

Analysis of the Current Filing Status of Traditional Chinese Medicine Preparations Using Traditional Technology in Medical Institutions of Shaanxi Province

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Abstract: *Objective:* To summarize and analyze the application of traditional technology in preparing traditional Chinese medicine (TCM) preparations in medical institutions in Shaanxi Province after implementing the “Implementation Rules for the Record Management of Traditional Chinese Medicine Preparations in Medical Institutions in Shaanxi Province (Trial)” (“Implementation Rules”), and to provide a reference for the filing of TCM preparations. *Methods:* The TCM preparations recorded by medical institutions in Shaanxi Province since March 2019 were statistically summarized. The filing status was comprehensively and systematically analyzed based on the number of institutions and preparations, the ratio of commissioned to self-production, dosage form distribution, and the level of medical institutions. *Results:* Since implementing the Implementation Rules, a total of 479 TCM preparations have been filed in the province. Among these, 262 were commissioned for production, and 217 were self-produced, covering 17 dosage forms such as granules, pills, capsules, mixtures, and powders. A total of 86 medical institutions have filed preparations, most of which are located in Xi'an, Xianyang, and Weinan, with these three cities accounting for the largest number of filings. *Conclusion:* The policy on the TCM preparation filing system has been widely recognized and deeply implemented in Shaanxi Province. Third-level medical institutions are the primary contributors to preparation filings. Regional differences exist in the development of preparation filing, indicating significant potential for further growth in the province's filing efforts.

Keywords: Shaanxi Province; Medical institutions; Traditional Chinese medicine preparations; Current filing situation

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1. Introduction

Pharmaceutical preparations in medical institutions refer to self-used, fixed-prescription formulations that are not commercially available and must be prepared by medical institutions based on their clinical needs, with the approval of relevant national administrative departments ^[1]. These preparations are divided into two categories: chemical preparations and traditional Chinese medicine preparations ^[2]. Among these, traditional Chinese medicine preparations in medical institutions represent a unique form of traditional Chinese medicine preparation in China. They are produced using safe and effective fixed prescriptions based on traditional Chinese medicine theory and extensive clinical application experience ^[3].

The development of traditional Chinese medicine is an indispensable part of China's medical and healthcare system. To better inherit and promote traditional Chinese medicine, ensure its sustainable development, and safeguard the physical and mental health of the Chinese people, the Standing Committee of the National People's Congress promulgated the "Law of the People's Republic of China on Traditional Chinese Medicine" on December 25, 2016 ^[4]. Article 31 of this law states: "The state encourages medical institutions to prepare and use traditional Chinese medicine preparations based on their clinical needs, supports the preparation of traditional Chinese medicine preparations using traditional techniques, and promotes the development of new traditional Chinese medicine drugs based on these preparations." Article 32 specifies: "Traditional Chinese medicine preparations made by medical institutions must obtain preparation approval numbers as prescribed by law. However, preparations using only traditional techniques may be produced after filing with the drug supervision and administration department of the provincial, autonomous region, or municipal government where the medical institution is located, without the need to obtain an approval number."

On February 12, 2018, the former General Administration of the Food and Drug Administration issued the "Announcement on the Implementation of Filing Management for the Preparation of Traditional Chinese Medicine Preparations by Medical Institutions Using Traditional Techniques" (No. 19, 2018) ^[5] (hereinafter referred to as the "Filing Announcement"). This announcement clearly defined the scope of "traditional techniques for preparing traditional Chinese medicine preparations," outlined the materials required for filing, and introduced "three exemptions and one strengthening" (exemption from clinical trials, exemption from efficacy and toxicity studies, and strengthening source and process control). It also distinguished traditional Chinese medicine preparation filings from registration materials, relaxed the qualifications for medical institutions to file traditional Chinese medicine preparations, and permitted commissioned production ^[6].

On March 19, 2019, the Shaanxi Provincial Drug Administration and the Shaanxi Provincial Administration of Traditional Chinese Medicine jointly issued the "Implementation Rules for the Filing Management of the Preparation of Traditional Chinese Medicine Preparations by Applying Traditional Techniques in Shaanxi Provincial Medical Institutions (Trial)" ^[7]. This document outlined the procedures and requirements for filing traditional Chinese medicine preparations in Shaanxi medical institutions, along with the scope of their use, marking the beginning of filing practices for traditional Chinese medicine preparations in Shaanxi Province.

