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Relevant policies research on traditional Chinese medicine equipment

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ABSTRACT

Traditional Chinese medicine (TCM) equipment is the industry representative possessing independent intellectual property rights and unique Chinese characteristics. By integrating TCM and information technology, TCM equipment is experiencing an unprecedented period of opportunity. Here, based on the practical significance, we reviewed the recent series of policies to promote the TCM equipment development. In accordance, we analyzed the current main problems and causes, and finally put forward some policy demand and suggestions to boost TCM equipment industry.

1 Introduction

Traditional Chinese medicine (TCM) equipment is the general term for apparatus, devices, consumables, and information systems, that have applied modern science and technology and have been guided by TCM theory to serve medicine, health care, education, scientific research, industry, culture, and other fields. As the industry representative, TCM equipment possesses independent intellectual property rights and unique Chinese characteristics. By integrating TCM and information technology, it is experiencing an unprecedented period of opportunity. Developing TCM equipment can give full play to "the leading role in diseases prevention, the synergistic role in major diseases treatment, and the core role in diseases rehabilitation" of TCM [1, 2]. Further more, taking advantages of its "unique health resources, economic resources with great potential, original sci-tech resources, excellent cultural resources, and important ecological resources", we can develop TCM industry, and strengthen the comprehensive national power. To sum up, it is necessary to accelerate the research and development of TCM equipment, so as to promote the industrialization, modernization, and globalization of TCM.

2 Practical significance on promoting key TCM technical equipment

TCM is an important carrier for developing manufacturing equipment industry with "China's discourse power" [3]. Since the 18th National Congress of Communist Party of China, our Party and the country have attached great importance to the development of TCM industry and equipment manufacturing industry, and put

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forward the general requirements of “paying equal attention to both Chinese and western medicine, inheriting and developing TCM” and “moving faster to build China into a manufacturer of quality and develop advanced manufacturing”. TCM is a great treasure house of the Chinese nation, and equipment manufacturing industry, known as “a pillar of the great power”, is an important part of the real economy, so TCM equipment industry demonstrates well the “always taking the initiative”. Meanwhile, by continuously promoting TCM equipment industry, we can deeply explore the essence from the TCM treasure house, promote the industry-university-research integration, and develop the TCM industrialization and modernization, which can effectively inherit, develop, and take advantage of TCM, the precious wealth left by our ancestors. The New Huangpu Institute of TCM Joint Innovation is the first multi-field and multi-disciplinary platform for TCM sci-tech innovation in China. It has achieved major breakthroughs in key components and technologies of “pulse diagnosis” and “tongue diagnosis”. Intelligent Acupuncture Diagnosis and Treatment Standard Unit, its first set of TCM equipment, has realized automatic adjustment of acupuncture diagnosis and treatment position, one-button reset, and real-time display of digital diagnosis information and curative effect. It has greatly upgraded the traditional acupuncture equipment and the overall level of disciplines, which provides ideas and reference for the research and development of TCM equipment in the new era.

TCM equipment manufacturing industry greatly helps implement the strategy of “healthy China”. The construction of “healthy China” is not only directly related to people’s livelihood and well-being, but also related to the overall and long-term development of the country, social stability, and sustainable economic development, which is of great strategic significance. TCM is the most distinctive health resource and medical technology in China’s health service system. At present, the TCM health service system has been established with richer connotation and wider coverage. However, the leading role of TCM in preventing diseases, the synergistic role in treating major diseases, and the core role in the process of disease rehabilitation have not yet been brought into full play. The problems like the poor quality of Chinese medicines, shortage of medical equipment varieties, and unstable product quality standards are still the fundamental obstacles that restrict the improvement of TCM health service. Therefore, it is urgent to promote TCM equipment industry and enrich healthcare services to meet multi-level needs of people's health.

Developing TCM equipment manufacturing industry greatly helps to improve economic performance. TCM industry has become a new economic growth point in China. In 2021, the business income of the national pharmaceutical industry was 3 277.2 billion yuan, of which the Chinese medicines industry grew steadily, with the annual business income reaching 691.9 billion yuan, accounting for 21.11% of the national pharmaceutical industry revenue [4], and the Chinese medicines health industry exceeded 10 trillion yuan, with great market development potential. For instance, as is mentioned in Three-Year Action Plan for the Development of Traditional Chinese Medicine Great Health Industry in Lishui (2023 - 2025), by 2025, the standardized planting area of Chinese medicines in Lishui will reach more than 300 000 mu (about 200 square kilometers), the business income of Chinese medicines health industry will exceed 10 billion yuan, and 20 enterprises with more than 100 million yuan will be established. However, the current industrial chain of TCM is not yet perfect [5] with the following disadvantages: low international competitiveness, extremely uneven development among regions, few well-known brands of TCM, small scale of enterprises, poor infrastructure and equipment, and weak research and development capability of key technologies. Consequently, it is necessary to cultivate a number of well-known brands and enterprises of TCM with international competitiveness by developing key TCM technical equipment, and enhancing its technology research and development capability, so as to tackle the core problem of low economic benefit and international market share of TCM industry, which is of great significance to promote the economic development of TCM industry as well as that of the whole nation.

Rapid development of TCM equipment manufacturing industry is the key to enhance the international competition of TCM industry. The TCM development has entered the new stage of global competition. So far, TCM has spread to 196 countries and regions [6], and 86 cooperation agreements on TCM have been signed with foreign governments and international organizations. Some countries and regions have even included TCM in medical insurance. Furthermore, TCM has been included in 16 free trade agreements, and 17 national export bases of TCM services have been built. The total import and export trade of TCM products has reached 28.19 billion dollars [6]. However, there also exist some problems. For instance, the economic and product structures of TCM service trade are not optimized, the export areas are relatively limited, the number and export share of high value-added TCM products are growing slowly, and TCM products are facing increasing international market risks. More than that, some developed countries have gradually realized the value of TCM and accelerated the legislation on traditional medicine. Moreover, many countries, curbing the internationalization of TCM, have accelerated the research and development of TCM by virtue of their own capital and technological advantages, and have applied for patents and seized the market, which has posed a severe challenge to China [7, 8]. With the release of

documents such as the 14th Five-Year Plan for Traditional Chinese Medicine Development and the Strategic Outline for the Development of Chinese Medicine (2016 - 2030), TCM has ushered in an unprecedented development opportunity and its development has gradually risen to a national strategy; under the framework of the inter-ministerial joint meeting of the State Council for TCM, the joint forces of the coordinated development of TCM have been greatly strengthened. A series of national-level plans, such as the development plan of TCM health service, and the protection and development plan of Chinese medicines, have been intensively introduced, which shows the effects of policy superposition. Hence, we must "follow the trend, seize the momentum, and move forward"; we need to focus on the core element of key TCM technical equipment, and highlight the unique industrial advantages of China's independent intellectual property rights, so as to rapidly promote TCM industry, exert a vital role in the TCM internationalization, and provide Chinese wisdom and solutions for building a human health community.

