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#### Review

# Current Policies and Measures on the Development of Traditional Chinese Medicine in China



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#### ABSTRACT

Traditional Chinese Medicine (TCM) is a medical science and cultural heritage empirically applied and reserved by Chinese people for thousands of years. With comprehensive prosperity of China and rapid elaboration of technology, healthcare status of Chinese people has become one of the most crucial concerns of the country. Nearly 30 policies and measures regarding TCM development have been issued since the 18<sup>th</sup> National Congress of the Communist Party of People's Republic of China in 2012. This review introduced a detailed evolutionary course of TCM in China with an emphasis on understanding the roadmap of TCM related policies and measures in China.

# 1. Current Developmental Status of TCM in China and Worldwide

### 1.1. Domestic achievements of TCM

Traditional Chinese Medicine (TCM) is one of the most important achievements of Chinese civilization which is also a medical science inherited over thousands of years. During the process of fighting against diseases, Chinese people formed and developed TCM empirically in their daily life. Recently, people in China and around world were infected by SARS-COV-2 who might exhibit severe lung injury and lymphopenia[1]. TCM has made great contributions to the treatment of COVID-19 [2] with over 90% involvement all over China [3] and showed high effective rate in a multicenter, prospective, randomized controlled clinical trial [4]. These effects are probably through the mechanism of inhibiting the SARS-COV-2 replication and reducing pro-inflammatory cytokines [5–7]. With its long history of absorption and innovation, TCM is not only a method of treatment, it also made great impacts on people's

pattern of life. The remedies of TCM against diseases combines a holistic view of harmony, individuality, simplicity and preventive treatment which is on account of assimilation from natural science and humanities [8]. The State Council has issued a new guideline to implement the country's Healthy China 2030 initiative focusing on disease prevention and health promotion[9]. TCM as a crucial contributor for enhancing Chinese people's health status, a large series of laws and policies have been issued for the heritage and innovation of TCM. The awarding of Nobel Prize in 2015 of Tu Youyou also highlighted the contributions of TCM to her research and raised artemisinin to a new status worldwide as "A gift from Traditional Chinese Medicine to the World" [10]. Since the launching of the 12th Five-year Plan, great efforts have been made to improve the development of TCM: Sixty-three State Science and Technology Awards were honored to the research in the field of TCM; Four TCM drugs have been allowed to conduct phase III clinical trial in US and a number of Chinese patent medicines have been recorded in European and US Pharmacopoeia [11]. It is undoubted that the central government and regulatory department are making every effort to

Abbreviations: CPC, Communist Party of China; GDP, Gross Domestic Product; ISO, International Organization for Standardization; NPC, National People's Congress; PRC, People's Republic of China; R&D, research & development; TCM, Traditional Chinese medicine; UNESCO, United Nations Educational, Scientific and Cultural Organization; WHO, World Health Organization.

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promote the development of TCM with the aim of modernization, standardization and informatization so as to provide a precise treatment with a wider coverage.

#### 1.2. International achievements of TCM

The international recognition of TCM is at the same time growing with the wide access of TCM across 183 countries and regions worldwide. TCM acupuncture and moxibustion have been recognized as important parts of the intangible heritage of mankind by UNESCO [12] and the Chinese medical classics Huangdi Neijing (Inner Canon of the Yellow Emperor) [13] and Bencao Gangmu (Compendium of Materia Medica) [14] have been included in the UNESCO Memory of the World. According to statistics from the WHO, 103 member states have authorized the use of acupuncture and moxibustion, of which 29 have established laws and regulations promoting traditional medicines, and

18 states have included acupuncture and moxibustion in their medical insurance systems [15]. The latest 2019 global report on traditional and complementary medicine[16] and WHO traditional medicine strategy: 2014-2023[17] have emphasized the contributions of traditional and complementary medicine to the goal of universal health coverage by improving equitable access to safe, quality and effective traditional and complementary medicine services. The global burden of chronic disease also urged the development and enhancement in the collaboration between conventional and traditional medicine [17]. International Organization for Standardization (ISO) created TCM technical committee ISO/TC 249 in 2009 focusing on quality and safety of raw materials, manufactured products and medical devices and of informatics [18]. In 2014, the first TCM ISO standard, ISO 17218:2014 was published which specified the requirements for the sterile acupuncture needles for single use. Currently under this committee, there are 49 published ISO standards and 43 under-development standards with 24 participating

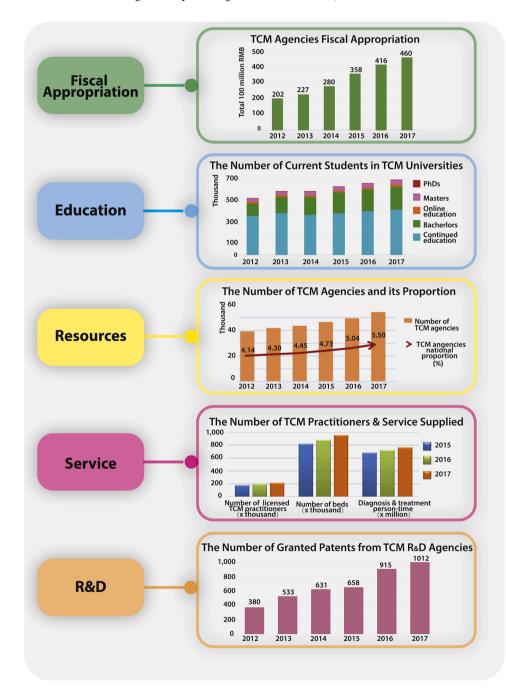


Fig. 1. Developmental status of TCM in China. The development of TCM was statistically concluded in five sections including fiscal appropriation, education, resources, service and R&D. In each section, representative diagrams were chosen with detailed number or percentage demonstrating the changes during 2012 to 2017.[20] As for the statistics in 2017 in China: total fiscal appropriation in TCM agencies was 46 billion RMB; the number of current students in TCM universities was 693,267; the number of TCM agencies was 54,243; 217,118 TCM practitioners were responsible for 951,850 bed with 764 million workload; 229 patents from TCM R&D agencies were authorized from local, ministerial and provincial levels. [20]

members and 19 observing members [19]. Sharing one set of standards could help with the development of TCM globally.