By analyzing filing data for traditional Chinese medicine preparations across different provinces, Sichuan Province has completed 3,168 filings, Jilin Province 1,008, Henan Province 726, Guangdong Province 402, Beijing 239, Jiangsu Province 198, Tianjin 182, and Shandong Province 138. As a major province for traditional Chinese medicine, it is worth investigating the filing situation in Shaanxi Province. This article examines the number of filings, varieties, commissioned production versus self-production, dosage forms, and other factors for medical institutions in Shaanxi Province. The goal is to provide references for improving the filing process

for traditional Chinese medicine preparations in Shaanxi Province and potentially across the country.

2. Methodology

- (1) Access the website of the Shaanxi Provincial Drug Administration (<https://mpa.shaanxi.gov.cn/>), navigate to the “Regulatory Information” section, and enter the “Query of Pharmaceutical Preparations Information in Medical Institutions” page. Select “Filing of Traditional Chinese Medicine Preparations” as the licensing matter and “Establishment” as the licensing type.
- (2) Access the website of the National Health Commission of the People’s Republic of China (<http://www.nhc.gov.cn/>), navigate to the “Services” → “List Query” → “Hospital Practice Registration” module in sequence.
- (3) Input the relevant information into an Excel spreadsheet to create a database titled “Filing Varieties of Traditional Chinese Medicine Preparations Prepared by Applying Traditional Techniques in Shaanxi Provincial Medical Institutions.”

3. Results

3.1. Cumulative number of filed traditional Chinese medicine preparations and filing medical institutions

As of June 27, 2024, a total of 479 traditional Chinese medicine preparations have been filed on the Shaanxi Provincial Drug Administration website. Among these, 5 were filed in 2019, 73 in 2020, 138 in 2021, 95 in 2022, 59 in 2023, and 109 between January and June 2024. The earliest filed preparation was Chuanzhi Xinnaotong Capsules, approved on July 15, 2019, and produced by the Shaanxi College of Traditional Chinese Medicine Pharmaceutical Factory, commissioned by Zhouzhi United Hospital. This marked the beginning of traditional Chinese medicine preparation filings in Shaanxi Province. These figures indicate that, following the implementation of the “Implementation Rules,” medical institutions in Shaanxi Province actively prepared and interpreted the relevant documents to proceed with filings.

A total of 131 medical institutions have applied for the filing of traditional Chinese medicine preparations. By year, there were 3 institutions in 2019, 16 in 2020, 33 in 2021, 29 in 2022, 19 in 2023, and 31 from January to June 2024. See **Table 1**.

Table 1. Number of filed traditional Chinese medicine preparations and cumulative number of filing medical institutions in Shaanxi Province from March 19, 2019, to June 27, 2024

City	Number of filed preparations (pcs)							Cumulative number of filing medical institutions (pcs)						
	2019	2020	2021	2022	2023	2024	Total	2019	2020	2021	2022	2023	2024	Total
Ankang	0	0	7	0	0	0	7	0	0	1	0	0	0	1
Baoji	0	17	0	5	0	0	22	0	2	0	2	0	0	4
Hanzhong	0	3	2	15	2	1	23	0	2	1	4	2	1	10
Shangluo	0	0	3	3	0	2	8	0	0	1	1	0	1	3
Tongchuan	0	0	5	1	5	0	11	0	0	2	1	1	0	4

Table 1 (Continued)

City	Number of filed preparations (pcs)							Cumulative number of filing medical institutions (pcs)						
	2019	2020	2021	2022	2023	2024	Total	2019	2020	2021	2022	2023	2024	Total
Weinan	0	9	12	10	6	13	50	0	2	2	3	2	5	14
Xi'an	5	31	60	37	29	74	236	3	6	17	13	9	18	66
Xianyang	0	7	23	16	12	16	74	0	3	7	4	4	5	23
Yanan	0	0	25	8	0	0	33	0	0	1	1	0	0	2
Yulin	0	6	1	0	5	3	15	0	1	1	0	1	1	4
Total	5	73	138	95	59	109	479	3	16	33	29	19	31	131

3.2. Production status of filed traditional Chinese medicine preparations

Of the filed traditional Chinese medicine preparations, 262 varieties (54.70%) were produced through commissioned production, while 217 varieties (45.30%) were self-produced. See **Figure 1**.