3 Relevant policies on TCM technical equipment

3.1 Sci-tech research and development

At present, China has established a relatively complete policy system covering sci-tech research and development, transformation of achievements, conditions, and standards for the output of sci-tech research achievements, funds management of sci-tech research activities, and industrialization of high and new technology and TCM. Equipment research and development, represented by equipment manufacturing industry of Chinese medicines, mainly relies on the implementation of major national projects. Since the reform and opening up, the Party and the country have issued a series of policy documents to adjust the industrial structure and encourage industrial upgrading, which has contributed to the upgrading of technical equipment. Meanwhile, several policies, laws, regulations, and implementation standards, which are related to sci-tech research and development, marketing and personnel training, have been issued to encourage equipment research and development, and transformation of sci-tech achievements in sci-tech research institutions and universities (Table 1).

The Law of the People's Republic of China (PRC) on Traditional Chinese Medicine regulates and guides the development of diagnosis and treatment, and pharmaceutical equipment of TCM in the form of legal norms. And the relevant laws in sci-tech research and development activities mainly include Law of the PRC on Scientific and Technological Progress, Law of the PRC on Promoting the Transformation of Scientific and Technological Achievements, Law of the PRC on Popularization of Science and Technology, Standardization Law of the PRC, etc. Furthermore, Patent Law of the PRC regulates the achievements of sci-tech activities, and Contract Law of the PRC regulates the rights and obligations of both parties in the process of sci-tech activities ("Technology Contract" chapter), etc.

Since the establishment of "the 12th Five-Year Plan", China has gradually strengthened the national deployment of sci-tech research and development in medical device field, and listed medical device as the strategic focus of China's sci-tech development. The release of Application Demonstration Project of Innovative Medical Equipment Products (selecting 1 000 medical institutions in 100 counties from 10 provinces or cities in China to pilot the application of 10 000 sets of innovative medical devices) and the Special Plan for Scientific and Technological Innovation of Medical Devices in the 13th Five-Year Plan (Guo Ke Ban She [2017] No. 44) has vigorously promoted the industry-university-research-medicine collaborative innovation, and the integration of medical device, sci-tech development, and finance. The Guidelines for Pharmaceutical Industry Development Planning (Gong Xin Ting Gui [2015] No. 24) proposes to take biomedicine and high-performance medical devices as key development areas, and accelerate cultivating strategic emerging industries such as biomedicine as pillar industries of the economy. The Outline of the Strategic Plan on the Development of TCM (2016 - 2030) (Guo Fa [2016] No. 15), the Notice on Several Policies and Measures to Accelerate the Development of TCM Characteristics (Guo Ban Fa [2021] No. 3), and other documents propose to encourage the comprehensive utilization of modern sci-tech means to develop a batch of diagnosis and treatment apparatus and instruments, and Chinese medicines manufacturing equipment based on TCM theory, so as to strengthen the construction of national sci-tech innovation bases serving the development of TCM technical equipment, and the demonstration of achievements transformation and application. Guiding Opinions on Promoting the Healthy Development of Pharmaceutical Industry (Guo Ban Fa [2016] No. 11) points out that it is necessary to accelerate the transformation and upgrading of medical devices, and actively explore the research and development of medical devices based on TCM theory, which clarifies the TCM characteristics and advantages from the policy guidance, and provides norms and basis for promoting the research and development of TCM equipment. The 13th Five-Year Special Program Plan for Scientific and Technological Innovation of Traditional Chinese Medicine (Guo Ke Fa She [2017] No. 146) jointly issued by the Ministry of Science and Technology and State Administration of TCM, clearly determines the research directions of vigorously promoting the research and development on the instruments, big data, the construction of internet plus

Table 1 Relevant policies on TCM technical equipment

No.	Level	Release time	Publishing unit	File name	Related content
1	Provincial and ministerial level	July 20, 2010	Ministry of Science and Technology, Ministry of Health, Demonstration Province	Innovative demonstration project of medical device product application	Aiming at "innovation and development, benefiting people's livelihood", 1 000 medical institutions in 100 counties from 10 provinces (cities) in China were selected to pilot the application of 10 000 sets of innovative medical devices by the end of the 12th Five-Year Plan
2	National level	February 22, 2016	State Council	Outline of Strategic Planning for the Development of TCM (2016-2030)	Effectively improving the ability of TCM medical service and promoting "Internet plus" TCM medical treatment; vigorously developing TCM health care services; solidly promoting the inheritance of TCM and the innovation of TCM; comprehensively improving the development level of TCM industry; vigorously promoting TCM culture; actively promoting the overseas development of TCM
3	Provincial and ministerial level	March 11, 2016	General Office of the State Council	Guiding Opinions on Promoting the Healthy Development of Pharmaceutical Industry	Promoting innovation ability and strengthening the construction of innovation ability of high-end medical devices; accelerating the transformation and upgrading of medical devices and actively exploring the research and development of medical devices based on TCM theory
4	National level	October 25, 2016	Central Committee of the Communist Party of China and State Council	Outline of Healthy China 2030 Plan	Developing internet-based health services and encouraging health services such as physical examination and consultation; promoting personalized health management services and cultivating a number of distinctive health management service industries; exploring the development of wearable devices, smart health electronic products, and health care mobile application services; improving the collaborative innovation system of government, industry, university, and research, and promoting pharmaceutical innovation, transformation, and upgrading; strengthening the innovative capabilities of high-end medical devices and others; vigorously developing high-quality Chinese medicines, high-performance medical devices, new auxiliary materials, and pharmaceutical equipment; promoting the industrialization of major drugs; accelerating the transformation and upgrading of medical devices, and improving the international competitiveness of medical diagnosis and treatment equipment and medical materials possessing independent intellectual property rights; accelerating the rehabilitation aids industry, and enhancing the ability of independent innovation; improving the quality standard system, improving quality control technology, and implementing green and intelligent transformation and upgrading
5	Provincial and ministerial level	October 26, 2016	Ministry of Industry and Information Technology	Guide to Development Planning of Pharmaceutical Industry	Grasping the direction of industrial technological progress, aiming at the major market demand, to vigorously develop new varieties of biological drugs and chemical drugs, high-quality Chinese medicines, high-performance medical devices, new auxiliary materials, and pharmaceutical equipment; accelerating the development and application of new technologies in various fields, and promoting the upgrading of products, technologies, and quality

