



The regulation of Chinese medicine in China

Qingle Hu

School of Law and Social Work, Dongguan University of Technology, Dongguan, China

Correspondence to: Qingle Hu. School of Law and Social Work, Dongguan University of Technology, No.251, Xueyuan Street, Guancheng District, Dongguan, China. Email: matteoqlhu@163.com.

Abstract: The value of Chinese medicine is getting a higher and higher recognition in China in recent years. Especially in fighting the Covid-19, Chinese traditional medicine is proved to be effective. This paper is going to analyze the current situation of regulation and reality of acupuncture and Chinese medicine through researching the legal documents and other types of related documents. It can be found that while the performance of traditional Chinese medicine (TCM) technology is restricted to medical institution, there is an informal way for studying TCM knowledge and technology to be granted with a certificate for practice TCM, such as the training program for countryside doctors. As for improving the TCM service, a new rule is introduced in 2017 to normalize the TCM clinics. And the introduction of Marketing Authorization Holder (MAH) in medicine in 2019 improves the regulated measures for guaranteeing the safety and quality of medicine including traditional Chinese medicine, while the certificates of Good Manufacturing Practice (GMP) and Good Supply Practice (GSP) were cancelled by the new revision of the Drug Administration Law, the general responsibility of guaranteeing the safety and quality of the medicine are burden by the MAH. It is speculated that Chinese people are getting a higher level of acceptance of Chinese medicine for its function of healthcare.

Keywords: Regulation; traditional Chinese medicine (TCM); practitioner specialized in TCM; Marketing Authorization Holder (MAH)

Received: 10 December 2020; Accepted: 02 March 2021; Published: 30 March 2021.

doi: [10.21037/lcm-2021-001](https://doi.org/10.21037/lcm-2021-001)

View this article at: <http://dx.doi.org/10.21037/lcm-2021-001>

Introduction

In recent year, the regulation of Chinese medicine has made some great progress, especially after the promulgation of the Law of the People's Republic of China on Traditional Chinese Medicine (TCM Law hereafter). The value of traditional Chinese medicine gets a higher recognition in the official government. As article 3 of the TCM Law stipulates, "The TCM undertaking is an important part of the medicine and health undertaking of the state. The state shall vigorously develop the TCM undertaking, carry out the principle of giving equal emphasis to TCM and western medicine, establish the management rules in compliance with TCM features, and maximize the role of TCM in the medicine and health undertaking of the state (1)". As a result, there is a trend of standardizing TCM with deregulation in the practice of TCM.

In fighting the Covid-19, TCM has proven to be effective. And in April 2020, Lotus Qingwen Capsule, a kind of non-prescription TCM is granted to newly increase a function of treating Covid-19 in a regular way.

Another great progress for the regulation of Chinese medicine is the introduction of Drug Marketing Authorization Holder (MAH hereafter) System by the new revision of Drug Administration Law of People's Republic of China (DAL hereafter) in August 2019 (2). Meanwhile, the certificates of Good Manufacturing Practice (GMP) and GSP were cancelled, and the general responsibility of guaranteeing the safety and quality of the medicine are falling on the MAH.

This article is going to introduce the regulation of Chinese medicine in China from three perspectives: (I) regulation and reality of studies in acupuncture and Chinese medicine; (II) regulation and reality of the professional

practice of acupuncture and Chinese medicine; (III) regulation and reality of Chinese phytotherapy. I present the following article in accordance with the guideline checklist.

Regulation and reality of studies in acupuncture and Chinese medicine

Generally speaking, there are three ways for studying acupuncture and Chinese medicine: (I) at regular medical school; (II) with a teacher who has enough experiment or professional qualification; (III) by special training programs for countryside doctor.

In China, the regular medical school is divided into three types of academic qualifications. The highest level comprises of the universities or colleges of Chinese medicine, and medical college in the comprehensive universities, which have the qualification to award the students bachelor degrees in TCM; and the second highest level is the junior college of medicine; the lowest is the technical secondary school, in which provide study opportunity so-called vocational education for the students graduated from the junior high school but not go for the high school.