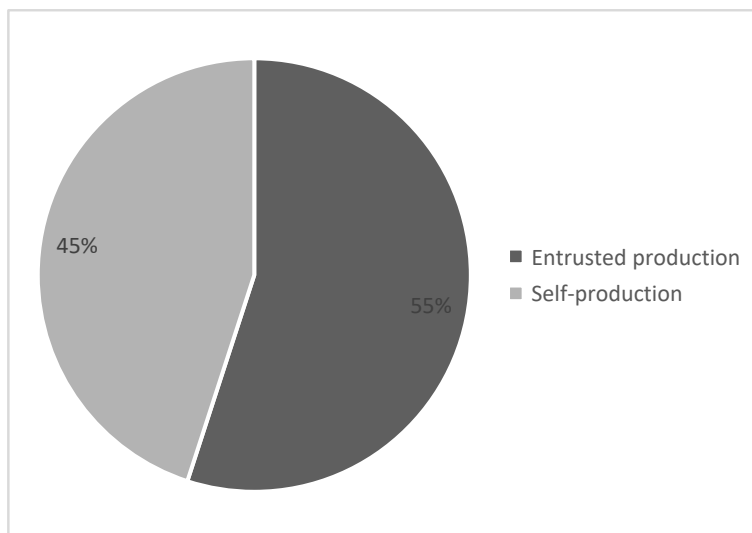


Figure 1. Entrusted production and self-production of traditional Chinese medicine preparations in Shaanxi Province

3.3. Dosage forms of filed traditional Chinese medicine preparations

The filed traditional Chinese medicine preparations encompass 17 dosage forms, including granules, pills, capsules, mixtures, and powders, covering most forms of traditional Chinese medicine preparations. Granules accounted for 29.44%, pills 25.05%, capsules 15.87%, and mixtures 6.05%. See **Figure 2**.

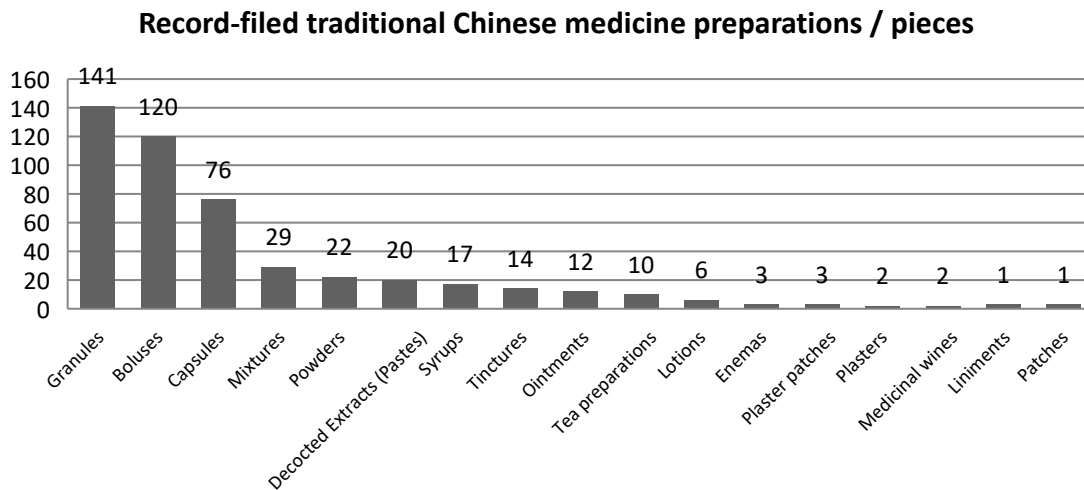


Figure 2. Distribution of dosage forms of filed traditional Chinese medicine preparations in Shaanxi Province (March 19, 2019–June 27, 2024)

3.4. Status of filing medical institutions

Geographically, significant disparities exist in the development of traditional Chinese medicine among cities and prefectures in Shaanxi Province. These differences are reflected in the number of filings and the number of filing institutions. From March 19, 2019, to June 27, 2024, of the 479 filed preparations, 236 (49.27%) were in Xi'an, 74 (15.45%) in Xianyang, and 50 (10.44%) in Weinan. Together, these cities accounted for 75.16% of all filings. See **Table 1**.