Table 1 Continued

No.	Level	Release time	Publishing unit	File name	Related content
6	Provincial and ministerial level	May 14, 2017	General Office of Ministry of Science and Technology	Special Plan for Scientific and Technological Innovation of Medical Devices in the 13th Five-Year Plan	Accelerating the overall transformation of the medical device industry to innovation-driven development, and improving the innovation chain of medical device research and development; breaking through a number of cutting-edge and common key technologies and core components, developing a batch of high-end and mainstream medical devices with high import dependence and urgent clinical needs, as well as intelligent, mobile and networked products suitable for grassroots, and proposing a set of application solutions based on domestic innovative medical device products; cultivating a number of leading enterprises with an annual output value exceeding 10 billion yuan and a quantity of innovative enterprises with strong innovation vitality; greatly improving industrial competitiveness, expanding the market share of domestic innovative medical device products to lead the reform of medical model and promote the leap-forward development of China's medical device industry
7	Provincial and ministerial level	June 12, 2017	Ministry of Science and Technology, National Administration of TCM	Special Plan for Scientific and Technological Innovation of TCM in the 13th Five-Year Plan	Carrying out research on TCM prevention, rehabilitation, instruments, TCM big data development and TCM "internet plus" service technology; building a TCM prevention technology system; exploring TCM risk identification and risk early warning model; developing TCM rehabilitation technology methods and programs; accelerating the research and development of TCM instruments and equipment, and promoting the development of "internet plus" TCM medical care and TCM big data to support the development of TCM health service industry
8	Provincial and ministerial level	January 15, 2019	National Administration of TCM, Ministry of Science and Technology, Ministry of Industry and Information Technology, National Health Commission	Guiding Opinions on Strengthening Scientific and Technological Innovation of TCM Medical Devices	With breakthroughs in the research and development of common key technologies and core components of Chinese medical devices, developing and transforming a number of refined, integrated, digital, and intelligent products that meet both clinical and market needs; strengthening the integration with modern technologies including microelectronics technology, information technology, materials technology, new generation manufacturing technology, sensing technology and biotechnology to significantly improve the performance, quality, and sci-tech content of Chinese medical devices; further strengthening the construction of scientific and technological innovation platform system for TCM medical devices; basically improving the standard system for TCM medical devices; cultivating a group of interdisciplinary talents and innovation teams who understand both TCM and modern science and technology; significantly enhance the innovative ability of TCM equipment manufacturers, to improve the industrial competitiveness and industrialization level

Table 1 Continued

No.	Level	Release time	Publishing unit	File name	Related content
9	National level	October 20, 2019	The Central Committee and the State Council	Opinions of the Central Committee of China and the State Council on Promoting the Inheritance, Innovation and Development of TCM	Establishing national TCM science and technology research and development projects, key technical equipment major projects, and international scientific plans; developing an intelligent auxiliary diagnosis and treatment system for TCM to promote online and offline integrated services and telemedicine services; promoting the research and development of a number of TCM rehabilitation instruments; developing a batch of advanced TCM instruments and pharmaceutical equipment
10	Provincial and ministerial level	January 22, 2021	General Office of the State Council	Notice on Several Policies and Measures to Accelerate the Development of TCM Characteristics	Consolidating the talent base of TCM; boosting the vitality of TCM industry development and enhancing the development momentum of TCM; improving the system of integrated Chinese and western medicine; implementing major projects for TCM development; promoting TCM development efficiency; creating a great environment for TCM development
11	Provincial and ministerial level	December 21, 2021	Ministry of Industry and Information Technology, National Health Commission, National Development and Reform Commission, Ministry of Science and Technology, Ministry of Finance, State-owned Assets Supervision and Administration Commission of the State Council, State Administration of Market Supervision, National Healthcare Security Administration, National Administration of TCM and National Medical Products Administration	The 14th Five-Year Plan for the Development of Medical Equipment Industry	Exerting the unique advantages of TCM in disease prevention, treatment, health care, and rehabilitation, deeply excavating TCM resources based on TCM theory; developing TCM characteristic equipment integrating new technologies such as big data, artificial intelligence, and wearability; prioritizing TCM equipment involving pulse diagnosis, tongue diagnosis, acupuncture, moxibustion, and rehabilitation; promoting the standardization, scalization, digitization, and long-distance of TCM clinical diagnosis and health services
12	Provincial and ministerial level	February 28, 2023	General Office of the State Council	Notice on the Implementation Plan of Major Projects for Revitalization and Development of TCM	Carrying out research on diagnosis and treatment equipment with TCM characteristics, and developing digital auxiliary diagnosis equipment with TCM characteristics, intelligent equipment with TCM characteristics, and modern equipment TCM for TCM disease prevention; carrying out research on engineering technology and equipment for intelligent identification and control of TCM quality, and promoting technical equipment for production and quality assurance of TCM, intelligent processing control, and dispensing engineering of TCM decoction pieces, digitalization and intelligent control of core processes of Chinese patent medicine manufacturing; carrying out the construction as well as application and transformation of measurable technical specification systems on common standards of TCM technical equipment, developing TCM modern “copper people”, and carrying out application demonstrations of TCM technical equipment in the prevention and control of chronic diseases

service technology system of TCM, green intelligent manufacturing of Chinese medicines and new technology of Chinese medicines preparations, processing of Chinese medicines, and quality assurance of formula granules. In 2019, the Guiding Opinions on Strengthening Scientific and Technological Innovation of TCM Medical Devices (Guo Zhong Yi Yao Ke Ji Fa [2018] No. 11) was jointly issued by the State Administration of TCM, the Ministry of Science and Technology, the Ministry of Industry and Information Technology, and the National Health Committee. It further puts forward specific requirements for strengthening sci-tech innovation of TCM medical devices, enhancing the innovation capability of TCM medical device industry, and better meeting the needs of TCM medical service and people's health.