According to the Medical Practitioner Law of People's Republic of China (MPL hereafter), students with different level of educational background are differential in their careers. Students with a medicine bachelor degree could join directly the exam for medical practitioners after they finish the one-year internship in institutions of medical treatment, healthcare or disease prevention, while the students holding the education background in junior college, as well as the student holding the education background in a technical secondary school could only join the exam for assistant medical practitioners. With the certificate of assistant medical practitioner, to join the exam for medical practitioner one needs a further two-years practice in such institution for the students holding the education background in junior college, which is 5 years for the students holding the education background in junior college (3).

Secondly, studying acupuncture and Chinese medicine from a teacher is lawful confirmed by several legal documents, such as TCM Law, MPL and Rules on Exams and Assessments of Medical Doctor for Apprentices and Personnel with Speciality in Traditional Medicine, etc. The apprentice who fulfills a 3-year study is eligible to apply for a certification, and join the exam for assistant

medical practitioners with another one year's internship in relevant institutions (4). From 20th December 2017, the apprentice who fulfills a 5-year study is eligible to apply for the Certificate of Qualification of Doctor with Speciality in Traditional Medicine, and practice after he/she registers in the competent authorities (5). To be noticed, the teacher supervising the apprentice should reach the following technical qualification: (I) holding the certificate of doctor in traditional medicine or ethnic medicine; (II) owning at least 15-year clinical work experience, or a professional qualification to serve as a deputy dean in traditional medicine or ethnic medicine. The teacher and the apprentice should sign a standard form of contraction drafted by the National Administration of TCM (3).

Statistics shows that until 2015, there were 17 universities in TCM and 25 independent TCM college throughout the country, and more than 200 universities in Western medicine or non-medical universities offering programs in TCM, enrolling as many as 752,000 students. In the course of implementing the program of training professionals for inheritance and innovation in TCM, efforts have been made to conserve and disseminate the academic ideas and practical experience of the fifth batch of prominent TCM experts. By 2015, 1,016 studios had been set up for carrying forward their expertise; 200 studios had been set up for passing on the expertise of prominent TCM experts at the grassroots level; 64 studios had been established for promoting various schools of TCM (6).

The third way of studying acupuncture and Chinese medicine is to join the program organized by the competent authorities, the purpose of which is to train doctors for serving in the countryside, however, with no qualification of assistant medical practitioner or medical practitioner. This type of doctors can be traced back to the middle of the last century in China, at which time the undeveloped China had no enough medical resource to allocate to the countryside, so a special group of doctors who did not have a medical practitioner certification was created, which were called "barefoot doctors" before. However, their titles were changed to "Countryside Doctor" in 1985, and in 2004, the Regulation on Administration of Countryside Doctor is enacted to regulate the performance of Countryside Doctors. A Certificate of Countryside Doctor could be granted if they fulfill the training program, although they have no qualification of assistant medical practitioner or medical practitioner. What they need to do for keeping their certificates is to join the training held by the competent authorities every two years and pass the training exam. To

be noticed, no new Countryside Doctor will be granted to practice in the countryside from the publication day of the Regulation on Administration of Countryside Doctor (7).

It is believed that the “barefoot doctor” was encouraged to use TCM instead of western medicine (8). In fact, the central government does emphasis on the importance of learning and practicing the TCM knowledge today, and encourages the Countryside Doctors to do so (7,9).

Regulation and reality of the professional practice of acupuncture and Chinese medicine

The professional practice of acupuncture and Chinese medicine should be performed by the practitioners holding the certificates, saying the certificate of practitioner or assistant practitioner specialized in TCM, Certificate of Countryside Doctor, Certificate of Doctor with Speciality in Traditional Medicine, and performed in medical institutions, otherwise their practice is likely to commit the crime of illegal medical practice.

The practitioners or assistant practitioners should practice in accordance with their certificates in which they are registered with the content of the administrative areas of practice, types of practice and scopes of practice (3). The practice of Chinese medicine is one type of practice registered by the certificate (10).

To be noticed, the registration for practice of Chinese medicine should apply to the local competent authority of TCM, others should apply to the local competent authority of medicine (10).

And the practitioner is entitled to apply for independent practice after serving in medical institutions, healthcare and diseases prevention for more than 5 years (3). While the assistant practitioner should practice under the supervision by the practitioner, and can only practice independently in medical institutions, healthcare and diseases prevention located in the countryside or small towns depending on the local situation or necessary (3).

