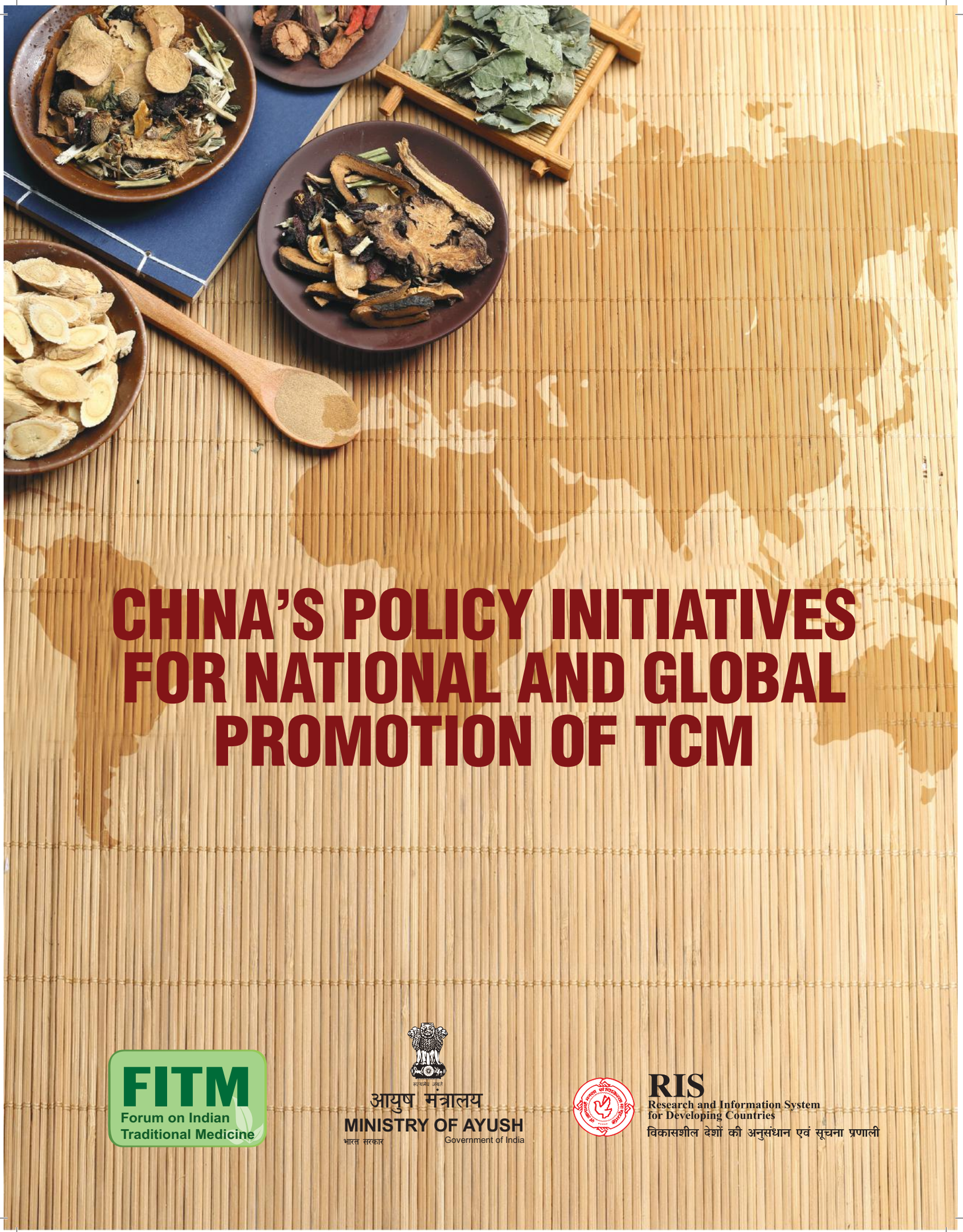

CHINA'S POLICY INITIATIVES FOR NATIONAL AND GLOBAL PROMOTION OF TCM

FITM
Forum on Indian Traditional Medicine

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आयुष मंत्रालय
MINISTRY OF AYUSH
भारत सरकार
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RIS
Research and Information System for Developing Countries
विकासशील देशों की अनुसंधान एवं सूचना प्रणाली

