

Development of traditional and herbal Chinese medicine (chemical and biochemical perspectives) with emphasis on legal systems

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Many chemical and biochemical mechanisms from herbal plants have been well known in China for example anti-oxidant or anti-cancer effects but lacking in legal construction of herbal or Traditional Chinese Medicine (TCM) is obvious in compared with its significance in Chinese public health care. Legislation and implementation of Traditional Chinese Medicine Law can accelerate greatly the construction of TCM legal system. At present, the legislative body is proactively bringing forward the legislation of TCM Law. TCM legal construction will be progressed to a great extent to form TCM legal system. Systematic construction is the basic development trend in China's TCM legislation. Current laws and regulations along with TCM Law (Draft) under review by legislative body, have exhibited several principles and basic content units for future construction of TCM legal system. With rapid growth of medical and pharmaceutical of herbal plants, it is need to legislate proper rules for achieve to effective applications and also more bio-ethics.

Keywords: Medicinal plants, Traditional Chinese Medicine (TCM), Chemical and Biochemical perspectives, Law, Development Trend

INTRODUCTION

TCM is representative of the great traditional Chinese culture, which impacted significantly over thousands of years on the procreation and development of Chinese people. As a part of public health care, TCM is also on the track of legalization little by little^[1-8]. A comprehensive legal system is required for the development of TCM cause, and it is a compulsory historical mission for Chinese legislators and academia. In recent years, TCM legal system is developing at an increasingly rapid pace.

As a basic law for TCM industry, TCM Law can lead the construction of TCM legal system after enforced. It is indispensable to study further the fundamental issues on construction of TCM legal system. In this text, Traditional Chinese Medicine Law of the People's Republic of China (Draft) is to be interpreted, and current TCM-related laws and regulations are to be organized and analyzed, whereby to form an analysis on the development trend of TCM legal system construction, and therefore to give more advice on the improvement of legal system.

Review on Current TCM legislation

In a society of rule of law, any social business is not regulated by a single law, but a relatively comprehensive system comprising multiple laws, regulations and normative documents. China has not

yet formulated TCM legal system, but some legal norms for TCM industry development. It is by the relatively loose combination between these legal norms that TCM industry is regulated lawfully.

Organization of Relevant Current Laws

As per retrieval and collection of public network and government sector websites, it can be concluded that TCM-related laws and regulations have reached a considerable scale, and formed a basis for the construction of legal system intended to regulate the entire TCM industry.

MATERIALS AND METHODS

The materials studied in this paper are derived from the laws enacted by State Legislative Branch as well as the normative documents published in the official website of National Health and Family Planning Commission of PRC (<http://www.nhfpc.gov.cn/>), China Food and Drug Administration (<http://www.sda.gov.cn/> / WS01 / CL0001 /), State Administration of Traditional Chinese Medicine (<http://www.satcm.gov.cn/>) and other government departments. Find out the development tendency of traditional Chinese medicine legislation by analyzing laws of regulations and normative documents.

By the end of 2015, the construction of TCM legal system is in the following basic condition:

Laws Promulgated and Enforced by National Legislative Body:

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12 laws are directly associated with TCM industry (two of them) :

No.	Name of Law	Date of Promulgation
1	Law of the People's Republic of China on Medical Practitioners	Jun 26, 1998
2	Drug Administration Law of the People's Republic of China	Sept 20, 1984

19 laws are partially associated with TCM industry (two of them):

No.	Name of Law	Date of Promulgation
1	Constitution of the People's Republic of China	Dec 4, 1982
2	Standardization Law of the People's Republic of China	Dec 29, 1988

Administrative Regulations Promulgated by the State Council:

2 regulations are special ones on TCM:

No.	Name of Administrative Regulation	Date of Promulgation
1	Regulations of the People's Republic of China on Traditional Chinese Medicine	Apr 7, 2003
2	Regulations on Species and Varieties of Traditional Chinese Medicine Drugs	Oct 14, 1992

26 administrative regulations are closely relative to TCM industry(three of them):

No.	Name of Administrative Regulation	Date of Promulgation
1	Measures of the People's Republic of China for Health Supervision at Frontier Ports	Dec 30, 1981
2	Regulations on the Administration of Sanitation at Public Places	Apr 1, 1987
3	Regulations of the People's Republic of China on Prevention and Treatment of Pneumoconiosis	Dec 3, 1987

26 Local Regulations Formulated by Local Governments

In addition to the above laws and regulations, up

to 200 departmental rules regarding TCM industry have been promulgated successively by competent authorities such as National Health and Family Planning Commission, State Administration of Traditional Chinese Medicine, and China Food and Drug Administration, etc.