A total of 86 medical institutions in Shaanxi Province have filed traditional Chinese medicine preparations. The top three cities were Xi'an with 40 institutions (46.51%), Xianyang with 16 institutions (18.60%), and Weinan with 10 institutions (11.63%). See **Figure 3**. These figures highlight that Xi'an, Xianyang, and Weinan have made significant progress in filing traditional Chinese medicine preparations.

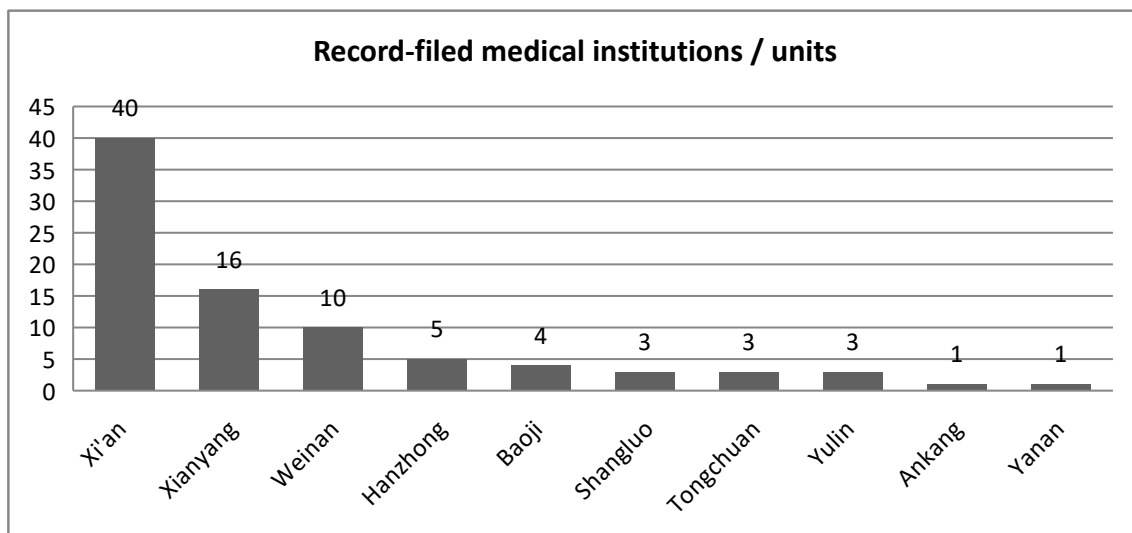


Figure 3. Geographic distribution of medical institutions filing traditional Chinese medicine preparations in Shaanxi Province

Among the 86 filing institutions, there were 24 tertiary medical institutions, primarily in Xi'an and Xianyang. Additionally, 23 were secondary medical institutions, 7 were primary medical institutions, and 32 were ungraded institutions. Tertiary institutions accounted for 218 filings (45.51%), secondary institutions 102 (21.29%), primary institutions 15 (3.13%), and ungraded institutions 144 (30.06%). See **Figures 4 and 5**.

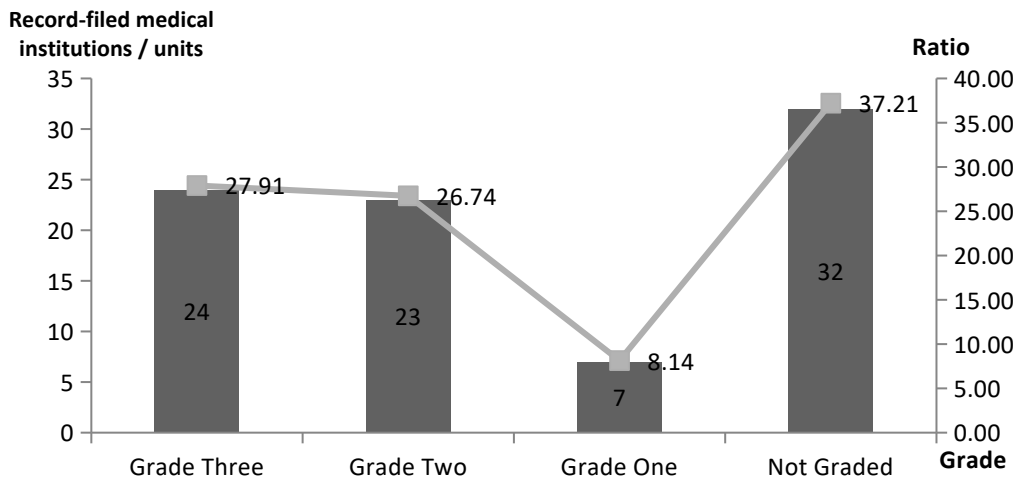


Figure 4. Distribution of filing institutions by grade in Shaanxi Province (March 19, 2019–June 27, 2024)