China's Policy Initiatives for National and Global Promotion of TCM

by

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Preface

Prof. Sachin Chaturvedi
Director General, RIS

Traditional medicines system have been major strength of old civilizations for dealing with multiple health issues. Since long efforts have been underway to integrate these oldest therapeutic systems globally. As this heritage of codified systems of medicine, established over centuries, effectively serve various healthcare needs, there have been sustained efforts towards integrating these systems within the larger healthcare ecosystem through legislations, quality control measures for products and services, R&D for innovation and new drug development and education policy restructuring. At the same time, mechanisms are being designed towards global outreach through collaborations in education and research and market entry of products and services.

Thus, there is need to study in detail the Traditional Medicine (TM) systems such as that of China. As a part of public healthcare system TCM is included in its insurance coverage, essential medicine list and is integrated with modern medical treatment facilities. These TM products occupy a significant proportion of China's pharmaceutical industry. Quality control through standards and new product development through R&D are being undertaken and backend linkages especially with reference to medicinal plants are being strengthened. Strategic education and training programmes are being designed to support both product and services industry.

For India, understanding China's experience in domestic and international policy making for promoting TM could assist in a comparative assessment of its own governance framework. A comprehensive study on policy initiatives for TCM has not yet been undertaken and this study has been undertaken by RIS with the objective of addressing this research gap. The study analyses various dimensions of TCM promotion through policy reforms in healthcare, education, R&D, drug registration, agriculture, manufacturing and export along with associated challenges. At a time when India, following the global acceptance of Yoga , seeks international growth of Ayurveda, this study will serve as a reference on the prospects and challenges therein.

Sachin Chaturvedi

List of Abbreviations

Active Pharmaceutical Ingredient	API
Adverse Drug Reaction	ADR
Arbeitsgemeinschaft für Klassische Akupunktur und Traditionelle Chinesische Medizin e.V	AGTCM
Australian Health Practitioner Regulation Agency	AHPRA
Australian Research Centre in Complementary and Integrative Medicine	ARCCIM
Australian Tertiary Admission Rank	ATAR
Average Length of Stay in Hospitals	ALOS
Ayurveda, Yoga, Unani, Siddha, and Homeopathy	AYUSH
Belt and Road Initiative	BRI
British Acupuncture Accreditation Board	BAAB
Chengdu University of Traditional Chinese Medicine	CUTCM
China Academy of Chinese Medical Sciences	CACMS
China Food and Drugs Administration	CFDA
Chinese Crude Drugs	CCDs
Chinese Ministry of Health	MOH
Chinese National Knowledge Infrastructure	CNKI
Chinese Pharmacopeia	CHP
Chinese Pharmacopeia Commission	CHPC
Chinese Pharmacopeia Commission	CPC
Chongqing Taiji Industry	CTI
Compound Annual Growth Rate	CAGR
Doctor of Clinical Medicine	DCM
Drug Administration Law	DAL

Dutch Medicines Evaluation Board	MEB
European Directorate for the Quality of Medicines	EDQM
European Federation of Biotechnology	EFB
European Medicines Agency	EMA
European Medicines Agency	EMA
European Traditional Chinese Medicine Association	ETCMA
Foreign Direct Investment	FDI
Forum on Indian Traditional Medicine	FITM
Good agricultural practice	GAP
Good Clinical Practice	GCP
Good Laboratory Practice for Non-Clinical Laboratory Studies	GLP
Good Manufacturing Practice	GMP
Good Supply Practice for Pharmaceutical Products	GSP
High Performance Capillary Electrophoresis	HPCE
High Performance Liquid Chromatography	HPLC
Indian Systems of Medicines	ISMs
Institute of Information on Traditional Chinese Medicine	IITCM
Intellectual Property Rights	IPR
International Classification of Diseases	ICD
International Organisation for Standardisation	ISO
Investigational New Drug Application	IND
Legislative Affairs Office of State Council	LAOSC
Masters of Clinical Medicine	MCM
Maternal and Child Health	MCH
Ministry of Civil Affairs	MOCA
Ministry of Finance	MOF
Ministry of Human Resources and Social Security	MOHRSS
National Development and Reform Commission	NDRC
National Health and Family Planning Commission	NHFPC

