

# Promotion of Standardization and Internalization of Traditional Chinese Medicine: Interpretation of Chapters in the 13<sup>th</sup> Five-Year Special Project for Scientific Innovation of Traditional Chinese Medicine

Editorial Board of Nursing of Integrated Traditional Chinese and Western Medicine

**ABSTRACT:** Traditional Chinese medicine (TCM) contains profound scientific connotation and has great potential in guiding the future development of bioscience, thus becoming the Chinese Treasure of Ancient Science and the Key to Open the Treasury of Chinese Civilization. 13<sup>th</sup> Five-Year Special Project for Scientific Innovation of Traditional Chinese Medicine has proposed to promote the standardization and internalization of TCM, including implementation of TCM standardized action, establishment of TCM standard system to complete system and adapt development requirements, establishment of a standard system for TCM that can complete system and meets the requirement of development to capture the advantages in international standardization competition, so as to seize the leadership and discourse power in the establishment of TCM international standardization; to promote the implementing great scientific TCM plan to accelerate the international registration of brand-name and high-quality TCM, expedite TCM service and products entering into international main markets of medicines and health care, propel the scientific cooperation and application of TCM in various countries along One Belt and One Road (B & R), and create Chinese standards and brands, so as to promote the TCM moving towards the whole world.

**KEY WORDS:** traditional Chinese medicine; standardization; internationalization; traditional Chinese medicine

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## Background

On May 12, 2017, it was proposed definitely in the 13<sup>th</sup> Five-Year Special Project for Scientific Innovation of Traditional Chinese Medicine [Guokeshefa (2017) No. 146] published by Ministry of Science and Technology of the People's Republic of China and State Administration of Traditional Chinese Medicine of the People's Republic of China<sup>[1]</sup> that more synergic, higher-efficacy and open system for scientific and technological innovation of traditional Chinese medicine (TCM) should be established until 2020 to resolve a series of critical scientific issues that inhibit the TCM develop-

ment, breakthrough a batch of key techniques that inhibit the TCM development, so as to accelerate TCM modernization and internalization, and promote the intelligent update of green industry of Chinese materia and medica.

TCM contains profound scientific connotation and has great potential in guiding the future development of bioscience, thus becoming the Chinese Treasure of Ancient Science<sup>[2]</sup> and the Key to Open the Treasury of Chinese Civilization<sup>[3]</sup>. The scientific connotation of TCM has been explored through scientific innovation to promote the generation and innovation of TCM, which is a significant strategy direction to realize TCM prosperity and de-

velopment, so as to promote TCM scientific innovation capacity, improve people's healthy level and the development of health industry. Of the strategies, 13<sup>th</sup> *Five – Year Special Project for Scientific Innovation of Traditional Chinese Medicine* has proposed to promote TCM standardization and internalization, which is interpreted as follows.

The special project has proposed to implement the TCM standardization action, establish a standard system for TCM that has complete system and meets the requirement of development, and capture the advantages in international standardization competition, so as to seize the leadership and discourse power in the establishment of international standardization for TCM, or to promote the implementation of great scientific plan of TCM, accelerate the international registration of brand-name and high-quality TCM, expedite the TCM service and products entering into international main markets of medicines and health care, propel the scientific cooperation and application of TCM in various countries along One Belt and One Road (B & R), and create Chinese standards and brands, so as to promote the TCM moving towards the whole world.

### Study on TCM Standardization

To emphatically conduct the development of guidelines for clinical practice of TCM (integrated Chinese and western medicines), the study on evaluation of using clinical technology standard of TCM, and the research and development of technical standards of TCM in prevention of diseases and rehabilitation, so as to promote the clinical technical level and service capacity of TCM, and ensure the safety and quality of medical treatment with TCM, thus playing the effects of TCM standards in the technical support and guidance.

#### Study on TCM basic standards

To enhance the study on the basic conditions and technical methods for the transformation of TCM practices and scientific and technical results into standards, and develop 50 – 80 basic standards like terms, common technical methods and information of TCM<sup>[4]</sup>.

### Study on evaluation of clinical technique standard of TCM

To launch a study on the key techniques in all steps in the application-evaluation-monitoring-feedback-persistent modification system for the standards of clinical diagnosis and treatment of TCM, and to form technical specifications for standard consistent test, application monitoring, and evaluation of feasibility and application efficacy, so as to improve the quality level and applicability of technical standards.

#### Research and development of technical standards of TCM in prevention of diseases and rehabilitation

To establish the methods, techniques and standards for the identification and classification of health status, establish standards for TCM interventions to regulate the healthy status of human body, and to develop the study on standardization of TCM rehabilitation techniques for cardio-cerebrovascular diseases, metabolic diseases and immunological diseases, and evaluate the outcomes of TCM rehabilitation to form effective protocols and clinical pathways<sup>[5-7]</sup>.