In addition, in terms of fund management, it involves 34 requirements of the "Technical Conditions and Standards" issued by the Ministry of Science and Technology, including 16 policies on sci-tech equipment; among them, Administrative Measures of Special Funds for the Development of National Major Scientific Instruments and Equipment (Trial) (Cai Jiao [2011] No. 352) and Several Opinions on Improving and Strengthening the Funds Management of Major Technical Equipment Development (Cai Jian [2007] No. 1) have direct guiding significance. The Opinions on Deepening the Reform of Project Evaluation, Talent Evaluation, and Institutional Evaluation, jointly issued by the General Office of the CPC Central Committee and the General Office of the State Council, is a programmatic document to implement the deployment of the National Science and Technology Innovation Conference and the requirements of Outlines on National Strategy for Innovation Driven Development, which determines the direction for sci-tech system reform. Meanwhile, Rules for Duty-free Importation Administration of Scientific Research, Sci-tech Development and Teaching Supplies for Scientific Research Institutes, released by authorities including the Ministry of Science and Technology, and the Ministry of Finance, provide tax support for imported scientific research equipment. In general, all the above policies guarantee funds for scientific research from different dimensions.

3.2 Promotion of marketization

If scientific research is a process of turning money into "paper", how can we better turn "paper" with innovative wisdom into economic benefits? As for TCM equipment, the transformation of scientific research achievements is also the process of marketization (patent certification, manufacturing, quality supervision, enterprise sales, and import-export), around which relevant supporting policies are also deployed. Since the 18th National Congress of the Communist Party of China, the Chinese government has issued a series of policies and measures to promote the information sharing, and strengthen the construction of trading platform for sci-tech achievements.

The Law of the Pepole's Republic of China on Promoting the Transformation of Scientific Technological Achievements, which was revised and implemented in 2015, clarifies that transformation of scientific and technological achievements should obey market rules, follow the principles of voluntariness, mutual benefit, fairness, honesty, and credibility. Profits and risks shall be shared according to laws or terms of contract. Intellectual property rights related to the transformation of sci-tech achievements shall be protected by law. The newly revised Law on Promoting the Transformation of Sci-tech Achievements has determined directions for the marketization of sci-tech achievements. Since then, the Ministry of Science and Technology, the Ministry of Education, and other departments have actively implemented it. In August 2016, the two ministries issued Several Opinions on Strengthening the Transfer and Transformation of Sci-tech Achievements in Colleges and Universities, which clearly points out that colleges and universities should establish the performance evaluation mechanism for the transfer and transformation of sci-tech achievements, and reward institutions and personnel with outstanding achievements. Intellectual property is the core element in the process of achievement transformation. In February 2020, the Ministry of Education, the State Intellectual Property Office, and the Ministry of Science and Technology jointly issued Several Opinions on Improving Patent Quality and Promoting Transformation and Application in Colleges and Universities to guide colleges and universities to gradually improve the intellectual property management system, optimize the evaluation system, elevate patent quality, and promote the transformation and application of patent achievements [9].

The Ministry of Science and Technology has vigorously promoted the construction of the national technology transfer system. By 2019, 11 national technology transfer regional centers and more than 40 technology trading markets had been built nationwide, and 453 national technology transfer institutions had been established. Meanwhile, the Ministry of Education actively promotes the market-oriented "Cloud Platform for Transformation of Sci-tech Achievements in Chinese Universities" at the level of universities, and apply internet, big data, and artificial intelligence to comprehensively display the information of sci-tech achievements in universities, so as to promote the transformation of sci-tech achievements in universities from "samples" to "products", and to "commodities", accelerate the landing of sci-tech achievements, and realize industrialization as soon as possible.

3.2.1 Equipment manufacturing industry According to incomplete statistics, the Ministry of Science and Technology has issued 45 policies on "sci-tech achievements

and intellectual property rights", mainly involving standardized management such as transformation and industrialization of sci-tech achievements, patent certification, and intellectual property management; there are 35 policies related to "enterprise technical progress and high-tech industrialization" to encourage enterprises to conduct technological innovation.

In terms of related normative standards, 98, 47, 36, and 114 policy documents have been respectively issued by Department of Science and Technology, Department of Information and Software Industry, Department of Industry, and Department of Equipment Manufacturing Industry under the jurisdiction of the Chinese Ministry of Industry and Information Technology. Among them, the notice of the three departments on printing and distributing the Special Action Guide for Promoting Quality Brand Promotion of Equipment Manufacturing Industry (Gong Xin Bu Lian Ke [2016] No. 268) and the notice of the three departments on printing and distributing the Standardization and Quality Improvement Plan of Equipment Manufacturing Industry (Guo Zhi Jian Biao Lian [2016] No. 396), the notice of the three departments on printing and distributing Guiding Opinions on Further Promoting the Integrated Management System of Informatization and Industrialization issued by Department of Information and Software Industry (Gong Xin Bu Lian Xin Ruan [2017] No. 155), and the notice of the on printing and distributing Opinions on Guiding Enterprise Innovation Management to Improve Quality and Efficiency by 11 departments of the Department of Industry all clearly put forward requirements such as standards for equipment manufacturing industry and the upgrading of industrial informatization.

In terms of support for research and innovation, eight ministries and commissions, including the National Development and Reform Commission and the Ministry of Science and Technology, jointly issued the Opinions on Promoting the Demonstration and Application of the First (Set) of Major Technical Equipment (Fa Gai Chan Ye [2018] No. 558) to strengthen the support for research and development, and innovation of major technical equipment. According to the central financial sci-tech plan (special projects, funds, etc.), the research and development of eligible major technical equipment and related common technologies should be supported as a whole. Moreover, some support policies like tax incentives, financial leasing, optimization of bank credit can be taken to optimize and upgrade technical equipment.