National Key Laboratory for TCM	NKL-TCM
National Medical Licensing Examination	NMLE
National Medical Products Administration	NMPA
Nederlandse Vereniging voor Acupunctuur	NVA
New Drug Application	NDA
Pan European Federation of TCM Societies	PEFOTS
Post Marketing Surveillance	PMS
State Administration for Market Regulation	SAMR
State Administration of Traditional Chinese Medicine	SATCM
Traditional Chinese Medicine	TCM
Traditional Chinese Medicine Language System	TCMLS
Unified Medical Language System	UMLS
United States Food and Drug Administration	US FDA
US Pharmacopeia Convention	USP
Western Medicine	WM
World Federation of Acupuncture-Moxibustion Societies	WFAS
World Federation of Chinese Medicine Societies	WFCMS
World Health Organisation	WHO

Executive Summary

One of the mandates of the Forum on Indian Traditional Medicine (FITM), established under the aegis of the Ministry of AYUSH and RIS, is to undertake in-depth studies on subjects of relevance to the traditional medicine sector. The present study on China's Policy Initiatives for National and Global Promotion of Traditional Chinese Medicine is of high relevance for the Traditional Medicine System in India. This study has involved desk research, field visit to China and interviews with relevant stakeholders. The main objective of this report is to identify the broad national and international policy strategies of China which will be of value for the policy makers on developing strategies for promotion of Indian System of Medicines (ISMs).

The single most important aspect of China's policy on TCM is its recognition as a system of medicine that has the potential to achieve objectives of its universal health programme and as an untapped knowledge resource for drug discoveries. It is a heritage unique to China and has emerged as an important soft power strategy of China's foreign policy. While TCM has been a priority for policy makers since 1949, when the People's Republic of China was founded, it has received a major boost recently under President Xi Jinping. Not only is TCM included as domestic health policy and poverty alleviation tool, it is also an important part of China's foreign economic and geopolitical strategy.

It forms an important part of the public healthcare system that includes insurance coverage, essential medicine list and is integrated with modern medical treatment facilities. Efforts are on to include TCM in the last mile coverage of primary healthcare represented through the village clinics. Lack of quality healthcare professionals is a challenge that TCM sector experiences in this endeavour.

TCM sector also occupies a significant proportion in China's healthcare industry. This includes services and products. Healthcare services include TCM hospitals, (graded as per the quality of services and infrastructure), the clinics and pharmacies. TCM hospitals are mostly controlled by public enterprises and profitability has risen from 0.9 per cent in 2007 to an estimated 5.4 per cent in 2018. The TCM manufacturing industry occupies a substantial if not a major proportion of the pharmaceutical manufacturing industry. It includes manufacturing of slices and decoctions, referred to as *Zongyaoyinpian*, and manufacturing of patent and proprietary products referred to as *Zongcgengyao*. In 2016, the total industrial output of TCM

pharmaceutical industry was 37.46 thousand tons, almost 10 per cent above the industrial output of chemical medicines. The profits of TCM *Zongcgengyao* as a percentage of the total profits of the pharmaceutical industry increased from 23 per cent to 25 per cent between 2010 and 2016. On the other hand, the percentage share of profits of the Chemical Medicine industry has come down from 50 per cent to 46 per cent during the same period.

Issues of safety, uniformity and quality have been a concern often associated with TCM and other traditional medicine systems. TCM accounts for approximately 14 per cent of total adverse drug reaction (ADR) in China. Domestic and international standards development, strong pharmacovigilance and post market surveillance has been a strong focus in policy strategies towards addressing this end. The Drug Administration Law 2001 is in the process of amendment to address these concerns with stronger penalties for manufacturers and distributors of substandard drugs.

At the same time back end linkages of the sector, especially with medicinal plants, are also being strengthened. Medicinal plants form essential raw materials for TCM. Collection from the wild has been the practice and depletion of resources has been a concern. Commercial cultivation by enterprises is being undertaken. At the policy level, China Herbal Industry Poverty Alleviation Action Plan (2017-2020), aimed at generating income for the farming community and ensuring sustainable supply of ever increasing demand, has been an innovative strategy. Medicinal plant cultivation cooperatives have been set up at the village level.