### TCM Standardization Action

To enhance the innovation of technical methods, increase the study level on quality standards of TCM, and develop and establish a batch of internationally and nationally recognized international standards, national standards and professional standards for TCM. To promote the quality standards of commonly used Chinese materia medica and TCM breeds related to internationally registered TCM products being included in *United States Pharmacopeia*<sup>[8]</sup> and *European Union Pharmacopeia*<sup>[9]</sup>.

#### Study on promoting quality standards of TCM

To enhance the basic study on quality standards of TCM, breakthrough critical techniques for validation of index ingredients of TCM pharmacological efficacy, analytic methods for evaluation of TCM quality, and micro-analysis of toxic ingredients of TCM, increase the whole study level of quality standards, develop study on modern quality

standards of 10-50 commonly used Chinese Materia Medica and decoction slices and 100 large-bred Chinese patent medicine, complete and perfect the system of quality standards of TCM, and establish modern methodological system for quality standards of TCM with integrality, scientificity and practicability, which strives for the aims of 50 exemplary quality standards of TCM being included into National Pharmacopoeia while 100 becoming the professional standards<sup>[10-12]</sup>.

#### **Study on internalization of quality standards of TCM**

The raw materials of 50 Chinese patent medicine products with high international recognition, large export share and planning of being internationally registered will be select to compile a monograph on their quality standards according to relevant technical requirements conforming to international main pharmacopoeia and international standard organization, such as *United States Pharmacopoeia*, *European Union Pharmacopoeia* and International Standard Organization (ISO). Meanwhile, the raw materials of 20 – 30 Chinese patent medicine products with planning of European Union traditional medicine registration will be selected to write a monograph on their safety and efficacy, which will be included in the lists of herbal monograph of European Medicines Agency (EMA) after they are audited by expert committee of EMA<sup>[13-14]</sup>.

#### **Study on Standardization of Acupuncture and Moxibustion**

To develop and revise a batch of standards for the application and instruments of acupuncture and moxibustion, which have great influence on the industrial development and can prominently promote the internalization of acupuncture and moxibustion, and to accelerate the transformation of national standards of acupuncture and moxibustion to the standards of ISO and World Health Organization (WHO), so as to ensure the leading position of national acupuncture and moxibustion in the competition of international standardization.

#### **Research and development of important technical standards for acupuncture and moxibustion**

To emphatically study the specifications for

clinical application of needling and moxibustion, establish guidelines for clinical application of common acupuncture and moxibustion techniques, such as moxibustion, electric acupuncture, fire needle, cupping, bloodletting, acupoint application, small needle-knife and knife needles; to establish the guidelines for about 50 clinical practices using acupuncture and moxibustion specific to diseases with improved symptoms, such as hypochondriac pain, tendovaginitis, varicosity, pain after ankle sprain, postoperative dysuresia, redness and pain of eyes, and odontalgia; and to establish 2 – 3 national and international standards for the terms and locations of acupoints on experimental animals like rats and rabbits<sup>[15]</sup>.

#### **Standards of instruments for diagnosis and treatment with acupuncture and moxibustion**

To emphatically establish the group and national standards for instruments of acupuncture and moxibustion, such as moxa for moxibustion, *Folium Artemisiae Argyi*, electric acupuncture, pyonex, fire needle, needle-knife and laser instrument for acupuncture and moxibustion, as well as ISO-established international standards for Detector for Diagnosis of Meridians and Collaterals and Infrared Moxibustion-mimic Therapeutic Apparatus, etc.

#### **Establishment of specifications for management and service of acupuncture and moxibustion**

To emphatically establish the group standards for acupuncture and moxibustion, such as the specifications for the management of continuous education of acupuncturists, the acupuncturists themselves, and the evaluation of techniques of acupuncture and moxibustion, and the international standards, such as specifications for basic service of outpatient of acupuncture and moxibustion and those of management of clinical quality security of acupuncture and moxibustion.

#### **International Registration of TCM**

To accelerate and propel the registration of large-breed TCM as traditional medicines or drugs in international main medical markets like America and European Union, so as to promote the interna-

tional prestige of TCM, and impel excellent products of TCM into international main medical markets.

#### **International registration of TCM as traditional medicines**

Brand-name and high-quality Chinese patent medicines with long history, definite efficacy and excellent capacity in treating complicated diseases in clinical practice will be selected to develop systematic study deeply according to corresponding laws and requirements of European Union traditional medicine registration, so as to realize the successful registration of 20 – 30 kinds of Chinese patent medicines as traditional medicines in EMA or European member countries<sup>[16–18]</sup>.

#### **International registration of TCM as drugs**

A total of 5 – 10 large-breed TCM with definite efficacy, large market share and profound basic study will be selected to conduct a systematic study on their safety, efficacy and quality standards according to corresponding laws and requirements of medical registration of Food and Drug Administration (FDA), EMA and European Union member countries, so as to enters international main medical market through drug registration in developed European and American countries.