The similar restriction is also implemented in countryside doctors and Doctors with Speciality in TCM. The countryside doctor is only entitled to practice in the country clinic for healthcare, disease prevention and some general medical services (7), such as primary diagnosis of disease, basis diagnosis and treating of common diseases and frequently-occurring diseases, including recovery guidance and nursing services; first aid for severe cases and its transfer service; transfer service for infectious disease and suspected cases (11). It is worth to know that the countryside doctors

who possess TCM knowledge and recognition capability are encouraged to grow and pick genuine regional by themselves and use them in practice activities according to the relevant regulations (1).

The Doctors with Speciality in TCM are entitled to practice independently in accordance with their registering scope of practice in the registering area (5). The scope of Doctor with Speciality in TCM could be divided into several kinds: doctor with speciality in internal medicine, doctor with speciality in external treatment, or their combination in the way one is predominant and the other is auxiliary. The defined scope is confirmed by the experts in the assessment. Their professions need to be reassessed every two years.

All the practitioners with certificates should practice in legal medical institutions, for example general hospital, TCM hospital, clinic or private clinic. Otherwise, they may face administrative punishment. From 20th December 2016, the practitioners who hold certificates but practice outside the legal medical institution are no longer committing the crime of illegal medicine practice for the judicial interpretation was introduced by the Supreme Court of People's Republic of China (12).

In fact, not all the external treatment which comes from TCM should be practiced by the practitioners with license in legal medical institution. Nowadays, there are lots of Chinese medicine healthcare and recuperation halls in the business centers or streets. They provide some services such as GUASHA, massage, moxa-moxibustion or meridian detoxification, while some of the external treatment with traumatic, invasive and dangerous technical measures such as the acupuncture and cupping (Bahuoguan), are banned from practice in these halls (13). In case the abovesaid banned external treatments are practiced, the so-called Chinese medicine health care and recuperation halls need to register as what a medical institution requires to do. The requirement for registering a smallest TCM medical institution so-called TCM clinic is going to present.

The TCM clinic is one type of common medical institutions which mainly used Chinese traditional treatment including Chinese medicine, acupuncture, cupping (Bahuoguan), Tuina (14). There are two kinds of TCM clinic, one is the TCM General Clinic requiring 85% of the treatment using Chinese traditional treatment, the other is TCM Clinic requiring 100%. Both clinics only need to be filed for registration with the local competent authority for TCM before operation (14). At least one practitioner specialized in TCM who has more than

3 years' experience for practice or one registered doctor with speciality in TCM should serve in the TCM Clinic, while for the TCM General Clinic the practitioners specialized in TCM requires more than 2 years' experience. In addition, it is necessary for the clinics to assign with a corresponding eligible technician at least, if they provide medicine with prepared slices of Chinese crude medicines.

Regulation and reality of Chinese phytotherapy

Chinese Phytotherapy has a long history for thousands of years. It is believed to have originated from the Huangdi Neijing and Shennong Bencao Jing which are the collections of knowledge of Chinese phytotherapy. And from generation to generation, these knowledge and experience is used and practiced in their daily life. Thus, it is hard to draw a clean boundary to what extent phytotherapy could only be practiced by the professional practitioners unless the regulatory departments introduce the relevant legal documents. The phenomenon of the homology of Chinese medicine and food is a persuasive case.

The Chinese phytotherapy is usually practiced in two ways, saying as internal or external treatment. Usually, the consumer will go to the pharmacy with the prescription from the TCM practitioners to buy the prepared slices of Chinese crude drugs (literally in Chinese: Zhong Yao Yin Pian) for treating their illness or healthcare. These prepared slices will be used for internal or external treatment after preparing a decoction. Usually, the prescription comes from the TCM practitioners, especially those who own a good reputation as old TCM practitioners (old means reputation and age here, we believe old practitioners have more experience thus higher professional skills).

In fact, there are some non-prescription prepared slices which used frequently in daily life could be sold without prescriptions, the competent authorities will publish the catalogs for prescription and non-prescription medicine which are binding for all activities concerning medicines. This is also the same case for TCM preparations. Many TCM preparations for treating of common diseases and frequently-occurring diseases are non-prescription medicines that could be freely sold and bought.