### 1.3. Developmental status of TCM in China

The developmental status of TCM in China could be introduced in the following five sections including TCM resources, the operation and service of TCM medical establishment, TCM education, TCM research & development (R&D) and financial appropriation income of TCM. (Fig.1) [20]

#### 1.3.1. TCM resources

Firstly, the number of TCM health agencies has increased steadily since 2010 including TCM hospitals, TCM & western medicine combined hospitals and ethnic hospitals which nearly reaching 60 hundred. However, the percentage it occupied in the total number of health agencies of national healthcare system is only around 6% (6000 over 1 million). Similarly, the number of TCM related professionals was almost doubled in 2017 (663,557) compared with that in 2010 (404,372), but its percentage in the number of medical professions of national healthcare system only increased 0.5%.

#### 1.3.2. Operation and service of TCM medical establishment

Based on the number of beds, the amount of diagnosis and treatment and the number of discharged patients, TCM healthcare agencies (hospitals, out-patient departments and clinics) play a crucial role in providing medical care service taking nearly 20% of national healthcare service but with only 10% TCM practitioners. Specifically, for advanced operation of TCM medical establishments, TCM hospitals have focused on the promotion of TCM features including preventive treatment of diseases, TCM characteristic techniques of diagnosis and treatment, TCM preparation room, TCM preparation range and TCM characteristic equipment.

# 1.3.3. TCM education

For the cultivation of TCM characteristic talents, higher education in TCM subjects serves as a solid support. Although the number of TCM institutions of higher education is almost the same (43), more and more western medicine and non-medical institutions are setting up TCM subjects. Moreover, the number of current and graduated students is increasing gradually including college students, bachelor students, master students and PhD students. The proportion of the education level is almost the same that most TCM-subjected students (nearly 90%) are general undergraduates and continuing education undergraduates, but the percentage of PhD students for TCM research is only around 0.7%.

### 1.3.4. TCM research & development (R&D)

TCM R&D is also carried on by ministerial, provincial and local organizations with published scientific articles and academic work, accepted and licensed patents, drug approval certificates, and other achievements at national standards. The number of professionals in TCM scientific research and technical development has increased steadily with more than half from provincial organizations working on scientific and technological activities. The key subjects involving R&D of TCM are evaluated by the number of agencies conducting them, including Chinese herbal medicine, traditional Chinese medicine, integrated traditional Chinese & western medicine, pharmaceutical chemistry *etc.* The total income of TCM R&D organizations has increased in the latest years which is comprised of scientific activities, production and operation and other incomes which has nearly reached one billion.

# 1.3.5. Financial appropriation income of TCM

Funding from the government and domestic and abroad non-government organizations also increased nearly 30% for supporting TCM research and development. Detailly, around 7% of national fiscal expenditure has been spent on the section of medical and healthcare,

among which, 3% of the money is for health administration and further divided 0.23% goes for TCM agencies. Both the amount of appropriation and its proportion increased gradually since 2010. From the aspects of healthcare departments, the appropriation specific for TCM occupies less than 1% of the health administration budget and almost half of them is earmarked from TCM agencies [20]. Therefore, TCM has improved gradually in the latest ten years in the above five sections but comparing with its proportion in the whole healthcare system, there still remains large number of challenges to be solved in the future.

### 1.4. Challenges and resolutions of promoting TCM in China

On the other hand, there still exist obstacles that TCM has to face because of the huge healthcare demand in China [21]. First of all, current TCM medical care system does not have a full coverage across the rural communities because of a limited number of infrastructure and practitioners [22]. According to the statistics in 2017, around 80% of TCM practitioners serve in urban areas while only 20% are in rural areas. Secondly, insufficient number of high-level TCM experts leads to a weak point during the operation of TCM inheritance and innovation program. According to a survey of current status of TCM, there are only three TCM practitioners every ten thousand people [23]. The TCM doctors are responsible for more than 7 person-time patients every day, which is slightly higher than the average number of general hospitals but the annual income of TCM doctors are only 80% of the average income of all doctors national wide. The income of TCM hospitals is less than 40% of that of general hospitals which could explain the lower annual income of TCM doctors[20]. Thirdly, the sustained development of TCM is threatened by the destruction of ethnic minority medicine and the declined quality of Chinese medical resources which also triggers a relatively low concentrated pharmaceutical industry. Chinese crude drugs even have the highest disqualification exposure rate of all the products examined by the regulatory departments in China [24]. There is an urgent request for the completeness of a TCM management system so as to increase its competitiveness under the global environment [22]. Fortunately, in order to overcome these difficulties, the government has not stopped guiding the direction in improving the environment for TCM development.

The Chinese government has set great store by TCM and rendered vigorous support to its development consistently after the founding of People's Republic of China in 1949. More importantly, since the 18<sup>th</sup> National Congress of the Communist Party of China (CPC) in 2012, the government has issued nearly 30 major policy decisions and plans on TCM so as to improve its normative implementation and development to the rule by law [25]. In President's report to the 19th CPC National Congress, the necessity to pay equal attention to the development of TCM and Western medicine and carrying forward the tradition and ensuring the development of TCM was emphasized [26]. TCM is therefore ready for its renaissance with the modernized technologies, normalized system and devoted professionals. The development of TCM is ushering in a fresh age with an integrated scope of treatment, fitness, research, education, industry and culture. People all over the world would benefit enormously from the TCM services in terms of both healthcare and economy.

