

Study on the Quality of Chinese Herbal Pieces and the Development of Enterprises

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Abstract. The quality of Chinese herbal pieces is related to the safety and effectiveness of drug use. In this paper, the production of Chinese herbal pieces, business links, quality control found problems and causes were analyzed. Some suggestions are put forward from the perspective of enterprise development. It is hoped that it will be helpful to the future development of traditional Chinese medicine enterprises.

Keywords: Chinese herbal pieces; quality problems; enterprise Development.

1. Introduction

Chinese Herbal Pieces are not only prescription drugs for syndrome differentiation and treatment of traditional Chinese medicine, but also an important material basis for the treatment of Chinese medicine, and a raw material for the production of proprietary Chinese medicines. The quality of traditional Chinese herbal pieces will directly affect the effectiveness of TCM clinical treatment and drug safety, affecting the quality of proprietary Chinese medicines, and it is also related to the rise and fall of the development of Chinese medicine.

However, in recent years, Chinese herbal pieces have been repeatedly reported, dyeing, excessive impurities, excessive production and management, and many other people in the industry have issued a call for the quality of Chinese herbal medicines. At the same time, we can see from the official website of National Medical Products Administration that the quality of Chinese herbal pieces is indeed not optimistic.

2. Data Source

According to the results of drug flight inspections published on the official website of National Medical Products Administration from 2013 to 2018, there were 56 Chinese medicine decoction enterprises with problems, and 160 problems occurred, and some enterprises found problems in multiple flight inspections. Among them, there were 101 cases of problems in the production process of Chinese herbal pieces enterprises, and 59 cases had problems in the operation.

3. Production Process Problems and Analysis

There are 28 cases of production records and inspection records suspected of being false or missing, accounting for 27.72% of the total problems in the production process, accounting for 17.50% of the entire link;

Production records and inspection records are of great significance for mastering product quality and product traceability. However, in the actual production process, because the company does not pay attention to it, some employees do not realize the role of the record, which leads to the situation that they are unwilling and have to fill in the record. They often fill in the time and often record the record as a memoir. Record issues such as perfunctory things.

here are 18 cases of production quality management confusion or major defects in the system, accounting for 17.82% of the total problems in the production process, accounting for 11.25% of the entire link;

Improper quality management of traditional Chinese herbal pieces will not only increase production costs, but also waste resources. At the same time, it may bring unnecessary troubles to subsequent production, and the quality of traditional Chinese herbal pieces is difficult to guarantee.

Material management confusion (including material procurement problems, storage problems, check problems), there are 18 cases, accounting for 17.82% of the total problems in the production chain, accounting for 11.25% of the entire link;

There are many kinds of traditional Chinese herbal pieces, which are susceptible to mold and worms, such as proteins, lipids and sugars. The management of these materials must meet their conditions.

The illegal production of traditional Chinese herbal pieces (including production after over-production and recovery of the "GMP certificate"), there are 11 cases, accounting for 10.89% of the total problems in the production chain, accounting for 6.88% of the entire link;

In order to gain a share in the Chinese medicine decoction production industry, some enterprises put into production and sales without obtaining a production license; some enterprises that have recovered certificates do not improve their production environment, but also illegally produce for the sake of temporary benefits. Enterprises do not pay attention to relevant laws and regulations.

Poor production environment, equipment and equipment can not meet the production inspection needs of the corresponding products or the lack of necessary equipment, there are 8 cases, accounting for 7.92% of the total problems in the production process, accounting for 5.00% of the entire link;

The production process of traditional Chinese herbal pieces is very complicated, and any one of the processes can not be mistaken. In the process of processing, ventilation, de-smoking, dehumidification and cooling are all necessary. However, many enterprises have insufficient investment in production funds for reasons such as cost reduction, and the production equipment is poor or missing, which will inevitably lead to a decline in production efficiency.

There are 7 cases of over-production of traditional Chinese herbal pieces or no corresponding toxic decoction pieces, accounting for 6.93% of the total problems in the production process, accounting for 4.38% of the whole link;

For a long time, China's traditional Chinese medicine decoction "Chinese Pharmacopoeia", "Regulations on the processing of traditional Chinese herbal pieces in various provinces and cities", "National Chinese Herbal Pieces Processing Specifications" and other standards. This also makes it difficult for many companies to formulate the corresponding toxic pieces to produce the production range and has the luck to make the company know the law and break the law in the production process.