#### **Internationalization of TCM**

To cooperate with advanced study institutes in foreign countries to conduct study on evaluation of international multi-center clinical efficacy as well as the evidence-based evaluation and recommendation of clinical study evidence, so as to form international specifications established by guidelines for clinical study implementation and clinical diagnosis and treatment using TCM, produce a batch of internationally recognized high-grade evidence-based proof, establish a batch of international guidelines for diagnosis and treatment for clinical practices, and further popularize TCM internationally, thus increasing the influence and recognition of TCM in international society<sup>[19]</sup>.

#### **International specifications for clinical study of TCM**

To study, establish and popularize the interna-

tional standards for the specifications of implementing TCM clinical study by using internationally recognized technical methods combing with the characters of TCM clinical study, so that TCM clinical study can be conducted following international specifications, consequently promoting the quality and reliability of TCM clinical study.

#### **International multi-center clinical evaluation study**

About 3 – 5 TCM therapeutic protocols that have certain working basis and can conduct clinical study in foreign countries will be selected to develop high-quality international multi-center clinical trials, striving for the inclusion of TCM into international guidelines for the diagnosis and treatment or revised guidelines of relevant diseases.

#### **The Belt and Road Strategy and TCM**

To firmly grasp the opportunity from the Belt and Road Strategy (B & R Strategy) is able to positively promote the internationalization of TCM by way of “going out”<sup>[20]</sup>. Linked by science, different promoting strategies will be established specific to the previous basis and cultural difference of TCM in different countries, in which the starting point should be highly concerned, and the strategies will be attempted by types steadily and promoted step by step.

To establish multiple study centers or combined experiments of TCM and ethnic medicines to develop international scientific and technological cooperation like combined research and development of products, protection of intellectual property of traditional medicines, and study on standards of cross-border ethnic medicines; to establish resource-protection platform and pilot scale experiment platform for herbal plants in B & R Strategy; and to promote the cooperation of protection application and theoretical study of relevant ethnic medical ancient works as well as the research and development of medical and healthcare products, cultivate a professional scientific research group for “Going out” of TCM, and to cultivate TCM scientific and technical talents in countries and regions with poor science and technology<sup>[21]</sup>.

## International Great Science Project for TCM

To establish theory of acupuncture and moxibustion under modern scientific semantic framework by displaying the internationally recognized evidences for clinical efficacy of acupuncture and moxibustion with great science study of acupuncture and moxibustion as precursor; to establish evidence for clinical efficacy that conforms to the specifications and standards for international diagnosis and treatment and enter into international guidelines for clinical drug administration focusing on TCM in prevention and treatment of serious diseases; and to accelerate the registration of TCM products in international main medical markets like USA and European Union following standard specifications, so as to promote the international prestige of TCM<sup>[22]</sup>.

### International multi-center clinical study on efficacy of acupuncture and moxibustion

Diseases that have definite efficacy using acupuncture and moxibustion, attack more frequently at home and abroad, but have poor efficacy using routine therapies will be screened to launch international multi-center large-scale randomized controlled study and case registration large-scale cohort studies using internationally common and recognized methods, so as to impact the establishment of international guidelines for clinical practice, thus promoting acupuncture and moxibustion into main medical system.

### International cooperation study on evaluation of clinical efficacy of TCM

About 1 – 3 TCM therapeutic protocols that have had clinical evidence-based evaluation proof, definite clinical efficacy, and have been specifically used in comprehensive hospitals or have been added on the basis of western medicines in China will be selected to conduct international cooperation study, so as to verify the efficacy and clinical value of TCM, and form a internationally recognized therapeutic protocol which will be included or supplemented into the international guidelines for the treatment of relevant diseases, thus establishing a

Chinese Protocol specific to clinical treatment with TCM.

### International scientific and technological cooperation study on theoretical connotation of TCM

To attract the powder of the best international study institutes embracing the great scientific issues of TCM, so as to develop high-level international scientific and technological cooperation study, strengthen the multi-disciplinary cross infusion, and jointly enhance the modern scientific study of theoretical connotation of TCM by fully using modern advanced techniques.

### International scientific and technological cooperation study on standards of TCM

To emphatically enhance the cooperation with the countries and regions in America and European Union, so as to jointly promote the study and establishment of international standards of TCM, establish internationally recognized TCM standard system, and accelerate the registration of TCM products in international main medical markets in American and European countries and regions, thus promoting the international prestige of TCM.

## Conclusion

The resolution of critical scientific issues and key techniques that inhibit the TCM development is critical in accelerating the modernization and internalization development of TCM, and promoting the intelligent update of green industry of Chinese materia and medica, for which effective strategies and protocols have been proposed in the 13<sup>th</sup> Five-Year Special Project for Scientific Innovation of Traditional Chinese Medicine to promote the standardization and internalization of TCM, so as to form international specifications and produce internationally recognized high-grade evidence-based proof to further increase the international influence, recognition and prestige of TCM.

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