# 2. Historical Events of TCM Development

### 2.1. Establishment of TCM since ancient China

TCM has always been a significant component of traditional Chinese culture since it grows with the course of Chinese history [8]. Dating back to the remote antiquity, Chinese ancestors had applied certain creatures, plants and minerals to relieve their symptoms. By assimilating the essence from natural science and humanity, the theories and methods of TCM were gradually formed and recorded in written works. The four diagnostic methods: inspection, auscultation & olfaction, inquiry and

palpation was summarized by Bian Que in the Spring and Autumn and Warring States Period (770-221BC) [27]. The theoretical frame work for TCM came in to place during the Qin and Han times (221BC- AD220) described in the Huang Di Nei Jing (Yellow Emperor's Inner Canon) [28]. One of the most important theoretical foundation of TCM was the Shang Han Za Bing Lun (Treatise on Febrile Diseases and Miscellaneous Illnesses) created by Zhang Zhongjing in the Eastern Han Dynasty (25-220), which discoursed how to propose corresponding diagnosis by differentiating the patterns of miscellaneous illnesses [29]. During the same period, the foundation of TCM pharmaceutical theory was advanced by the masterpiece: the Shen Nong Ben Cao Jing (Shennong's Classic of Masteria Medica) which guided the prescription and safety application of TCM so as to enhance their therapeutic effects [30]. Later in the Ming Dynasty (1368-1644), Li Shizhen complied the Ben Cao Gang Mu (Compendium of Materia Medica), the first book in the world that categorized medical herbs scientifically, which enriched the TCM pharmaceutical theory in details [31]. These books transformed the clinical experience into summation of theories of TCM which systematically exposed its principles and methods of treatment, the human physiology, the symptoms of illness, and the preventative treatment.

### 2.2. Cornerstone events of TCM since 1949

The application of TCM also prospered with the development of the People's Republic of China (PRC) since 1949. In the early period of PRC, one of the three guidelines for health work was uniting Chinese and Western medicine. The first edition of Chinese Pharmacopoeia was published in 1953 for guiding the pharmaceutical industry in China while TCM was first recorded in the second edition of Pharmacopoeia in 1963 [32,33]. Later in 1978, the CPC Central Committee transmitted the Ministry of Health's "Report on Implementing the Party's Policies Regarding TCM and Cultivating TCM Practitioners" across the country which forcefully promoted the development of TCM. Furthermore, the Constitution of the PRC stipulates the promotion of modern medicine and TCM to protect the health of Chinese people [8]. In 1986, a relatively independent administration of TCM was founded by the State Council, following by the establishment of respective TCM administrations in all provinces, autonomous regions and municipalities which functioned as basic organization of TCM management in China. Then in 1991, at the 4<sup>th</sup> Meeting of the 7<sup>th</sup> National People's Congress, putting equal importance on Chinese and Western medicine was made as one of the five guidelines for health work in the new period PRC. Later on, the policy system on TCM was gradually completed by the two documents issued in 2003 and 2009 separately, the Regulations of the PRC on TCM and the Opinion on Supporting and Promoting the Development of TCM

# 2.3. National awareness of TCM development since the $18^{th}$ CPC National Congress

More recently, the Party and government have granted greater emphasis on the development of TCM since the CPC's 18th National Congress in 2012 by the formation of a series of major policy decisions and plans out of this concern [25]. The Outline of the Strategic Plan on the Development of Traditional Chinese Medicine (2016-2030) and the 13<sup>th</sup> Five-year Plan for the Development of Traditional Chinese Medicine published in 2016 systematically planed TCM development and made it a national strategy [21]. At the National Conference on Hygiene and Health held in August 2016, the importance of revitalization and development of TCM was stressed [34]. Later in October 2016, the Outline of Healthy China 2030 Plan issued by the CPC Central Committee and the State Council also specified a series of tasks and measures on the implementation of TCM development program to improve the health of Chinese people in the next 15 years. [35] More importantly, the Law on Traditional Chinese Medicine was issued in the late 2016 which provided a sounder policy environment and legal basis for TCM

development [36]. The Guideline of Encouraging Innovation in Drugs and Medical Equipment by Expanding the Reform of Review and Approval System issued in 2017 approved the heritage and innovation of TCM by the establishment of a complete registration and inspection system with TCM characteristics [37]. As for ensuring a modernized development of TCM, Guiding Opinions Promoting the Technology Innovation in Healthcare Service of Traditional Chinese Medicine was issued in 2018 [38]. In August 2019, the Drug Administration Law of the People's Republic of China was revised in order to ensure the quality of drugs in China with several sections regarding the approval, production, circulation *etc.* of TCM drugs [39]. These statements revealed the management rules for TCM which adhering to safety first, risk management, whole-process management and control, scientific supervision, and social co-governance.

These historical events from ancient China to the latest days provide strong evidence on the importance of TCM which is the backbone of Chinese society and Chinese culture. The prosperity of TCM would play a critical role in the completeness of a medical and healthcare system providing better healthcare service with Chinese characteristics.

# 3. Elaboration of TCM Related Policies and Measures and Their Correlation

Because of the crucial importance of TCM, there are approximately 26 policies and measures issued by the Chinese government focusing on TCM development since the  $18^{th}$  National Congress of CPC in 2012. Most of the policies and measures are for national healthcare development with partial focus on TCM, while the others are issued exclusive for TCM supporting the national strategies. The publishing date and authorities of each policy and measure is listed in the Table 1 in chronological order. The hierarchy and characteristics of different policies and measures together with their directing areas is illustrated in Fig. 2.

### 3.1. National policies involving TCM

The policies and measures focusing on the healthcare or medical service of China are mostly issued by the Central Committee of CPC or the State Council of PRC regarding the promotion of national healthcare service in China with the aids of TCM.

# 3.1.1. National policies involving TCM before the 13th five-year plan

In September 2013, the State Council issued Several Opinions on Promoting the Development of Healthcare Service, which stated that the integrated development of healthcare service of TCM was one of the major tasks of medical and healthcare system [40]. In March 2016, Guiding Opinions on Promoting the Sound Development of the Medical Industry was established by the National Development and Reform Commission and then issued by the State Council. This document guided the development of healthcare industry as a whole and set advancing the modernization of TCM as a main duty [41].