RESULTS AND DISCUSSION

Characteristics of Current TCM Legal System

Firstly, in respect of the contents, current TCM laws and regulations have involved treatment, healthcare, research, education, industry, culture, etc.^[5-8], showing an embryo TCM legal system to regulate the industry.

Secondly, in respect of legal level, there were three distinct levels, i.e., law, administrative regulation, local regulation, which are also the three levels of Chinese law.

Thirdly, in respect of the progression of legal construction, from 21st century, the construction of TCM legal system is apparently speeding.

Deficiency of Current TCM Legal System

Incomplete System

A complete legal system is to be based on constitution and to consist of laws, administrative regulations, local regulations, rules and other normative documents, wherein laws is positioned as the core. From the statistics aforementioned, it can be inferred that relevant issues on TCM industry have been provided in other laws, but not in a "Traditional Chinese Medicine Law" or "Traditional Medicine Law". Since there has always been a lack of a law specifically regulating traditional medicine industry, there is no "basic law" on TCM industry.

Negligence of TCM Industry Features

TCM has its own principle of development, which shall be observed, and only by the actual situation of TCM should laws be made to propel TCM into rapid healthy development^{[2][4]}. Large numbers of current laws and regulations, on the contrary, are based on criteria and standards of modern medicine, which provide TCM related issues sparsely in other special laws or regulations. Consequently, current legislation is inadequate to the fulfillment of promotion and protection of TCM industry, even on some level inhibit its development^[6].

Indistinct Definition of Regulatory Scope

On the grounds that administrative regulation and departmental rules are more intended to standardize and regulate concrete issues, not to analyze or bound fundamental concepts or scopes in the industry, some basic issues have not yet been clarified in terms of

TCM. By way of illustration, no laws have provided the scope of "TCM" in the concrete.

Systematic Construction as the Development Trend of TCM Legislation

In the context of extensive construction of a society of rule of law, no industry can be completely covered or regulated merely by a single law or several regulations, which entails a whole legal system, as is the case with TCM industry.

Factual Basis of TCM Legal System

Social demand is the primary basis and also an indispensable incentive for legal construction. Since the founding of PRC, there has been a progress in service, healthcare, education, research, culture and industry, etc. of TCM. An unprecedented opportunity offered for TCM development especially during the implementation of 12th and 13th five-year plan, where TCM received full recognition from society. The full development of TCM industry has brought forth unprecedented demand which laid the social foundation for TCM legal system construction.

Leading Role of "Basic Law" Enforced In the Industry

Law is the core of a legal system for an industry. China is striving for TCM Law, which is intended to be promulgated and enforced recently. TCM Law will immediately fill the gap in "basic law" in TCM legal system. Such a TCM Law is to be a radical implication for the foundation of whole legal system, whereby other regulations are amended and modified to make a compatible "Set of Laws and Regulations" premised thereon, so that an embryo of TCM legal system is brought in.

Promotion of Legal System Construction by Academic Research

Academic research is the prerequisite and basis for legislation, which deserves more attention than it had always received. Over the last decade, the formulation of TCM Law by legislature brought TCM legal construction to more attention from academia. TCM and legal academia are increasingly progressing the joint study on TCM legal construction, a discernible boom is arising in legislative and statute study.

Three Principles of TCM Legislation

Based on "TCM Law (Draft)" and implementation of administrative and local regulations concerning TCM over recent years, three fundamental principles could be drawn. In the meantime, these are the major ideology of Chinese TCM legislation in a future period. And we can have these principles ready to

hand when deciding the trend of TCM legislation.

Functional Position of Legal System as Support and Promotion

For any industry, the legal system regulates, restricts, ensures and boosts it. The emphases of legislative values will differ according to industries and the specific stages in their development. From the status quo, it can be inferred that the emphases of legislative values of TCM will remain ensuring and promoting development of TCM industry. TCM Law (Draft) under review by national legislature reflects this principle.

More Clear Definition of TCM

From the academic perspective of medicine, traditional medicine in China comprises traditional Chinese medicine and minority medicine. There are meanwhile several minority medicines besides TCM, such as Tibetan medicine, Mongolian medicine, Uighur medicine, Dai medicine, Zhuang medicine, etc., which are collectively referred to as ethnic medicine or minority medicine. Notwithstanding TCM is not yet clearly defined from a legal perspective. In general, laws in effect presently do not adopt "TCM" as a term, but instead "traditional medicine", "traditional physic", etc. (Note: e.g. the Constitution of the People's Republic of China provides in Article 21, "China supports medicine and hygiene, along with modern medicine and traditional medicine..."; Drug Administration Law of the People's Republic of China provides in Article 3, "China supports modern drugs and traditional drugs...".) On the contrary, the industrial administrative regulations, i.e. Regulations of the People's Republic of China on Traditional Chinese Medicine adopted distinctly "TCM" as a term, which is defined almost the same way as "TCM" in medical academia; Therein are adopted "TCM.