In order to better carry out the phytotherapy and develop the initiative and expertise of the medical institution, the medical institution can request the approvals from the competent provincial departments to make preparation products as prescription medicine for the patients (2). Usually, the TCM hospitals make Chinese materia medica

preparation as prescription medicines for the local patients. However, they could only provide the preparation products which are not supplied in the market, and they are not allowed to provide TCM injections (15).

The quality of the medicines is very important for Chinese phytotherapy. Thus, there are strict rules for guaranteeing the quality of Chinese crude medicine, prepared slices of Chinese crude medicine and Chinese medicine preparations.

For the Chinese crude medicine (literally Zhong Yao Cai in Chinese), prepared slices of Chinese crude medicine and Chinese medicine preparations (literally Zhong Cheng Yao in Chinese) which are listed in the Pharmacopeia of People's Republic of China (Pharmacopeia hereafter) should conform to standards and producing standards stipulated in the Pharmacopeia. For those not listed in the Pharmacopeia, they may need to meet the binding requirements listed in other national standards or provincial standards. The new Pharmacopeia 2020 collects 9,585 kinds of Chinese medicine preparations, and 1,252 kinds of a total amount of Chinese crude medicine and prepared slices of Chinese crude medicine (16).

Chinese crude medicine is also regarded as a type of agricultural products and the farmer's market can sell Chinese crude medicines freely. As a result, the Chinese crude medicine should meet the requirement for agricultural products. Because Chinese crude medicine is the original materials for all TCM medicines, experts strongly approve that all Chinese crude medicine should be produced by the producers with a Certificate for Producing Medicines (17). The competent authorities introduced the Good Agricultural Practice (GAP) for Chinese crude medicines and opened for applying GAP certificate, even though it is not compulsory for the producers, however, it is cancelled in March 2016 (18).

GMP and GSP should be abided by the producers and distributors for producing and selling prepared slices and Chinese medicine preparations, although from 1st December 2019, the producers and distributors do no longer need to apply for the GMP and GSP certificates. The MAH system is introduced by the new Drug Administration Law, the qualities of the prepared slices and Chinese medicine preparations are responsibility of the MAH.

Level of acceptance by the population

Health is a hot issue nowadays in China. At the end of 2019, Jinri toutiao, one of the most popular new media,

published the Data Analysis of Health in 2019, it is said that 35 million people read information related to healthy every day in 2019, which is 60.7% more than that in 2018 (19). And in 2018, the traditional Chinese medicine matrimony and ginger, and the traditional way for healthcare named Paojiao is listed as the 10 top keywords in the Data Analysis of Health (20). As Chinese medicine is known for its effect in healthcare and prevention of disease, it could be inferred that Chinese medicine is getting a high level of acceptance by the population.

In addition, there are some official data that could also be the proof to indicate the level of acceptance of Chinese medicine in China. The relevant data published by the China's State Council Information Office shows that, until the end of 2015, "there were 3,966 TCM hospitals across the country, including 253 hospitals of ethnic minority medicine and 446 hospitals of integrated Chinese and Western medicine; there were 452,000 practitioners and assistant practitioners of TCM (including practitioners of ethnic minority medicine and integrated Chinese and Western medicine); there were 42,528 TCM clinics, including 550 for ethnic minority medicine and 7,706 for integrated medicine; there were 910 million visits that year to TCM medical and health service units across the country and 26,915,000 inpatients treated (6)". Other statistics present a more visualized phenomenon of the level of its acceptance—"The medical care services provided by TCM institutions in the national total increased from 14.3 percent to 15.7 percent in the few years from 2009 to 2015 (6)". It seems that patients are prefer western medical institutions, and Chinese medicine is still not in a higher level of acceptance for treating diseases, on the contrary its function for healthcare is confirmed.

As an observer living in China, the author believes that the acceptance of Chinese medicine is going higher and higher these days. We can see that there are more and more TCM clinics and Chinese medicine healthcare and recuperation halls in the business center and streets.