# 3.1.2. National policies involving TCM after 13<sup>th</sup> five-year plan

According to the strategies at the 5<sup>th</sup> Meeting of the 18<sup>th</sup> National people's Congress, the Outline of the Healthy China 2030 Plan was completed in October 2016. This plan was approved at the congress of the Political Bureau of the Central Committee of the CPC aimed to accelerate the construction of healthy China and to further reinforce the state of health of Chinese people. The 9<sup>th</sup> Chapter of this plan emphasized that fully taking the superior advantage of TCM would play a significant role of improving the medical service in China [9]. Following this plan, Several Opinions on Accelerating the Development of the Rehabilitation and Assistive Device Industry issued in October 2016 also covered the promotion of TCM rehabilitation techniques [42]. Later in November 2016, Several Opinions on Further Popularizing the Experience in Deepening the Reform of the Medical Service and Health System was released, which highlighted the strengths of TCM service in the

 $\begin{tabular}{ll} \textbf{Table 1} \\ \textbf{Current Policies and Measures on TCM development since the 18$$^{th}$ CPC National Congress the corresponding date and issue authorities.} \end{tabular}$ 

dongress the t	corresponding date and issue aut	normes.
Time	Policies and Measures	Authorities
2012.11.16	The Outline of the Medium-and Long-term Development Plan for the Standardization of Traditional Chinese Medicine	State Administration of Traditional Chinese Medicine of the People's Republic of China
2013.09.28	(2011-2020) Several Opinions on Promoting the Development of Healthcare Service	State council of the People's Republic of China
2015.04.14	The Plan of Protecting and Developing Chinese Medicinal Plants (2015-2020)	General Office of the State Council of the People's Republic of China
2015.04.24	The Plan of Developing Healthcare Service of Traditional Chinese Medicine (2015-2010)	General Office of the State Council of the People's Republic of China
2015.06.05	The 10 <sup>th</sup> Edition of Chinese Pharmacopoeia	China Food and Drug Administration
2016.02.22	The Outline of the Strategic Plan on the Development of Traditional Chinese Medicine (2016-2030)	State council of the People's Republic of China
2016.03.11	Guiding Opinions on Promoting the Sound Development of the Medical Industry	General Office of the State Council of the People's Republic of China
2016.08.11	The 13 <sup>th</sup> Five-year Plan for the Development of Traditional Chinese Medicine	State Administration of Traditional Chinese Medicine of the People's Republic of China
2016.10.25	Outline of the Healthy China 2030 Plan	The Central Committee of the Communist Party of China; State council of the People's Republic of China
2016.10.27	Several Opinions on Accelerating the Development of the Rehabilitation and Assistive Device Industry	State council of the People's Republic of China
2016.11.08	Several Opinions on Further Popularizing the Experience in Deepening the Reform of the Medical Service and Health System	General Office of the Central Committee of the Communist Party of China and General Office of the State Council of the People's Republic of China
2016.12.06	Traditional Chinese Medicine in China (White Paper)	State Council Information Office of the People's Republic of China
2016.12.22	The 13 <sup>th</sup> Five-year Plan for the Development of Traditional Chinese Medicine Informatization	State Administration of Traditional Chinese Medicine of the People's Republic of China
2016.12.25	Law of the People's Republic of China on Traditional Chinese Medicine	Order of the President of the People's Republic of China
2016.12.26	The "One Belt, One Road" Plan of Developing Traditional Chinese Medicine (2016-2020)	State Administration of Traditional Chinese Medicine and National Development and Reform Commission of the People's Republic of China
2016.12.27	The 13 <sup>th</sup> Five-Year Plan for Deepening the Medical and Health System Reform	State Council of the People's Republic of China
2016.12.27	The 13 <sup>th</sup> Five-Year Plan for Healthcare	State Council of the People's Republic of China
2017.02.09	Several Opinions on Further Reform and Improvement of Drug Production, Circulation and Use Policies	General Office of the State Council of the People's Republic of China
2017.02.14	The 13 <sup>th</sup> Five-Year Plans for National Drug Safety	State Council of the People's Republic of China
2017.02.28	The 13 <sup>th</sup> Five-Year Plan for Developing Undertakings for the Elderly and Establishing the Elderly Care System	State Council of the People's Republic of China
2017.03.13	The Implementation Opinions on Improving the Development of Traditional Chinese Medicine	State Administration of Traditional Chinese Medicine of the People's Republic of China

Healthcare Elderly Care Service

Table 1 (continued)

Time	Policies and Measures	Authorities
2017.04.25	Key Tasks in Deepening the	General Office of the State
	Medical and Healthcare System	Council of the People's Republic
	Reform in 2017	of China
2017.05.12	The 13 <sup>th</sup> Five-Year Special Plan	State Administration of
	for the Scientific and	Traditional Chinese Medicine of
	Technological Innovation in	the People's Republic of China
	Traditional Chinese Medicine	
2017.10.08	The Guideline of Encouraging	General Office of the State
	Innovation in Drugs and Medical	Council of the People's Republic
	Equipment by Expanding the	of China
	Reform of Review and Approval	
	System	
2018.08.13	Guiding Opinions Promoting the	State Administration of
	Technology Innovation in	Traditional Chinese Medicine;
	Healthcare Service of Traditional	Ministry of Science and
	Chinese Medicine	Technology
2019.01.15	Guiding Opinions on Improving	State Administration of
	Science and Technology	Traditional Chinese Medicine;
	Innovation in Medical Devices	Ministry of Science and
	Used for Traditional Chinese	Technology; Ministry of Industry
	Medicine	and Information Technology;
		National Health Commission
2019.08.26	Drug Administration Law of the	Standing Committee of the
	People's Republic of China	National People's Congress of
		the People's Republic of China