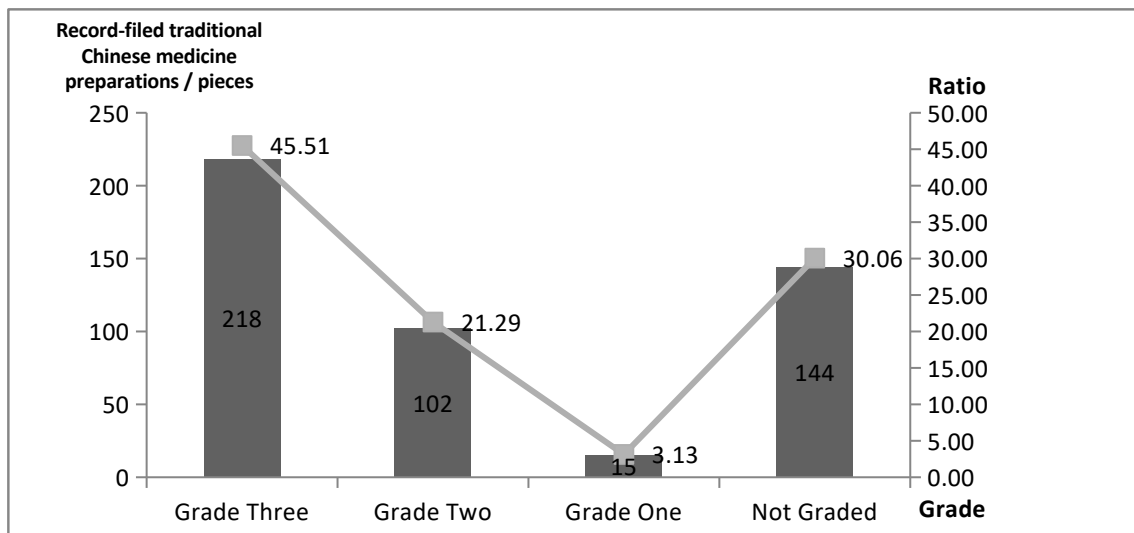


Figure 5. Number of traditional Chinese medicine preparations filed by medical institution levels in Shaanxi Province

4. Discussion

Traditional Chinese medicine preparations in medical institutions are an integral part of traditional Chinese medicine. For a long time, they have played a vital role in safeguarding the physical and mental health of people in China and globally. When used rationally under the guidance of traditional Chinese medicine's foundational theories, these preparations contribute significantly to various aspects, such as establishing distinctive clinical specialties, preserving and inheriting traditional prescriptions, and transforming scientific and technological

advancements in traditional Chinese medicine.

In clinical practice, these preparations meet the needs of traditional Chinese medicine and fill gaps in the availability of marketed Chinese patent medicines. Their advantages have been particularly evident in the prevention and control of major public health events, such as novel coronavirus infections. Furthermore, traditional Chinese medicine preparations provide abundant resources and clinical experience, serving as a foundation for the research and development of new traditional Chinese medicine drugs. Based on the statistical analysis of the filing status of traditional Chinese medicine preparations in Shaanxi Province, the following conclusions and considerations are drawn:

4.1. The policy of filing traditional Chinese medicine hospital preparations has gained widespread recognition in Shaanxi Province

Since the implementation of the policy on filing traditional Chinese medicine preparations in medical institutions in Shaanxi Province on March 19, 2019, a total of 479 preparations have been filed, averaging approximately 80 filings annually. These filings involve 86 medical institutions across the province, including tertiary, secondary, primary, and ungraded institutions, as well as public and private hospitals and clinics.

Among these, ungraded medical institutions represent 37.21% of the total filing institutions, constituting the largest proportion. They are followed by tertiary (27.91%), secondary (26.74%), and primary medical institutions (8.14%). This distribution demonstrates the widespread acceptance and implementation of the traditional Chinese medicine preparation filing system in Shaanxi Province.