Other problems, there are 11 cases, accounting for 10.89% of the total problems in the production chain, accounting for 6.88% of the entire link.

4. Operational Link Problems and Analysis

Suspected and open bills, facilitating the illegal production and operation of pharmaceutical enterprises, or failing to fulfill the procurement of drugs, there are 15 cases, accounting for 25.42% of the total problems in the operation, accounting for 9.38% of the entire link;

During the operation of traditional Chinese herbal pieces, some producers and operators share the same pollution and conceal each other, ignoring the quality of the pieces for their own interests. Not open or virtual invoicing in order to evade taxes, the sense of responsibility as a citizen is not strong.

There are problems with the packaging label, serial number, batch number, etc. There are 10 cases, accounting for 16.95% of the total problems in the operation, accounting for 6.25% of the whole link;

The non-standardization of Chinese medicine product packaging is not conducive to the construction of Chinese medicine brands, and the false confusion of the number and drug batch number is not convenient for management and recording. Although it saves the trouble of applying for the batch number, it is not conducive to the development of the enterprise, and these are not enterprises. Figure 1 is convenient or can be exchanged in front of the small profits.

suspected outsourcing of Chinese herbal pieces (not tested) for OEM sales, there are 7 cases, accounting for 11.86% of the total problems in the operation, accounting for 4.38% of the entire link;

Some enterprises use their own brand effect to sell the insured Chinese medicine pieces that cannot be guaranteed. Although they save the cost of inspection, they live up to the trust of consumers and disregard the safety of consumers and the future development of enterprises.

The sales of the goods in the ticket are inconsistent, and no complete purchase and sales records have been established. There are 7 cases, accounting for 11.86% of the total problems in the operation, accounting for 4.38% of the whole link;

The sale of traditional Chinese herbal pieces that have not been tested by standard or untested, there are 5 cases, accounting for 8.47% of the total problems in the operation, accounting for 3.13% of the whole link;

There are 5 cases of doubts about the authenticity of the reliability of the data on the decoction pieces, accounting for 8.47% of the total problems in the operation, accounting for 3.13% of the whole link;

Other problems, there are 10 cases, accounting for 16.95% of the total problems in the operation, accounting for 6.25% of the entire link.

5. Countermeasures

5.1 Enterprises Should Strengthen the Education and Training of Employees

Strengthen the training of relevant staff on production records, inspection records knowledge and role, and ensure implementation. Enterprises should appoint some truly competent and responsible professionals; they should promptly train the operators on the method of filling in the records, especially when using new records, and strengthen the training to ensure that the records are filled in according to regulations. In the process of setting up and analyzing the records, all members must be involved. Only when the operators participate in the record setting and fully listen to their opinions, can the records be more relevant to the actual work, and they are inevitably given their responsibility to make the records more consciously ensure the accuracy and completeness of the operation information; Do a good job in record analysis; be able to consciously discover problems in the operation process; and cooperate with management personnel to improve the current standard specifications. The formulation of national laws is of course important. It requires the active cooperation of relevant personnel and the strengthening of the legal awareness of production enterprises is particularly important. In addition to inspections of production enterprises, relevant regulatory authorities may also arrange professional personnel to conduct legal guidance and study on production enterprises. Strengthen the legal awareness of relevant participants.

5.2 Starting from the Source, It is Recommended that Enterprises Establish a Traceability System for the Quality of Traditional Chinese Herbal Pieces.

Starting from the quality of Chinese herbal medicines at the source of traditional Chinese herbal pieces, it is first necessary to determine which Chinese herbal medicines need special discrimination to prevent the purchase of fake and inferior Chinese herbal medicines. In addition, the fixed origin of Chinese herbal medicines is also an important link to ensure the quality of traditional Chinese herbal pieces. Environmentally differentiated management of different Chinese herbal medicines, reducing the mildew of the medicinal materials due to environmental reasons, resulting in waste of resources.

The establishment and improvement of the enterprise quality assurance system plays an important role in improving quality and reducing costs. At the same time, a sound system requires the high attention and strict implementation of staff and enterprises. In order to avoid record fraud, in the process of production and inspection of decoction pieces, multiple or more procedures can be verified and supervised to ensure the accuracy and reliability of the data, which can reduce the probability of data errors and reduce the probability of data errors. Some people lack self-management and the data is missing.