prevention and treatment of common diseases, frequent diseases and chronic diseases [43]. The State Council published the 13<sup>th</sup> Five-Year Plan for Deepening the Medical and Health System Reform and the 13<sup>th</sup> Five-Year Plan for Healthcare on December 27<sup>th</sup>, 2016. These two plans were formulated based on the achievements made during the 12<sup>th</sup> five-year plan and the national requirements of healthcare service in the next five-year plan. The application, heritage and innovation of TCM was emphasized again on playing a crucial role in the implementation of these two plans [44,45]. In February 2017, two policies regarding drug quality were issued: Several Opinions on Further Reform and Improvement of Drug Production, Circulation and Use Policies and the 13<sup>th</sup> Five-Year Plans for National Drug Safety. These two plans stated that classical TCM prescription drug registration should be prioritized and the standardization and modernization of TCM should be supported [46, 47]. At the end of February 2017, the 13<sup>th</sup> Five-Year Plan for Developing Undertakings for the Elderly and Establishing the Elderly Care System was issued by the State Council which suggested to supply the elderly care institutions with TCM healthcare service [48]. In April 2017, the General Office of the State Council released Key Tasks in Deepening the Medical and Health Care System Reform in 2017 which further stressed that TCM service should be practiced constantly in the construction of the healthcare system [49]. Continuedly, on October 8<sup>th</sup> 2017, the General Office of the State Council issued the Guideline of Encouraging Innovation in Drugs and Medical Equipment by Expanding the Reform of Review and Approval System. This policy suggested that a drug registration management and evaluation system with TCM characteristics should be constructed in order to support the heritage and innovation of TCM [37]. Recently in August 2019, Standing Committee of the National People's Congress of the People's Republic of China announced the revised Drug Administration Law, aiming to regulate the whole procedure involving pharmaceutical industry [39].

### 3.2. National policies and measures issued specifically for TCM

13 policies and measures aimed for the heritage and development of TCM specifically, among them, five policies were issued from State Council of PRC or the President from a nationwide guiding prospective.

3.2.1. National policies and measures issued specifically for TCM before the  $13^{th}$  five-year plan

The Plan of Protecting and Developing Chinese Medicinal Plants

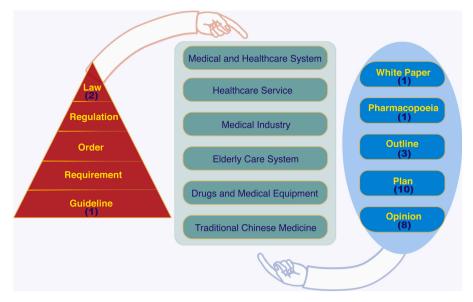


Fig. 2. Categories and relationship between different policies and measures and their guiding areas. The legal hierarchy are illustrated in the triangle from top to bottom. The other categories of the policies and measures are listed in the oval box. The numbers below each icon show the number of policies and measures in this category. The box in the middle contains six major areas involving TCM related policies and measures.

(2015-2020) was issued by the General Office of the State Council of PRC in April 2015 and further implemented by 12 related ministries. By 2020 this plan indented that: the protection and inspection system of Chinese medicinal plants should be basically completed, the scientific and technological level of Chinese medicinal plants should experience a significant increase, and an initial shape of a modern circulation system of Chinese medicinal plants should be formed [50]. The Plan of Developing Healthcare Service of Traditional Chinese Medicine (2015-2020) was published in April 2015 which was the first national plan on the development of TCM healthcare service aiming to improve the physical and mental health of Chinese people directed by the theory, method and techniques of TCM [51]. In February 2016, the State Council issued the Outline of the Strategic Plan on the Development of Traditional Chinese Medicine (2016-2030). This outline clarified the development direction and working focus of TCM development in the coming fifteen years which is a programmatic document pushing TCM development into a new era [21].

### 3.2.2. Traditional Chinese Medicine in China (White Paper)

The State Council Information Office published Traditional Chinese Medicine in China (White Paper) in December 2016, which was translated into several foreign languages including English, French, Russian, German, Spanish, Japanese, Arabic *etc.* The White Paper discoursed current process of TCM development in four aspects: the historical development of TCM, policies and measures on TCM development, carrying forward the tradition and ensuring the international communication and cooperation in TCM. This document raised the status of TCM to a higher level contributing to the economy progression in China [8].

### 3.2.3. Law of the People's Republic of China on Traditional Chinese Medicine

At the 25<sup>th</sup> meeting of the 12<sup>th</sup> National People's Congress Standing Committee on December 25<sup>th</sup> 2016, Law of the People's Republic of China on Traditional Chinese Medicine was approved which, for the first time, clarified the important status, development policies and supporting measures of TCM in a legal dimension. The Law of PRC on TCM has nine Chapters and sixty-three Articles focusing on five main aspects: clarification of the important status and developing policies, construction of the management system with TCM characteristics, promotion of the support to TCM industry, enhancement of the supervision to TCM

medical service and production & operation and increase in the penalties to illegal activities involving TCM [36].

# 3.3. Ministerial policies and measures on TCM development piloted by State Administration of TCM

During the same period, 8 policies and measures were issued by State Administration of TCM. As the state administration responsible for the regulation of TCM industry, the State Administration of TCM issued these policies and measures to further implement the orders from the state.

# 3.3.1. The Outline of the Medium-and Long-term Development Plan for the Standardization of Traditional Chinese Medicine (2011-2020)

Right after the 18<sup>th</sup> CPC National Congress in November 2012, the Outline of the Medium-and Long-term Development Plan for the Standardization of Traditional Chinese Medicine (2011-2020) was issued by State Administration of TCM. This document elucidated major tasks of the standardization of TCM in 5 different aspects including TCM theory and technology, TCM standardized system, TCM supporting system, the implementation and promotion of TCM and the international TCM standardization. By 2020, it aimed to construct a system of TCM standardization with relatively reasonable structure to fulfill the demand of TCM development [52].