3.2.2 Medical and health industry (i) Industrialization in medical field. The Guide also puts forward specific tasks in aspects of enhancing industrial innovation, improving quality and safety level, strengthening supply guarantee capability, promoting green transformation and upgrading, boosting the deep integration of industrialization and informatization, optimizing industrial organization structure, elevating international development level, expanding new fields, and developing new formats.

The Guide to the Development Planning of Pharmaceutical Industry (Gong Xin Ting Gui [2015] No. 24) (hereinafter referred to as the "Guide") was compiled by the Ministry of Industry and Information Technology and jointly implemented by the National Development and Reform Commission, the Ministry of Science and Technology, the Ministry of Commerce, the National Health and Family Planning Commission, and the State Food and Drug Administration, aiming to carry out the 13th Five-Year Plan and Made in China 2025 in accordance with the relevant requirements of the Notice on Printing and Distributing the 13th Five-Year Plan System of the Ministry of Industry and Information Technology. The Guide is the strategic deployment of equipment manufacturing in medical field, and it is the national pillar in medical field established for the development of national health and well-being.

In the aspect of medical equipment quality supervision and examination, the Regulations on the Supervision and Administration of Medical Devices is the highest-level legal document on medical device supervision in China. According to the regulations, the drug regulatory authorities are responsible for supervising the whole process of medical devices from development, production, operation to putting them into use. On August 9, 2015, the Opinions on Reforming the Examination and Approval System of Drugs and Medical Devices (Guo Fa [2015] No. 44) issued by the State Council further standardizes the examination and approval system of medical devices.

In terms of localization of medical equipment, the Healthy China 2020 Strategic Research Report, issued by the former Ministry of Health in 2012, proposes that tasks such as localization of key medical devices and modernization of TCM will significantly enhance the sci-tech support capabilities for preventing and treating major diseases and the development of health industries; it clearly proposes an appropriation of 109 billion yuan for the equipment construction of county hospitals, which has secured support for state-owned and large-scale medical equipment from national policies and special funds.

(ii) Intelligentization of medical equipment. In terms of medical equipment intelligence, the joint promulgation of the 14th Five-Year Plan for the Development of Medical Equipment Industry (Gong Xin Bu Lian Gui [2021] No. 208), issued by the Ministry of Industry and Information Technology and other nine ministries and commissions, clearly points out that the development of new nursing and rehabilitation equipment based on robot, intelligent vision and voice interaction, brain-

computer interface, man-machine-electricity integration and intelligent control technology, and technical breakthrough on key intelligent equipment (such as intelligent rehabilitation robot, intelligent walking aids system, multi-modal rehabilitation wheelchair, and exoskeleton robot system) can promote the systematization, customization, and intellectualization of traditional healthcare and rehabilitation equipment applied in massage, traction, phototherapy, electrotherapy, magnetic therapy, energy therapy, exercise therapy, chiropractic and bone setting, and rehabilitation aid. In terms of TCM diagnosis and treatment equipment, the unique advantages of TCM should be fully embodied in disease prevention, treatment, healthcare, and rehabilitation. Guided by TCM theory, the original TCM resources should be deeply excavated, and TCM characteristic equipment should be developed by integrating new technologies including big data, artificial intelligence, and wearability, especially the equipment involving pulse diagnosis, tongue diagnosis, acupuncture, moxibustion, rehabilitation and others. Thereout, clinical diagnosis and treatment as well as health services of TCM can be developed towards standardization, long-distance, scalization, and digitalization. Moreover, the Outline of the Healthy China 2030 Plan also proposes to strengthen medical technology innovation, implement green and intelligent transformation and upgradation, and build an advanced manufacturing system that features by being innovation-driven, green, low-carbon, intelligent and efficient.

(iii) TCM industrialization. In terms of upgrading the TCM industrialization, in 2016, the State Council promulgated the Outline of the Strategic Plan on the Development of TCM (2016 - 2030) (hereinafter referred to as the "Outline") at the national strategic level. It points out that relying on modern sci-tech industrial base of TCM, technology entrepreneurs in TCM health industry should be cultivated to promote the integration and development of the primary, secondary, and tertiary industries of TCM. Concretely, it is necessary to promote the digitalization, networking, and intelligent, construction of TCM industry, strengthen technology integration and process innovation, so as to promote the manufacturing level of TCM equipment. Meanwhile, the standardization and modernization of TCM production process should be accelerated to enhance the intellectual property application ability of TCM industry, thus gradually forming large-scale TCM enterprise groups and industrial clusters.

In the construction of modern Chinese medicines circulation system, the Outline requires a construction plan for the circulation system of Chinese medicines. According to the plan, a batch of primary processing and warehousing logistics centers, closely linked with the supplier management and quality traceability system of production enterprises, should be built to realize the standardization, intensification, scalization, and traceability of authentic Chinese medicines. At the same time, Chinese medicines e-commerce platforms should be established based on big data to realize production information collection, price dynamic monitoring analysis, and predictive warning of Chinese medicines. Furthermore, the whole process quality management and traceability system for production and circulation of Chinese medicines as well as the third-party testing platform should be constructed to ensure the quality of Chinese medicines.

To sum up, the relevant policies of TCM technical equipment at the market level mainly focus on the industrialization of TCM pharmaceutical equipment, while less policy support is given to manufacturing enterprises of diagnosis and treatment equipment and other related equipment, especially for private enterprises.

3.3 Talent team construction

There are 38 relevant policies on the cultivation and development of sci-tech talents issued by the Ministry of Science and Technology, including six policies on promoting innovative development of talents in universities and scientific research institutions, and three on the evaluation and incentive methods of scientific research personnel in enterprises. However, there are few talent development policies on incentive mechanism and professional title evaluation for front-line researchers in equipment manufacturing industry, especially in private enterprises.

In terms of laws and regulations, in 1999, the State Council promulgated Decree No. 396, that is the Regulations on National Science and Technology Awards, which was revised and merged by the three Regulations, namely Regulations on Invention Awards, Regulations on Natural Science Awards, and Regulations on Science and Technology Progress Awards. It was revised again in October 2020. It mainly regulates and rewards citizens and organizations that have made great contributions in sci-tech progress activities. And it plays an important role in mobilizing the enthusiasm and creativity of sci-tech workers, and promoting the sci-tech development in China.