Similarly, policy support for innovation and R&D in TCM has been strong. The push for drug discovery based on TCM has yielded some results as evidenced from the Nobel Prize awarded medicine innovation of anti-malaria drug artemisinin from *Artemisia annua* L. Though further spectacular successes have not been as forthcoming, large TCM companies and public institutions have invested in innovation in products and drug administration. Between 2007 and 2016 investments and expenditure on new product development has increased by approximately 450 per cent.

Stress on innovation in TCM education is another notable feature of the Chinese systems which contributes to the holistic growth of the sector. This includes education/training support to address the entire TCM pharmaceutical industry. Modern medicine education already includes education in TCM. Other innovative education programmes include, for example, the establishment of premier TCM universities with disciplines in economics, commerce, humanities, management. The end objective is to build a workforce that meets the needs of the entire TCM sector including manufacturing, R&D and sales, distribution and marketing.

Globalisation of TCM has been an important foreign policy focus. Global health platforms like WHO and international TCM NGOs have played an important role on securing legitimacy of TCM. Academic institutions in countries outside China are encouraging education and research in TCM. Finally, geopolitical initiatives like the Belt and Road Initiative are expected to play an important role in expansion of TCM in related countries and invite medical tourism to lesser developed provinces of China along the Belt.

The study attempts to analyse the relevance of these initiatives when applied to the Indian context, i.e., the development of the Indian System of Medicine (ISM) sector.

Introduction

TCM forms an important feature of China's public health system both in terms of medicinal products and services; it is covered by China's health reimbursement system, including doctors' visits. China's Traditional Medicine system has witnessed substantial growth domestically and internationally. Out of the 520 essential medicines in China, 203 are Traditional Chinese Medicine (TCM) products.[1] The IBIS world report on TCM industry in China estimated the total revenue of the industry as USD 37.41 Billion as of 2018.[2] The "Healthy China 2030" plan estimates that the value of the TCM market may reach 5 trillion RMB by 2030 (USD 737.9 billion).[3] China is also promoting global outreach of the TCM use to foster domestic economic development. Trade in Chinese medicinal products has consistently maintained a rapid growth, and the export value of Chinese medicines has been estimated to be USD 1.07 billion.[4] Frost & Sullivan have estimated that the segment would continue to expand rapidly and deliver an 8.2 per cent compound annual growth rate (CAGR) in sales during 2016-20.[5] Moreover, TCM education and treatment is increasingly becoming a part of medical treatment in many countries. Various factors may be attributed to the growth of TCM.

TCM: Brief Description of Concepts, Products and Treatments

TCM can be traced through written scripts as far back as 3000 years.[6] One of the earliest text books on the subject is the *Huang TiNei Ching* or *The Yellow Emperor's Manual of Corporeal Medicine*.[7] This book can be dated back to the 2nd century BC although certain practices of TCM like acupuncture are believed to be much older.[8]

TCM is founded upon the holistic concept of treatment and an acknowledgment of the body's ability to return to its balanced state of health with the correct stimulus. Treatment is, therefore, undertaken bearing in mind the cause of the imbalance which manifests itself in symptoms, rather than addressing the symptoms primarily and leaving the cause unaddressed. It takes into account that the body is a self-repairing mechanism and any interference should be aimed at encouraging this self-healing ability. Major theories of TCM include *Tao* (*Yin and Yang*), *Chi,* i.e., 'the vital energy that circulates through the body at all times', the five phases (*Wu Xing*), i.e. wood (*mu*), fire (*huo*), earth (*tu*), metal (*jin*), and water (*shui*), the human body Meridian/channel system and *Zang Fu* organ theory.[9] Clinical phenomena were interpreted by reference to systems

based on these theories of bodily function and syndromes are differentiated according to the four pairs of contradictory principles, namely, negative (*yin*) and positive (*yang*); exterior and interior; cold and heat; and deficiency (*xu*) and excess (*shi*). These systems are interpreted within a more holistic observational diagnostic framework. This framework utilises a phenomenological (interpretative) paradigm, rather than a reductionist (normative) paradigm which is the predominant paradigm used in the contemporary modern medical system.[10]