# 3.3.2. The $13 { m th}$ Five-year Plan for the Development of Traditional Chinese Medicine

After the completion of the 12<sup>th</sup> five-year plan, the State Administration of TCM issued the 13<sup>th</sup> Five-year Plan for the Development of Traditional Chinese Medicine in August 2016 aiming to supply basic TCM healthcare service to all residents by 2020. This plan stated nine major tasks of TCM development including vigorous development of TCM medical service, rapid development of TCM healthcare service, strong encouragement of TCM heritage and innovation, enhancement of the professional team construction, rapid promotion of TCM culture, advancement of Chinese medicinal plants protection, expansion of the service forms of TCM, modernization of the governance system of TCM and active promotion of TCM development overseas [53].

# 3.3.3. The 13th Five-year Plan for the Development of Traditional Chinese Medicine Informatization

The  $13^{\mathrm{th}}$  Five-year Plan for the Development of Traditional Chinese Medicine Informatization issued in December 2016 stated key missions of providing information and technique supports for the enhancement of TCM healthcare service by building a TCM information platform, organizing a TCM application system, enhancing TCM medical information service, improving TCM healthcare bigdata development and promoting "Internet + TCM" service [54].

### 3.3.4. "One Belt, One Road" Plan of Developing Traditional Chinese Medicine

In order to open up a new pattern of TCM comprehensively, the State Administration of TCM and National Development and Reform Commission issued the "One Belt, One Road" Plan of Developing Traditional Chinese Medicine in the late December of 2016. This plan listed detailed missions of corporation with the countries along the silk road from a national strategic perspective for TCM promotion [44].

# 3.3.5. Implementation Opinions on Improving the Development of the Elderly Care Service

In March 2017, the State Administration of TCM issued the Implementation Opinions on Improving the Development of the Elderly Care Service, which clarified detailed implementation opinions on applying the theories, methods and techniques of TCM to provide the elderly caring service such as diseases prevention, physical and mental fitness maintenance, constitution improvement and disease treatment [55].

# 3.3.6. The 13th Five-Year Special Plan for the Scientific and Technological Innovation in Traditional Chinese Medicine

Then the 13<sup>th</sup> Five-Year Special Plan for the Scientific and Technological Innovation in Traditional Chinese Medicine was issued by the State Administration of TCM in May 2017 in order to push the scientific innovation of TCM from the protection of medicinal materials to the synthesis of TCM information platform [56].

# 3.3.7. Guiding Opinions Promoting the Technology Innovation in Healthcare Service of Traditional Chinese Medicine

In August 2018, the State Administration of TCM together with the Ministry of Science and Technology issued Guiding Opinions Promoting the Technology Innovation in Healthcare Service of Traditional Chinese Medicine in order to expand the healthcare service area that TCM could cover ranging from prevention, treatment to rehabilitation [38].

# 3.3.8. Guiding Opinions on Improving Science and Technology Innovation in Medical Devices Used for Traditional Chinese Medicine

At the beginning of 2019, four national ministries and commissions including the State Administration of TCM released Guiding Opinions on Improving Science and Technology Innovation in Medical Devices Used for Traditional Chinese Medicine in order to fulfil the technical requirements of TCM medical devices from the aspects of precision, integration, digitalization and intelligence [57].

### 3.4. The Pharmacopoeia of the People's Republic of China

The Pharmacopoeia of the People's Republic of China has always played a crucial part in promoting drug quality control, technology progression and product modernizations. Current Pharmacopoeia of the People's Republic of China 2015 edition is the 10th edition of Chinese Pharmacopoeia since the first edition in 1953 comprised of four volumes [32,33]. This edition of pharmacopoeia emphasizes on establishing the control requirements of drug safety and efficacy through referencing cutting-edge quality control technologies and experiences worldwide, as well as revealing existing pharmaceutical evaluation procedure. Comparing with the 9th edition, this edition recorded a significantly increased number of medicinal products, which contains a total of 5608

types of medicinal product, with 1082 new revisions. Volume I contains a total of 2598 types of medicinal materials and the prepared slices of Chinese crude drugs, vegetable, oil fat and extracts, single-item preparations, etc., including 440 new admissions, 517 new revisions and seven rejections. Volume II contains a total of 2603 types of chemical drugs, antibiotics, biochemical drugs and radioactive drugs, including 492 new admissions, 415 new revisions and 28 rejections. Volume III contains a total of 137 biological products, including 13 new admissions, 105 new revisions and six rejections. The standard system of this publication is also improved because it has consolidated common appendices of various volumes and renamed the original appendices into general requirements of preparations, testing method, standard substances, reagents and guiding principles. A standard coding system has been reissued and the general requirements and pharmaceutical excipients were separately concluded as Volume IV of the Chinese Pharmacopoeia. Moreover, this edition has expanded the application of new technologies and new methods to increase the sensitivity, specificity and stability of testing. Specifically for TCM, methods for DNA barcode molecular identification, pigment testing, fungal toxin testing, near-infrared spectrum and gene chip drug evaluation technology were established in this edition. More importantly, this edition emphasized drug safety issues including general requirements for medicinal materials and prepared slices of Chinese crude drugs, drug processing, pharmaceutical excipients, national standard drug substances etc. The guiding effect of pharmacopoeia has been strengthened from screening and adjustment of products to admission of advanced testing methods and formulation of technical guideline. By collaborating international drug quality control standardization and the realities of drug manufacturing in China, equal emphasis has been set to the safety and accessibility of medications. The ISO9001 quality management system has been introduced into the whole drafting process to ensure the quality of pharmacopoeia. Through increasing the authoritativeness and international influence of the Chinese pharmacopoeia, the Chinese Pharmacopoeia Commission aims to expedite a sound development of China's pharmaceutical industry.

### 4. Relationship between different policies

### 4.1. Timeline of TCM related policies (Fig.3)

The issue date is based on certain development stage of China that nearly 20 policies and measures were distributed in 2016 and 2017. From the chronic sequence of these policies, is it obvious to find out that the National People's Congress (NPC) of the PRC, the CPC National Congress and the Five-year Plan of the country inspired the issue of national policies regarding healthcare, which consequently determined the formation of TCM related policies and measures. Since the 13<sup>th</sup> Five-Year Plan could secure a decisive victory in finishing the building of a moderately prosperous society in all respects and making major breakthroughs in deepening reform, 7 policies and measures focused on the development of TCM in the 13<sup>th</sup> Five-Year Plan. At the same time, the reform of the Medical and Health System has a great advancing impact on the elaboration of TCM policies that the General Office of the State Council of the PRC would announce the key tasks in deepening the medical and healthcare system reform every year.

