Pharmacy workers in some medical institutions have insufficient knowledge about the maintenance of Chinese herbal medicines. They are not stored in accordance with the prescribed procedures, and they do not distinguish between expensive, toxic, or volatile Chinese herbal medicines. Careful storage has led to the loss of the efficacy of the herbal medicines or improper delivery. Wasted Chinese Herbal Pieces<sup>[12]</sup>

## 2.4 Regulatory objects

Whether the regulated object itself complies with laws and regulations to regulate the quality of TCM decoction pieces, and whether it cooperates with the supervisor to conduct quality inspections are related to whether the quality supervision of TCM decoction pieces can be effectively carried out, which directly affects the quality of TCM decoction pieces. According to the literature summary, scholars can summarize these problems through the research and investigation of various Chinese herbal medicine production enterprises and Chinese pharmacies: first, the sense of responsibility of the main body of the enterprise is weak, and the high incidence of quality problems of herbal medicines is mainly due to Driven by interests, Chinese medicine decoction companies have turned a blind eye to the problems found by the regulatory authorities, or they have changed the situation but they have remained the same since then. Even if they are investigated and dealt with in violation of the law, they are only fined. The violation has not been fundamentally corrected, and there is no way to improve the level of production and operation. The production and circulation of Chinese herbal medicines are scattered and various types of enterprises are small and numerous. There is a lack of excellent modern enterprises like Kangmei Pharmaceutical and Tongrentang that have complete process standards and clear process structures. Due to the strict punishment mechanism, small enterprises' self-management and It is not uncommon to produce according to your own specifications. Secondly, in order to reduce the acquisition cost, some medical institutions will also choose the lowest quality Chinese herbal decoction pieces, resulting in the breeding of low-quality decoction pieces and seriously affecting the development of the industry. Moreover, due to the lack of social co-governance in supervision, it is difficult for the government to supervise the quality of Chinese herbal medicines in hospitals. Whether medical institutions actually carry out the storage, storage, and maintenance of Chinese herbal medicines in accordance with the rules and regulations will affect the final clinical application of Chinese herbal medicines. For example, Wang Hongyu (2019) believes that the managers of Chinese herbal medicines stored



in pharmacies do not arbitrarily place the preparation of the sliced preparations according to the requirements, so that the slices that are not exposed to direct sunlight are exposed to the sun, so that the effective ingredients of the slices are invalid or deteriorated, causing certain losses<sup>[13]</sup>

### 3. Conclusion and Prospect

All in all, the indispensable important part of Chinese medicine decoction is to ensure the quality of Chinese medicine decoction. The quality supervision of TCM decoction pieces has a strategic position. By reading the literature searched on HowNet for the quality supervision of TCM decoction pieces, combing the current research on the status quo of supervision, it can be seen that all circles have passed the research on the status of quality supervision of TCM decoction pieces To improve the overall quality has been quite effective. As of 2020, the quality of Chinese herbal medicine has been significantly improved and played an extremely important role in this new coronary pneumonia epidemic. However, we should also be deeply aware that the supervision of traditional Chinese medicine decoctions has a long way to go, and it will never be solved overnight. Through a review of the current situation research and improvement suggestions, we hope to provide some help to improve the quality supervision level of Chinese herbal medicines in my country, promote the development of Chinese medicine more vigorous and brilliant, and escort the health of the people.

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