The Special Plan for Scientific and Technological Innovation of Medical Devices in the 13th Five-Year Plan (Guo Ke Ban She [2017] No. 44) (hereinafter referred as the Plan), formulated by the Ministry of Science and Technology, proposed "combining medicine and engineering", the concept of interdisciplinary talents, and improving the talent training mode and introduction mechanism. Firstly, it emphatically puts forward the talent construction based on scientific research institutions to support the construction of medical device related disciplines. Also, relevant enterprises are encouraged to carry out in-depth cooperation with universities, scientific

research institutions, and medical facilities to foster leading talents in sci-tech innovation, senior engineering and technical talents, interdisciplinary management talents as well as young and middle-aged experts, meanwhile, the construction of innovative teams should be vigorously strengthened to consolidate the talent base for industrial development. What's more, the Plan has made it clear that relying on key laboratories, engineering technology research centers, major projects, major talent introduction plans, a group of world-class and high-end talents shall be introduced and more overseas high-level medical device talents shall be encouraged to return to China for innovation and entrepreneurship. Nevertheless, the Plan does not emphasize the cultivation of interdisciplinary talents, as well as the construction of scientific research and technical talents in enterprises.

With regard to the construction of TCM talents, the Special Plan for Sci-tech Innovation of TCM in the 13th Five-Year Plan, jointly issued by the Ministry of Science and Technology and National Administration of Traditional TCM (Guo Ke Fa She [2017] No. 146), focuses on the introduction and development of high-end talents as well as the optimization of talent evaluation mechanism. While the 14th Five-Year Plan for the Development of TCM clarifies the following main contents of building a high-level TCM inheritance protection and sci-tech innovation system. Firstly, a number of national-level research platforms for TCM should be built to study and deploy planning of national key laboratories, national clinical medical research centers, national engineering research centers, and national technological innovation centers. Also, it is necessary to promote the construction of national center for inheritance and innovation of TCM, national clinical research base of TCM, and evidence-based medicine center of TCM. In addition, China Academy of Chinese Medical Sciences should give full play to its role as the "national team" in sci-tech innovation of TCM.

The above two plans both focus on formulating talent policies that are conducive to introducing and attracting high-end talents at home and abroad and cutting-edge talents in other disciplines to carry out sci-tech innovation of TCM. According to the two plans, the characteristics of TCM disciplines and the growth law of innovative talents of TCM should be respected to improve the training mechanism of TCM talents, strengthen the construction of innovative talents, and establish diversified evaluation standards for sci-tech talents oriented by knowledge value, scientific research ability, innovation achievements, and application development. Moreover, the income distribution system based on job responsibilities and sci-tech performance evaluation as well as the incentive mechanism for income distribution in transformation of sci-tech achievements should be improved to fully exert to the innovation vitality of scientific research personnel. And sci-tech personnel of TCM are encouraged to start businesses, promoting the two-way flow of scientific research talents. To sum up, following the research law of TCM and the cross-integration of different disciplines, the plans highlight the importance attached to the innovative development, evaluation, and training of TCM sci-tech talents, and they also pay much attention to the introduction of high-end TCM talents as well as the improvement of talent flow mechanism. However, the working path for planning and construction of interdisciplinary talents in the fields of medical, sci-tech, and manufacturing industry needs to be further improved.

4 Main problems and cause analysis of TCM equipment

The problems existing in TCM equipment restrict the development of TCM industry. Generally speaking, the high-tech application of TCM equipment is still in its infancy [10], with small industrial scale, weak technical foundation, insufficient investment in research and development, and uneven distribution. So far, the conducive environment to technological innovation of TCM equipment has not yet been formed, and difficulties have remained to develop TCM products that adapt to international competition. In addition, the disconnection between scientific research and industrialization still exists. Moreover, the intellectual property technology system of TCM equipment is incomplete. Most enterprises, with insufficient capacity for technological development and innovation, also lack the capacity to participate in international competition.

4.1 Small-scale, scattering, and disordered TCM equipment manufacturing enterprises

It is extremely urgent to speed up the research on key technical equipment of TCM and up-grade TCM industry [11]. TCM equipment enterprises are generally small-scale, low-quality, and unbalanced distributed. For instance, as to the equipment enterprises of Chinese medicines, the level of pharmaceutical equipment indicates the quality of pharmaceutical technology and pharmaceutical preparations, which directly influences the TCM development. At present, there are over 7 000 pharmaceutical machinery manufacturers in China. The pharmaceutical machinery industry has been developed slowly. Concretely, the innovation ability and technological level of products are behind those of developed countries. Moreover, the companies have always been in the low-level, low-price, and imitation competitions. As to the production technology and pharmaceutical equipment of Chinese medicines, they are backward and typically characterized by narrow varieties and small sizes, poor standardization and capacity, low automation level, and backward quality testing equipment.

4.2 Insufficient policy implementation

China has established systematic policies, laws, and regulations in the fields of TCM medical devices and pharmaceutical equipment. However, in practice, the TCM characteristics and advantages in health services are not fully considered, and the policies are not implemented enough. For example, there is a contradiction between TCM theory and the examination and approval standards of medical devices, and it is difficult to develop clinically needed TCM diagnosis and treatment equipment. Taking moxibustion apparatus as an example, the existing examination and approval standards for medical devices stipulate that the temperature of apparatus contacting skin should be controlled within 42 °C, but 42 °C can not meet the treatment needs in clinical practice at all [12]. Therefore, enterprises pursue quick success and instant profit by following the research and development ideas of western medical devices and borrowing TCM theory to package and go public, thus resulting in harmful effects.

Interdisciplinary integration is necessary to develop TCM equipment manufacturing industry, and the demand for interdisciplinary talents is particularly urgent. TCM is different from modern medicine. Because the general biomedical engineering personnels are short of theoretical knowledge and practical experience of TCM, they can not combine TCM theory with medical engineering due to the incomplete knowledge structure. While researchers in TCM research institutions have profound knowledge of TCM, but lack professional knowledge of engineering or computer science [13]. In addition, the existing policy orientation and economic security are unable to gather high-tech professional teams, which restrict the development of TCM equipment to a great extent.