# 4.2. Authorities involving TCM related policies and measures (Fig. 4)

As the development of TCM covers diverse aspects of the country, including science, techniques, economy, culture *etc.*, a subsequent policy involving TCM would be issued to ensure its sound development in related field. This could further elucidate the crucial role and widespread coverage of TCM in people's livelihood. Because of the critical functions of TCM in enhancing the healthcare condition of Chinese people, most of the policies and measures discussed in this review are at a national perspective. Therefore, the authorities involving the

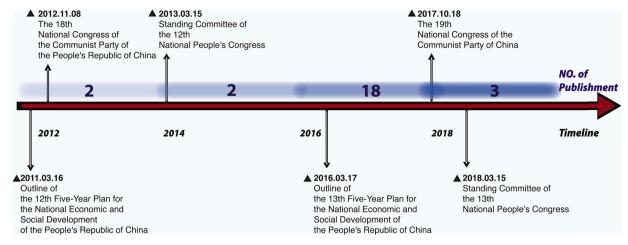


Fig. 3. Number of TCM related policies and measures displayed in timeline according to their publishing date. The timeline started from 12th Five-Year Plan for the National Economic and Social Development of the People's Republic of China in 2011 till now. Cornerstone events of China or the CPC party are titled in the timeline. The number of TCM related policies and measures in each 2-year-period is also displayed above the timeline.

statement of TCM related policies include the highest organ of state power the National People's Congress of the PRC and the subsequent governmental agencies including the Standing Committee of the National People's Congress of the PRC, the President of PRC, the State Council of the PRC, General Office of the State Council of the PRC, State Council Information Office of the PRC, and ministries and commissions under the State Council including State Administration of TCM of the PRC etc. together with the political bodies comprising the Central Committee of the Communist Party of China and the General Office of the Central Committee of the Communist Party of China. Based on this review, the authorities involved the largest number of policies and measures are the State Administration of TCM, General Office of the State Council of the PRC and State Council of the PRC regarding 8, 7 and 4 policies respectively. The State Administration of TCM took part in the

statement of 8 policies and measures owing to its direct responsibility in TCM related areas.

### 5. Implementation of TCM related policies and measures

The aim of these policies and measures on TCM development is to resolve the major obstacles met by TCM so as to improve the health status of Chinese people. The holistic characteristic of TCM could explicate its thriving impacts on a number of subsequent fields.

### 5.1. Implemental achievements in scientific field

Construction of a complete scientific framework of TCM has been a long-term goal for a breaking-through improvement in TCM, which is

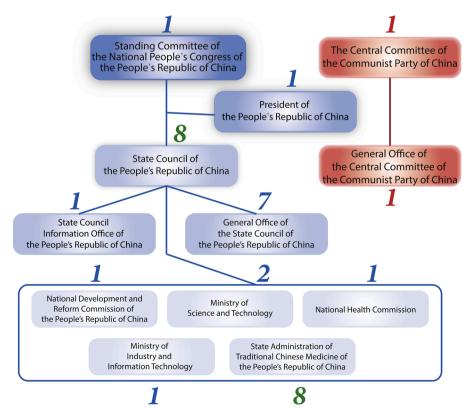


Fig. 4. Authorities involving in issuing TCM related policies and measure. The organs of state power are displayed in the blue icon from the highest Standing Committee of the National People's Congress of the People's Republic of China to the ministries. The political bodies of the Central Committee of CPC are listed in red icons. The number of related policies and measures of each authority is marked next to each icon. State Council of the People's Republic of China and State Administration of Traditional Chinese Medicine of the People's Republic of China have the largest number of TCM related policies and measures.

emphasized in a series of policies and measures. The reinforcement of an innovative platform, the cultivation of specialized scientists and the completion of information system are all decisive factors to ensure a scientific development of TCM. As a result, a wide range of scientific fields are offering solid supports for its innovation, standardizing and modernization. The innovation of TCM depends heavily on cutting edge technologies in biology, chemistry, medicine, information etc. A clear understanding of the biological and chemical principles behind TCM provides theoretical basis for database construction and further data analysis. For a more comprehensive implementation of TCM in prevention, diagnosis, treatment and rehabilitation, the combination of TCM and Western Medicine demands the transformation of TCM theory from the medical field into clinical practice. Another important task of TCM development, the standardization of TCM requires the collaboration with informatics and computational professionals for the establishment of a circulatory system starting from the medicinal plants to the production of Chinese patent medicine and the supply of TCM service. More specifically, corporation with agriculture and geography experts with modern cultivation techniques is necessary for the protection and development of Chinese medicinal plants. Recent trends of artificial intelligence and big data also inspires the investigation in wearable medical devices. The guiding opinions in the medical devices for TCM also encouraged the research and development of artificial intelligence embedded medical devices in TCM theory-based diagnosis, treatment and rehabilitation. Therefore, the effective implementation of TCM related policies urges an alliance of diverse scientific potencies.

#### 5.2. Implemental achievements in industrial field

On the industrial perspective, the supply chain of TCM is roughly composed of seven parts: Chinese medicinal herb growing, Chinese patent drug manufacturing, general hospitals, health clinics, medical supplies manufacturing, pharmacies and TCM hospitals. A variety of industries are helping to guarantee the proceeding of the measures including education, artificial intelligence, environmental protection, sports, endowment, insurance, rehabilitation services, etc [58]. For example, the promotion of TCM as an important componence of Chinese culture involves media, tourism and diplomacy. Moreover, the improvement of TCM healthcare service especially in the elderly healthcare system, infrastructure construction and the training of nursing assistants are crucial. The cultivation of high-level TCM professionals is the foundation of the heritage and innovation of TCM which advances the reform of education system with TCM characteristics. The completeness of the evaluation and management system of TCM drugs is also an important task for administrations and legal office at all levels. The special characteristics of TCM in diseases prevention also opened a wide market in healthcare products. The market size of healthcare products in China is expected to reach nearly 300 billion RMB in 2019 and the portion of TCM products is enlarging each year [59]. These facts have approved that a large amount of scientific and industrial partnership has involved in the extensive implementation of TCM related policies and measures by the supplements of both theoretical foundation and practical completion.