TCM products are divided into the following :(1) Chinese patent medicines (*Zongcgengyao)*, (2) decoction of herbs which are often extracted with water to make an aqueous extract *(Zongyaoyinpian)*, and (3) Chinese herbs.[11] Chinese patent medicines are defined as any Chinese herbal medicines formulated into a finished dose form while decoctions are mainly Chinese herbs which are processed further. Decoction of herbs was first invented and further developed between 2000 and 474 BC. The medical ingredients were extracted by boiling in water or alcohol, with special preparation times that depend on the properties of the ingredients. Following this, the decoction was filtered and the resulting liquid was taken by patients. In modern China, the method of decoction is still the most commonly used process in TCM though Chinese patent medicines account for about 50 per cent of all Traditional Chinese Medicines sold.[12] Single herbs, or multiple herbs combined in one formula, can be used to make multi-component TCMs. Multi-component therapeutic formulae are the most important and are most commonly used in TCM for clinical applications.

Treatments under TCM can be classified broadly under: (i) drug therapy that includes patent medicines, decoction pieces and herbs, (ii) Acupuncture, i.e., the practice of inserting needles into the superficial skin, subcutaneous tissue, and muscles at the particular acupuncture points and manipulating them, (iii) Moxibustion, i.e. the practice of burning moxa (mugwort root) made from dried *Artemisia vulgaris* (spongy herb) to facilitate healing, and (iv) Tuina, which can be described as a massage therapy.[13]Acupuncture and moxibustion are as important as the drug therapy in TCM.

Chinese population consists of a large number of ethnic groups. The central government has recognised 55 of them as minority groups and the Han as the majority.[14] Most of them have their own traditional medicinal practices. The government, however, recognises 35 distinct ethnic medical traditions. Of these, the most established are *Tibetan, Uyghur, Mongolian,* and *Dai* medicine, all of which have a system of professional accreditation overseen by the Ministry of Health.

Indian Systems of Medicine Landscape

Indian Systems of Medicines (ISMs) also boast of a long history dating back to the 6th century BC. The major systems of medicine in India are *Ayurveda, Siddha, Unani, and Sowa Rigpa. Yoga* is a common practice all across the country. There are different local folk traditional medicinal practices among particular communities.

Ayurveda like TCM is composed of concepts that include five basic elements: (*Pancha Mahabhoota*), i.e., *Aakash* (Ether), *Vayu* (Air), *Agni* (Fire), *Apas* (Water) and *Prithvi* (Earth). The human body is made up of *Doshas* (bio-humours), *Dhatus* (body matrix) and *Malas* (excretable products). *Vata, Pitta* and *kapha*, known as *Tridoshas* are physiological entities of the body which are responsible for carrying out all the functions of the body. *Dhatus* are the structural entities of the body. *Agni* (metabolic fire) is in thirteen different forms and carries out the whole metabolism of the body. The waste products of the body which are excretable are produced in the body as by-products of metabolism. All bio-transformations within the body occur through *Srotases* (body channels) which are the sites for action of *agni*.

Yoga is one of the six systems of Vedic philosophy."*Yoga Sutras*" (aphorisms) advocate the eight folds path of Yoga, popularly known as "Ashtanga Yoga" for all-round development of human beings. These steps are believed to have a potential for improvement of physical health by enhancing circulation of oxygenated blood in the body, retraining the sense organs thereby preventing psychosomatic disorders and improving an individual's resistance and endurance.

The Unani System of Medicine that originated in Greece, was introduced in India by Arabs, and under the patronage of successive governments has taken firm roots in India. The basic theory of Unani system is based upon the well-known four-humour (blood, phlegm, yellow bile and black bile) theory of Hippocrates.

In Siddha, principles and doctrines, both fundamental and applied, have a close similarity to Ayurveda, with specialisation in Iatro-chemistry.

Sowa-Rigpa is based on the principles of Jung-wa-nga (cf. Skt: *panchamahabhutas*) and Ngepa-Sum (Skt: *Tridosa*). Bodies of all the living beings and non-living objects of the universe are composed of Jung-wa-nga; viz. *Sa, Chu, Me, Lung* and *Nam-kha* (Skt: *Prithvi, Jal, Agni, Vayu* and *Akash*). The physiology, pathology pharmacology and *materia medica* of this system are established on these theories.