Acknowledgments

Thank you so much for the invitation by Dr. Ramon M^a Calduch and his encourage for me to prepare this article. For the information what I need to finish this paper, Vicky Wong gave me a kind help. And thanks for *LCM* Journal accepting me as an invited author, so I could take the chance to furtherly research in this topic.

Funding: None.

Footnote

Provenance and Peer Review: This article was commissioned by the Guest Editor (Ramon Calduch Farnòs) for the series "Regulation of Chinese Medicine in the Different Countries of the World" published in *Longhua Chinese Medicine*. The article has undergone external peer review.

Conflicts of Interest: The author has completed the ICMJE uniform disclosure form (available at <http://dx.doi.org/10.21037/lcm-2021-001>). The series "Regulation of Chinese Medicine in the Different Countries of the World" was commissioned by the editorial office without any funding or sponsorship. The author has no other conflicts of interest to declare.

Ethical Statement: The author is accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Open Access Statement: This is an Open Access article distributed in accordance with the Creative Commons Attribution-NonCommercial-NoDerivs 4.0 International License (CC BY-NC-ND 4.0), which permits the non-commercial replication and distribution of the article with the strict proviso that no changes or edits are made and the original work is properly cited (including links to both the formal publication through the relevant DOI and the license). See: <https://creativecommons.org/licenses/by-nc-nd/4.0/>.

References

1. Law of the People's Republic of China on Traditional Chinese Medicine issued by the Standing Committee of the National People's Congress on 12-25-2016.
2. Drug Administration Law of People Republic of China issued by the Standing Committee of the National People's Congress on 08-26-2019.
3. Medical Practitioner Law of People's Republic of China issued by Standing Committee of the National People's Congress on 08-27-2016.
4. Rules on Exams and Assessments of Medical Doctor for Apprentices and Personnel with Speciality in Traditional Medicine issued by Health Department on 12-21-2006.

5. Interim Measures for Assessment and Registration of Doctor for Personnel with Speciality in Traditional Medicine issued by Health and Family Planning Commission on 11-10-2017.
6. White Paper of Traditional Chinese Medicine in China issued by Information Office of the State Council on 12-06-2016.
7. Regulation on Administration of Countryside Doctor issued by State Council on 08-05-2003.
8. Blakeney M, Cheung C. Protecting Traditional Medicinal Knowledge to Promote the Economic Interests of the State. *European Intellectual Property Review* 2018;40:775-83.
9. Opinions on the Implementation of Further Improving the Building of the Group of Countryside Doctor issued by the General Office of State Council on 03-06-2015.
10. Rules on Administration of Registration for Practitioner issued by Health and Family Planning Commission on 02-28-2017.
11. Interim Rules on Administration of Countryside Clinic issued by the Health and Family Planning Commission on 06-03-2014.
12. The Supreme Court's Decision on Amendment of the Interpretation of Several Issues on Implementing Laws Hearing the Crime of Illegal Medical Practice on 12-12-2016.
13. Reply of the Office of the National Administration of Traditional Chinese Medicine on Fire Therapy Projects Carried Out by Non-medical Institutions issued by General Office of National Administration for TCM on 05-15-2018.
14. Interim Rules on Administration of Record for TCM Clinic issued by the Health and Family Planning Commission on 09-22-2017.
15. Interim Rules on Administration of Registration for Preparations made by Medical Institutions issued by Chinese Food and Drug Administration on 06-22-2005.
16. Lan F, Hong X, Song Z, et al. Overview of the Chinese Pharmacopoeia 2020 Edition. *Drug Standards of China* 2020;21:185-188.
17. Sun Xiaohui, Tan Ronghua. Analysis of Countermeasures on the Current Situation of Traditional Chinese Herbal Medicine Market Supervision. *Vocational Technology* 2019;11:105-8.
18. Council State's Decision on Cancelling 13 Items of Licensing in the Departments issued by the General Office of Council State on 02-03-2016.
19. Available online: <https://www.jiemian.com/article/3733936.html>. Last log on 08-29-2020.
20. Available online: <http://society.people.com.cn/n1/2018/1201/c1008-30435757.html>. Last log on 08-29-2020.

doi: 10.21037/lcm-2021-001

Cite this article as: Hu Q. The regulation of Chinese medicine in China. *Longhua Chin Med* 2021;4:7.