### 5.3. Local and worldwide implemental achievements

Detailed implementation of TCM related policies and measures have been carried out in local and international districts. For example, in December 2017, Beijing Association of Traditional Chinese Medicine published a series of classic courses on TCM to improve TCM education system. TCM professionals would share their own academic spirits and clinical experience by their seminars and books so as to promote the heritage of TCM [60]. Because of the widespread education institution of TCM, the number of licensed TCM clinical physicians is expanding overseas. Academician of Chinese Academy of Sciences Prof. Zhang noticed that 70% of the TCM clinical physicians overseas are foreigners

providing TCM service to patients of whom 70% are foreigners [61]. The innovation of TCM was realized by the combination of TCM with artificial intelligence that the first online TCM clinic was established in November 2017 in Zhejiang Province which could supply local patients with professional treatment all over China. Local implementation measures were also released on the strategic plan on the development of TCM such as Shanghai, Sichuan and Fujian Province [62–64]. Internationally, TCM has played an important role in the professionals, production and finance supply chain overseas especially along the "one-belt, one-road" countries [65,66].

### 6. Discussion and future perspectives

The development of TCM has achieved enormous progress after the 18<sup>th</sup> CPC National Conference. The primary reason is the emphasis and support from the National People's Congress and the Central Committee of the Communist Party of People's Republic of China. From the point of improving the healthcare status of Chinese people, central government and local regulatory departments issued a series of policies and measures. The strategic status of TCM has advanced significantly since the announcing of effective actions on TCM. Therefore, the innovation and heritage of TCM has experienced breaking through improvement including the Nobel Prize and the award for scientific and technological advancement. The system of TCM prevention, diagnosis and treatment has kept on completing and enhancing by the establishment of TCM hospitals from rural to urban areas. The prosperity of TCM treatment system has also brought the prosperity of industries related to TCM such as tourism, agriculture and the elderly care. The enhancement of TCM is not limited domestically, the overseas influence of TCM is expanding to a larger scale ever since. Foreign people are not only getting contact with Chinese culture by the introduction of TCM, but also adopting TCM as a therapeutic method. This meaningful period of time witnessed the renaissance of TCM to a higher level.

It is clear that with these achievements and opportunities of developing TCM also brought in a number of challenges. Although there exist large number of incentives for using TCM, China and other member states are facing several regulatory issues related to practices of TCM. The lack of research data about the mechanisms to control and regulate herbal products and medicines, the lack of expertise in national health authorities and control agencies, the lack of sharing information between different channels and the lack of educating and training of TCM practitioners etc. are all the difficulties to be considered. Most of these challenges have their corresponding strategic actions in the policies and measures reviewed in the article including the understanding and recognizing of the role of TCM, the construction of the generation and sustaining of TCM resources, the recognition of regulating the quality and safety of TCM products and medicines, the encouragement of TCM education, training and skills development etc. As for the detailed situations in China, current proportion of healthcare related production only occupies 5% of the gross domestic product (GDP) in China, which is only half of those in the developed countries [59]. With the implementation of Healthy China 2030 outlines, the healthcare related market size could be three times bigger than the present status. The major plans issued regarding the development of TCM are from different aspects and the crucial purpose is to establish a TCM healthcare service system embedded with technology and innovation. As the implementation of the Law on TCM, it is the opportunity of completing and improving the system and mechanism of TCM. The level of TCM healthcare service is expected to be increased to fulfill the medical care requirement of people across China. The innovation and heritage of TCM would still be supported by all-aspects collaboration according to the policies and measures. Starting from the material basis of TCM, the cultivation of medicinal plants affects the quality of subsequent TCM crude drugs and TCM patent drugs. More detailed regulations regarding quality control process of medicinal plants based on Drug Administration Law of the People's Republic of China should be formulated in the

future. A well-defined path is required to indicate the transformation from medicinal plants to TCM products or service in the future policies. The main tasks in the Outline of the Strategic Plan on the Development of Traditional Chinese Medicine (2016-2030) have included most of the key issues relevant to TCM such as the medical service, scientific innovation and industry transformation etc. but the more detailed management policies are still required for the development in each prospective. The overseas development and corporation of TCM with foreign countries would also enlarge the level and scale of TCM service. TCM culture should be widely promoted guided by the principle of creative transformation and innovative development. Most importantly, cultivation of a TCM talent team would serve as the foundation of TCM revitalization. By 2030, the TCM medical and healthcare service system could cover every community of China with modernized medical equipment, high-level professionals and safe & efficient TCM drugs. Consequently, with the prosperity of Chinese national power, TCM would be accepted all over the world not only as a carrier of Chinese culture but also as a medical science to prevent and cure diseases.

#### 7. Conclusion

The Central Committee of the Party together with the State Council and TCM administration departments have made great efforts on the renaissance of TCM. These policies and measures guide the principle of TCM development with detailed tasks in terms of healthcare, economy and culture. The implementation of these policies would contribute to a brighter future for TCM and benefit the well-being of mankind. In conclusion, people should have a strong faith in the reliability of TCM since the government is leading the administrators and experts to make every endeavor to support the development of TCM.

#### Author contributions

LL and BSS supervised all research and revised the manuscript. WYW, HZ and YFW collected information. WYW and HZ analyzed the data and prepared the manuscript.

### **Declaration of Competing Interest**

The authors declare no conflicts of interest.

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