In terms of fiscal policy, financial investment, subsidies, credit and other means have been adopted, but there still exist the following problems. (i) The total investment in scientific research expenses for TCM equipment is insufficient. During the 11th Five-Year Plan Period, 51.17 million yuan was invested in TCM industry; during the 12th Five-Year Plan Period, 131.05 million yuan was invested, including 32.66 million yuan for the research and development of rehabilitation equipment. Generally speaking, the investment in TCM equipment industry has increased year by year, but the investment scale was relatively small, accounting for a low proportion of fiscal expenditure. (ii) The financial management system of sci-tech funds is imperfect. Low efficiency in using scientific research funds, and homogenized and repeated investment in low-level research have been shown. (iii) There is lack of special fund support for technological innovation in TCM technical equipment. It is difficult to apply for common national research programs, as well as research and development of TCM equipment and follow-up clinical trials. Therefore, universities and hospitals, the main body of TCM research and development, have lost their enthusiasm.

The reasons are as follows: the management of sci-tech projects is not coordinated with the management of funds; the sources of financial investment in science and technology are scattered, with overlapping management of government investment in science and technology. Overlapping management exists within sci-tech departments, economic and trade departments, and financial departments. In the specific implementation process, there exists a lack of communication among relevant departments in project arrangement, leading to overlapping project funding to some extents.

4.3 Imperfect standards related to TCM technical equipment

It's necessary to strengthen the international standardization of TCM equipment and promote the great development of TCM equipment industry. By January 2022, 77 international standards of TCM had been promulgated by the International Organization for Standardization (ISO) [14]. According to ISO/TC249 standard, most therapeutic equipment, such as acupuncture needles, cupping devices, moxibustion apparatus, TCM decoction equipment, has a wide application foundation worldwide. However, the extensive dissemination and use of diagnostic equipment, such as four diagnostic instruments developed under the guidance of modern science and technology, due to the obvious insufficient corresponding international standards, has been restricted overseas. The root cause lies in the fact that there is still a big gap in the technological strength between Chinese medical device industry and that of developed countries, which is due to the limited scale of enterprise, the lack of motivation and funds to participate in or lead the revision of international standards and so on.

4.4 Inadequate industry-university-research cooperation and imperfect sharing mechanisms of sci-tech resources

To promote the development of TCM equipment, it is urgent to establish multi-disciplinary and multi-field cooperative working mechanisms. It is necessary to establish a close industry-university-research cooperation system, and form a sharing mechanism of sci-tech resources.

The basic theoretical research of TCM industry is disconnected from the transformation and transfer of sci-tech achievements. Searching the medical devices with registration number in the database of the State Food and Drug Administration, except for the conventional therapeutic instruments such as acupuncture needles, cupping

devices, and scraping plates, there are very few registered medical devices of TCM. Besides, according to the statistics of the State Food and Drug Administration, 7801 registration certificates for the second type of medical devices were issued nationwide in 2018, among which only 14 were for Chinese medical devices [15]. There have been more than 300 scientific papers on designing and developing modern diagnosis and detection devices of TCM. Most of the scientific research achievements are still at the research stage and difficult to transform, among which there are some practical and excellent achievements reflecting the TCM characteristics.

The research and development of TCM diagnosis and treatment equipment is disjointed from clinical needs. There is a phenomenon of "working behind closed doors" in the research of diagnosis and treatment equipment, which is divorced from the needs of clinical practice but for the sake of research. TCM diagnosis and treatment equipment must be developed under the guidance of TCM theory, designed and manufactured according to clinical characteristics. There are many devices in the market that are not designed according to TCM theory, while many devices that meet clinical needs cannot be developed due to the restriction of relevant access system.

5 Policies needs and suggestions on TCM equipment

5.1 Policy suggestions proposed according to the current TCM equipment policy, and combined with the development history of foreign equipment manufacturing industry and promotion policies

5.1.1 Improving laws and regulations, and strengthening policy support Sci-tech developed countries promote the rapid development of equipment manufacturing industry, through sci-tech innovation, government procurement, tax incentives and other related support policies, based on the existing laws and regulations system. We could learn advanced experience from other countries, complete supporting policy system on the Law of the PRC on TCM, combining the unique advantages of TCM. We should make full use of advantages of the interministerial joint conference system of the State Council on TCM, and provide policy guarantee for the development of key technical equipment of TCM modernization.

5.1.2 Improving sci-tech level and enhancing innovation ability Sci-tech level and innovation ability are the key factors that determine the development level and prospect of TCM equipment manufacturing industry. We should adopt the development mode of technological progress strategy, combine "technology import" with "inheritance and innovation", support the introduction of foreign advanced technology, and promote the popularization and application of "industry-university-research" mode. Therefore, we can comprehensively enhance the scientific research level of the industry, improve the independent innovation ability of enterprises, and provide sustainable power for the development of equipment manufacturing industry.

5.1.3 Gathering talents and attaching importance to interdisciplinary talents construction We should continually increase investment and support in the education system, make full use of the talent introduction strategy in the field of TCM equipment, and attract high-tech talents from different industries to join the TCM equipment manufacturing industry. These measures can provide sufficient primary power for promoting TCM equipment manufacturing industry.

5.1.4 Preferential industrial policy for promoting the comprehensive development We should support and protect state-owned enterprises to set TCM brands and improve their international competitiveness and industrial status, through fiscal, taxation, trade, and other policies. We should increase policy support, to enhance the competitiveness of Chinese enterprises, especially private enterprises. In addition, we should form a group of world-class multinational companies with international competitiveness on the premise of realizing scale effect, realize the cluster of small and medium-sized enterprises, and give full play to the team role of small and medium-sized enterprises in competition.

5.2 Policy suggestions on industrialization process and key elements according to the characteristics of TCM equipment industry

5.2.1 Industrialization process (i) Intellectual property protection system. It is necessary to explore the construction of a comprehensive protection system for intellectual property rights of TCM equipment with a long-term protection mechanism. To be specific, the commercial secrets of TCM equipment should be protected, and the dispute arbitration and rapid mediation system involving intellectual property should be further improved. Also, we should give full play to the self-discipline role of TCM industry, raise intellectual property awareness of enterprises, thus promoting the registration and protection of cluster brands in TCM equipment industry as well as the development of industrial clusters, brand bases, and intellectual property service industry. Meanwhile, the international mutual recognition mechanism to certify the intellectual property management system should be established to encourage enterprises to apply for foreign patents, thus setting up corresponding overseas patent layout.