Legal Promotion of TCM Modernization

As always, TCM is perceived as traditional medicine, which is more inherited than reformed by the masses who is even suspicious of the hybrid of modern technology and TCM. It has to be understood that TCM is not only traditional but also modern. Legal system construction shall ensure healthier development of TCM in modern society^[7].

Basic Modules of TCM Legislation

TCM cause involves medicine, healthcare, education, scientific research, culture, industry, etc. In respect of the contents, the law shall contain some aspects as basic modules, which are to be intertwined to form the skeleton contents of TCM legal system. In regard to TCM Law (Draft) under review by

legislature, these modules are gradually discernible, namely TCM medical service, TCM drug, TCM education, TCM scientific research, TCM inheritance and culture diffusion.

TCM Medical Service

Medical service represents TCM cause to the most significant extent, and is the core of TCM legal contents. As far as legal construction is concerned, provisions in relation to TCM medical service shall comprise three major aspects:

Firstly, clarify the position of TCM medical service. TCM medical service are carried out and constantly progressing on the fundamental basis of definite legal position. Secondly, construct TCM medical institution. China will encourage and support social powers to found TCM medical institution, which is largely benefit to the development of TCM medical institution. Thirdly, quicken the qualification of TCM service provider. In addition to qualification by medical licensing examination, people with TCM inheritance from mentor and actual skill are entitled more specifically in law to take examinations on practical skill and efficacy, by which to qualify as medical practitioner.

TCM Drug Protection and Development

As the most important means of treatment, TCM drug is inseparable from TCM. The law is in particular more protective of the quality of TCM drugs and the planting of TCM drugs. Moreover, evaluation system of genuine regional drug is to be established, where the market repute and value is maintained by encouraging use of geographical marks etc. for genuine regional drug of good quality. The distribution system of TCM drugs will be set up subject to more specific requirements^[4].

In reference to the two traditional administration method, i.e., TCM decoction pieces and in-house TCM formulation by medical institution, China will set forth more systematic way of management. The law is to allow distinctly for reprocessing of TCM decoction pieces by medical institution. It is unambiguously specified that TCM medical institution can commission drug manufacturer to produce in-house TCM formulations. Such provisions will empower TCM medical institution to use more flexibly and widely TCM decoction pieces and in-house TCM formulations.

Considering the contents of TCM Law (Draft), it has been more clarified that research and development and manufacture of TCM investigational new drug is encouraged and supported on a national basis. Apart from the protection of traditional technique and craft for TCM drug

processing, as well as the promotion of manufacture of TCM patient drug in traditional dosage form, it is encouraged that TCM patient drug be researched and developed by modern science and technology.

TCM Education

Perfect TCM education system lays the prerequisite and foundation for nurturing TCM experts. TCM education is an integral part of national educational cause, which is on a fundamental basis regulated by education-related laws and regulations. Thus TCM-related provision in TCM legislation is not intended to provide a systematic and comprehensive solution for problems in educational fields. TCM legal construction is mainly focused on two issues about TCM education: Firstly, broaden the paths for talent training. Secondly, emphasize the TCM involvement in TCM education.

TCM Scientific Research

TCM scientific research concerns two aspects: one is the inheritance of classical TCM; the other is the innovation of TCM in the context of modern science and technology. Meanwhile, China has inspired researchers in law to use modern science and technology to study TCM, and to progress innovation of TCM knowledge and technology.

TCM Culture Inheritance and Diffusion

TCM is typical of Chinese great traditional culture with clinical values and immense cultural values in addition. It will be a long time of construction and refinement before TCM legal system achieves maturity. TCM legal system construction will be propelled substantially by the formulation and implementation of TCM Law. It is anticipated that in about 5 years after the implementation of TCM Law, there is bound to be an extensive construction and amendment of TCM-related laws and regulations, gradually forming a relatively complete legal system. This legal system will be indispensable as regards its promotion and consolidation of the full development of TCM industry.

CONCLUSION

By analyzing the current situation of Chinese medicine legislation, we can draw the following two basic conclusions: First, it will play a leading role in the Fundamental Law by the promulgation and implementation of Chinese Medicine Law. China will gradually build a "regulations group" to guarantee traditional Chinese medicinal development based on the Chinese Medicine Law, and then forming a juristic guarantee system of traditional Chinese medicine development. Second, traditional Chinese

medicine will develop more rapidly and more standardized in the protection of legal system, then gradually become a new economic growth point and a competitive national soft power carrier.

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