4.2. Tertiary medical institutions are the main contributors to traditional Chinese medicine preparation filings

Tertiary medical institutions account for 27.91% of the total filing institutions, yet the preparations filed by these institutions represent 45.51% of the total filings. This indicates that tertiary institutions play a leading role in the filing of traditional Chinese medicine preparations.

4.3. Most filings of traditional Chinese medicine preparations are through commissioned production

In Shaanxi Province, 54.70% of filed traditional Chinese medicine preparations are produced through commissioned production, representing a majority. Many of the filing institutions are relatively small, such as outpatient departments and clinics, which lack the facilities and resources required for preparation and quality inspection.

Due to these limitations, these institutions rely on commissioning qualified medical institutions or pharmaceutical manufacturers to produce and prepare traditional Chinese medicine preparations. Previous research has highlighted that up to 80% of medical institutions in Shaanxi Province face challenges related to suboptimal production environments and inadequate inspection facilities for pharmaceutical preparations. Additionally, personnel dedicated to preparation account for only 10% of pharmacy staff, and there is a notable shortage of qualified professionals. A lack of modern quality management practices further exacerbates the risk of quality issues in preparations ^[8].

The “Law of the People’s Republic of China on Traditional Chinese Medicine and the Filing Announcement” stipulates that medical institutions must obtain a “Pharmaceutical Preparation License for Medical Institutions” to prepare traditional Chinese medicine preparations. Institutions without this license or lacking specific preparation

dosage forms authorized by the license may commission qualified units to handle production ^[4,5].

The commissioned production model effectively supports the preparation and supply of traditional Chinese medicine preparations in medical institutions. Compared to the traditional “small workshop” production model, commissioned production ensures higher standards of quality control and safety evaluation ^[9].

4.4. Regional differences in the development level of traditional Chinese medicine preparation filings in Shaanxi Province

The proportion of traditional Chinese medicine preparations filed in Xi’an, Xianyang, and Weinan cities accounts for 75.16% of the total filings in Shaanxi Province, with 76.74% of filing institutions located in these cities. This indicates significant regional disparities in the development level of traditional Chinese medicine preparation filings across the province. Uneven geographical distribution and varying quality levels of pharmaceutical preparations in medical institutions can be mitigated by establishing regional medical preparation centers, which would enhance the effective utilization of existing resources ^[9]. Current regional medical preparation centers in Shaanxi Province include Xi’an Chinese Medicine Encephalopathy Hospital ^[10], Shaanxi Panlong Pharmaceutical Co., Ltd., and Yangling Biomedical Science and Technology Co., Ltd. ^[11].

4.5. Significant potential for increased filings of traditional Chinese medicine preparations in Shaanxi Province

According to the 2022 Statistical Bulletin of the Development of Health Services in Shaanxi Province ^[12], the province has 34,779 medical and health institutions, including 1,280 hospitals, 32,978 primary-level institutions, and 407 public health institutions. Leveraging the entire province’s medical resources could yield numerous proven, safe, and effective empirical prescriptions, ancient classical formulas, and modified prescriptions with extensive clinical use.

From 2019 to 2024, only 86 medical institutions applied for traditional Chinese medicine preparation filings, representing just 0.25% of all institutions. In 2019, the number of applications was only five, likely due to the system’s early-stage implementation. From 2020 onward, the number of filings exceeded 50 annually. Among the institutions submitting applications, the top three—Shaanxi Provincial Hospital of Traditional Chinese Medicine (62 filings), Yan’an Hospital of Traditional Chinese Medicine (33 filings), and the Second Affiliated Hospital of Shaanxi University of Traditional Chinese Medicine (26 filings)—account for 25.3% of the total filings. These figures highlight the untapped potential for further filings in the province.

4.6. Active policy support for traditional Chinese medicine preparation filings in Shaanxi Province

The Filing Announcement issued by the former General Administration of the Food and Drug Administration states:

“Traditional Chinese medicine preparations prepared by medical institutions using traditional techniques include:

- (1) Solid (pills, powders, pellets, lozenges, etc.), semi-solid (ointments, plasters, etc.), and liquid (decoctions, etc.) traditional dosage forms made from Chinese herbal pieces by pulverization or only by water or oil extraction;
- (2) Granules made from Chinese herbal pieces by water extraction and capsules made from pulverized

Chinese herbal pieces;

(3) Medicated wines and tinctures made from Chinese herbal pieces by traditional extraction methods”^[4].