5.3 Chinese Herbal Medicine Production Enterprises Need to be Bigger and Stronger

In order to ensure the quality of the pieces, enterprises must be equipped with appropriate inspection and testing equipment, and must be equipped with appropriate personnel, which requires the company to pay attention to it and increase capital investment. On the other hand, domestic Chinese herbal medicine production enterprises have long been small, scattered, and weak in technical strength. In terms of production equipment and other aspects, the capital investment is very limited, which has led many companies to fail to purchase some necessary equipment to save costs, and the introduction of necessary professional talents cannot be realized. Therefore, the merger and reorganization between Chinese herbal pieces production enterprises is becoming bigger and stronger, and it is imperative to shape the brand.

5.4 Establish and Improve the Legal and Regulatory System Related to Chinese Herbal Pieces

First of all, it is imperative to establish and improve the relevant laws and regulations for Chinese herbal pieces. Only in this way can there be a way to rectify the illegal enterprises. For some companies that have been identified many times, it is a law-breaking offence. Enterprises with such repeated violations should also increase their punishment;

Secondly, the regulatory authorities can establish an anonymous reporting mechanism, open a reporting channel, and verify that the company does have problems. It should be strictly punished and reward the whistleblower. Furthermore, it is also necessary to increase the frequency of inspections of illegal enterprises and the penalties for violations.

Finally, it is the improvement of the standard of decoction pieces. Traditional Chinese herbal pieces are prescription drugs. Like other medicines, we should establish a national uniform quality standard for Chinese herbal pieces, a unified standard, and implement the approval number management for Chinese herbal pieces. In addition, in different regions, there will be some differences in the production range of corresponding toxic flakes, which will allow many manufacturers to take advantage of the loopholes. This requires the relevant departments to formulate the production scope of the corresponding toxic flakes, so that the production of Chinese medicinal flakes is more standardized.

5.5 Establishing a Training System for Chinese Medicine Talents

Colleges and universities should increase the training of Chinese pharmacy professionals. As a source of relevant talents, some relevant Chinese medicine majors and universities should increase the training of Chinese pharmacy professionals. Cultivate talents of Chinese medicine with both ability and political integrity, inject new vitality into the development of Chinese medicine, and condense a group of Chinese medicine talents with leading academics, exquisite medical skills and high medical ethics, and promote exchanges and cooperation between Chinese medicine and traditional Chinese medicine. Can solve problems in development and gradually improve quality.

The quality of traditional Chinese herbal pieces has an important impact on the safety and effectiveness of clinical use. At present, the frequent occurrence of adverse quality of traditional Chinese herbal pieces in China needs to actively strengthen quality supervision and quality control, speed up the pace of modernization, standardization and standardization, Chinese medicine The management of the decoction pieces can embark on a virtuous cycle and lay the foundation for the Chinese medicine to finally go to the world. It is hoped that pharmaceutical production enterprises and operating enterprises can effectively assume the main responsibility of enterprises. First, they should pay attention to the quality of medicines from the ideological point of view, and regard quality assurance as the lifeline for the long-term development of enterprises. At the same time, the drug supervision departments should also strengthen the quality supervision of Chinese herbal medicines and the violation of laws. Penalty. In order to achieve the clinical efficacy of TCM, ensure the safety of medication, safeguard the health of the people, enhance people's well-being, and let Chinese medicine play an important role in achieving the healthy China 2030 strategic goal.

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References

- [1]. Huang Yongqin. Thinking on the quality supervision and management of traditional Chinese medicine decoction pieces[J]. Chinese Journal of Integrated Traditional and Western Medicine on Cardiovascular Diseases. 2018(05).
- [2]. Zhou Jiajia, Lu Baizhen. Analysis and countermeasures on the quality and safety of traditional Chinese medicine decoction pieces [J]. Journal of Traditional Chinese Medicine Management. 2011(07).
- [3]. Hou Shaoyuan. Problems and Countermeasures in the Supervision and Management of Traditional Chinese Medicine Decoction Pieces [J]. Qilu Pharmaceutical Affairs. 2010(03).
- [4]. Xia Jizi. Strengthening the comprehensive supervision of the production, management and use of traditional Chinese medicine decoction pieces [J]. Capital Food and Medicine. 2017(04).