(ii) Integration with technologies in other fields. Starting from the key technologies that restrict the development of TCM, the service ability of TCM healthcare can

be enhanced with the integration of TCM equipment with emerging technologies such as cloud computing, big data, Internet of Things, machine learning, sensors and control systems, and human-computer interaction. Then, the digitalization and intelligence of TCM equipment as well as the research and industrialization of core technical equipment such as industrial control systems and intelligent sensing components should be accelerated to promote the intelligent upgrading of Chinese medicines production equipment. A sound traceability mechanism for the circulation of Chinese medicines can ensure the quality, safety, and reliability of Chinese medicines. Furthermore, the traceability system for production, circulation, and utilization of Chinese medicines should be constructed to improve the quality and safety level of TCM products. In addition, it's necessary to develop intelligent TCM services, give play to the leading role of high-quality medical resources, encourage social participation, integrate online and offline resources, and regulate medical Internet of Things and health care application management. Furthermore, applying informationized and intelligent equipment, Chinese medical facilities should be guided to carry out remote services for grassroots, remote and underdeveloped areas.

(iii) Policies for the application and transformation of sci-tech achievements. With the rapid development of TCM, a multi-level and wide-coverage TCM service network has been basically established. As a result, advanced TCM equipment should be applied in medical facilities at all levels to improve service quality. At the same time, the research and development of medical equipment based on TCM theory should be fostered for the transformation and upgrading of TCM equipment. We also can expand the application scope in the new format of health servicesas, and promote the popularization and application of mature TCM equipment in geriatric diseases, rehabilitation, nursing, and other fields.

(iv) Access and supervision. TCM equipment is the main object of access and supervision, so it is suggested to reduce the product classification levels of TCM equipment, speed up the approval of innovative products, and try to focus on both prior examination and approval and post-supervision instead of paying attention to prior examination and approval. Pre-listing examination and certification are only part of effective management, so the lack of the "post-listing tracking" system will objectively cause misleading of absolute safety. As a result, the relevant system of post-listing supervision should be further improved in China, and the optimized standard system of TCM equipment is conducive to international mutual recognition. Moreover, TCM equipment enterprises should be promoted to build production lines that meet international quality standards, so as to elevate the levels of international production and operation management, accelerating the international certification of TCM equipment.

5.2.2 Key factors affecting the development of TCM equipment (i) Talent policy. A sound mechanism of talent introduction, cultivation, and incentive can create a great environment to make the best use of their talents and their capabilities. Therefore, it is necessary to attract overseas high-level talents and teams in product innovation and high-tech fields to come to China for innovation and entrepreneurship. In addition, taking improving quality management level of TCM equipment and the competitiveness of enterprises as the core, TCM equipment enterprises should be encouraged to set up postdoctoral research workstations, actively carry out various forms of training, and cultivate a group of leading TCM equipment talents. Moreover, TCM equipment enterprises are also encouraged to cooperate with universities and medical facilities to cultivate practical technical talents.

(ii) Fiscal and taxation policy. As a national industry, TCM equipment industry should be given preferential support of finance and taxes. Gradually, the value-added tax transformation policy should be improved, broadened, and refined to encourage equipment manufacturing enterprises to intensify technological transformation and accelerate the renewal of manufacturing equipment. As for major technical equipment and products supporting the development of TCM equipment industry, their import duties and import value-added tax could be exempted by negotiating with customs, taxation and other departments if it is necessary to import some key components and raw materials. The applied scope of refunds on value-added tax of molds, numerical control machine tool and others should be adjusted to guide enterprises to develop high-tech and high value-added products. And the proportion of other taxes of enterprises should be appropriately reduced to cut operating costs. Moreover, the threshold standard of enterprise project declaration should also be appropriately lowered, and the support for TCM equipment enterprises should increase. Actually, TCM equipment enterprises should be given a higher proportion of matching funds. In addition to a certain amount of funding given at the time of establishment, a certain proportion of matching funds will be given in stages if the equipment is effective after being checked and accepted.

Furthermore, it is necessary to improve the utilization efficiency of sci-tech funds, perfect the management system of financial technology funds, and coordinate sci-tech projects and funds management, so that universities, research institutions, and enterprises can achieve complementary advantages through effective communication.

(iii) Investment policy. Through budget allocation and guiding the flow of extra-budgetary funds, the social

and economic foundation can be consolidated and strengthened, and the industrial structure can also be adjusted. Accordingly, the investment of the identified projects in TCM equipment field as well as strategic acquisitions of some key projects should be promoted through the establishment of TCM industry investment funds, investment companies, direct investment and additional investment. This is not only beneficial to solve the problem of enterprise capital, but also conducive to the development of advanced equipment manufacturing as well as the improvement of enterprise investment structure. In addition, the cooperation between medical device manufacturers and financial leasing companies should be explored, providing installment payment for medical institutions of all types of ownership to purchase large-scale medical equipment.

(iv) Guiding policy. TCM medical device manufacturers should be encouraged to cooperate with medical service institutions and research institutions, so as to build innovative demonstration application bases and training centers, which can form a virtuous circle of demonstration application-clinical evaluation-technical innovation-spread popularization. In addition, advanced agricultural technologies should be encouraged to apply in standardized planting and breeding of Chinese medical materials. Meanwhile, we should develop and apply new technologies for extraction, purification, and quality control of effective components in Chinese medicines, and encourage to develop production process control technologies and equipment for TCM modern dosage forms. Finally, we can develop the innovative technology of decoction pieces, and the secondary development and production of Chinese patent medicines.

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Competing interests

The authors declare no conflict of interest.

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中医药装备相关政策研究与思考

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【摘要】中医药装备是具有我国自主知识产权、独具中国特色的产业代表。作为中医药与信息技术融合的产物，其发展正处于前所未有的机遇期。本文结合发展中医药技术装备的现实意义，对近年来推动中医药装备发展系列政策进行梳理，分析目前中医药装备存在的主要问题及产生原因，对中医药装备行业发展提出几点政策需求和建议。

【关键词】中医药；技术装备；问题对策；政策需求；思考展望