Subsequently, with the introduction of the “Implementation Rules (Trial),” the scope of these definitions was retained. As the filing of traditional Chinese medicine preparations progressed in Shaanxi Province, and in response to local circumstances, the “Implementation Rules (Trial)” were abolished. The “Notice of Shaanxi Provincial Drug Administration on Soliciting Public Opinions on the ‘Implementation Rules for the Filing Management of Traditional Chinese Medicine Preparations Prepared by Applying Traditional Techniques in Shaanxi Provincial Medical Institutions (Draft for Soliciting Opinions on Revision)’” (Shaanxi Drug Administration Letter [2024] No. 78)^[13] was then issued.

Article 3 of the Draft for Soliciting Opinions on Revision introduced a revised definition of traditional Chinese medicine preparations. It retained the definitions outlined in (1) and (3) of the original Filing Announcement while updating (2) to include:

“Granules and capsules made from some or all of the Chinese herbal pieces by water extraction or direct pulverization.”

This enriched the connotation of traditional Chinese medicine preparations, fostering their inheritance, innovation, and development. Examples include Qutan Huoxue Tongbi Capsules, Weifukang Capsules, and Qibi Xingshen Granules.

Additionally, Shaanxi Province has implemented relevant policies regarding medical insurance payment and the dispensing of pharmaceutical preparations in medical institutions. Examples include:

- (1) The notice of Shaanxi Provincial Medical Insurance Bureau on including some therapeutic pharmaceutical preparations in medical institutions in the scope of medical insurance payment^[14].
- (2) The announcement on implementing emergency review and approval and emergency dispensing and use of pharmaceutical preparations in medical institutions for epidemic prevention and control.
- (3) The notice of the Office of Shaanxi Provincial Drug Administration on standardizing the management of dispensing and use of traditional Chinese medicine preparations in medical institutions.
- (4) The notice on further optimizing and guaranteeing the supply as well as dispensing and use of traditional Chinese medicine preparations for epidemic prevention.

These measures have facilitated the inclusion of certain therapeutic traditional Chinese medicine preparations in the Shaanxi Provincial Medical Insurance Fund’s payment scope. They have also actively promoted the dispensing and use of these preparations in medical institutions across the province, including within medical consortia.

Other provinces have introduced similar policies. For instance, Jiangxi Province allows varieties with a “Registration Approval Document for Pharmaceutical Preparations in Medical Institutions,” a “Re-registration Approval Document for Pharmaceutical Preparations in Medical Institutions,” or a “Filing Receipt for Traditional Chinese Medicine Preparations Prepared by Applying Traditional Techniques in Medical Institutions” from the Provincial Drug Administration to be dispensed in medical institutions with collaborative relationships within the province for two years. These varieties must have been used clinically for over two years with proven efficacy, safety, and stability and no serious adverse reactions^[15].

Jilin Province, similarly, has announced the first batch of 195 traditional Chinese medicine dispensing varieties. It requires that the listed preparations must have been used clinically for over three years, demonstrating efficacy, safety, and stability without serious adverse reactions. These preparations can be used

across public medical institutions within the province with collaborative relationships^[16].

These policies have reduced patients' economic burdens, encouraged medical institutions to file traditional Chinese medicine preparations, and supported the long-term development of such preparations in medical institutions^[17].

5. Conclusion

In conclusion, the work of filing traditional Chinese medicine preparations in medical institutions in Shaanxi Province has achieved significant results over six years. However, it is equally important to recognize the common challenges associated with the filing process in Shaanxi Province and across the country. These challenges include deficiencies in personnel, equipment, production environments, funding, and quality management within the traditional Chinese medicine preparation rooms of medical institutions. Additionally, there is a lack of intellectual property protection for traditional Chinese medicine preparations and insufficient awareness of new drug transformations^[18-20].

It is recommended that relevant governmental functional departments adopt a long-term perspective and increase investment to foster a favorable environment for the filing and management of traditional Chinese medicine preparations in medical institutions. Such efforts would contribute to the sustainable and high-quality development of outstanding traditional Chinese medicine preparations not only in Shaanxi Province but also nationwide.

Disclosure statement

The authors declare no conflict of interest.

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