The traditional systems of medicine and Homeopathy are administered by the Ministry of AYUSH (Ayurveda, Yoga, Unani, Siddha, and Homeopathy). As of 2019, there are 3,986 AYUSH hospitals, with 56,586 beds, 27,199 dispensaries, 7,99,879 registered practitioners, 702 AYUSH undergraduate colleges with admission capacity of 46,835 students all over India.[15]

Methodology

The study is based on the literature review and field visits in China. The field survey was conducted in Sichuan Province and Chongquing Municipality in China. During the survey, the following institutions were visited:

Chengdu University of TCM

- Visit to the TCM Museum, Chengdu University of TCM
- Sichuan Tianxiang Orthopaedic Hospital
- Chengdu Jinniu Erma Clinic Qiang Medical Centre
- Affiliated Hospital of Chengdu University of Traditional Chinese Medicine
- Taiji Pharmaceuticals, Yubei District, Chongquing
- Chongzhou Alpine Traditional Chinese Medicine Industry Association of Chengdu City
- Chengdu Lotus Pool Medicine market for raw materials

The survey also included interviews with the following personnel:

- Professor Wenjun Zou (Centre of Intellectual Property Operation of TCM and Professor, National Key subject of Traditional Chinese Medicine, School of Pharmacy, Chengdu University of Traditional Chinese Medicine, Chengdu)
- Liping Qu Graduate Student School of Pharmacy, Chengdu University of Traditional Chinese Medicine, Chengdu)
- Chough Shan Zhen, Chairman of Zhong Kang Fu Group
- Professor Guanghua Lu (Dean, School of Ethnic Medicine, Chengdu University of Traditional Chinese Medicine
- Professor Guihua Jiang, Deputy Director of Ethnic Medicine and Expert on TCM herbs, Chengdu University of Traditional Chinese Medicine
- Dr Junzhi He, Director , Sichuan Tianxiang Orthopaedic Hospital
- Dr Fushou Yang, Director, Jinniu Erma Clinic Qiang Medical Center
- Cynthia Jiang, Taiji Group

- Qin Yao, Director, Taiji Group
- Prof. Yin Hongxiang, Associate Professor, Chengdu University of TCM, Expert in botanical plants and agricultural research
- Professor Wang Zang, Associate Professor Director of Research Institute of Traditional Indian Medicine of Chengdu University of Traditional Chinese Medicine

Apart from the field survey, the study also does analysis of primary and secondary source material, namely, official statistics and governmental instructions. Secondary sources of reference include published research work in the form of books, monographs, articles and papers including conference papers, markets research papers and discussion papers. A comparative analysis of TCM and ISM is also done with an objective of coming up with specific policy recommendations to promote ISM.

TCM Governance in China: Overview of Policies, Laws and Regulations

1.1 Introduction

TCM has received strong policy support ever since the establishment of the People's Republic of China in 1949. The objective of developing TCM and facilitating its growth has been expressed in declarations by all successive state leaders and policy makers. Policies on TCM have passed through several phases.[16] In the period following the establishment of the People's Republic of China in 1949 to 1960s, policy initiatives on TCM included formation of a TCM department in the Ministry of Health, new TCM academies, institutes, recording of Chinese *material-medica* in Chinese Pharmacopoeia and the development of acupuncture and moxibustion. Between 1954 and 1960, China's ten most prestigious TCM universities and its national TCM academy were established.[17] Following economic liberalisation in the late 1970s, integration of TCM with modern medicine became a new priority. TCM hospitals also received a major boost during this time. In the year 1982 the Chinese constitution promulgated that TCM be given full recognition through Article 21 which states that,

"*The State develops medical and health services, promotes modern medicine and traditional Chinese medicine, encourages and supports the setting up of various medical and health facilities by the rural economic collectives, State enterprises and institutions and neighbourhood organizations, and promotes health and sanitation activities of a mass character, all for the protection of the people's health*".[18]

Also, in 1992, the regulations on protection of different types of TCM were issued. From the meagre tally of 184 in 1977, the number of TCM hospitals increased to 3015 in 2013, an increase of 93.9 per cent after economic liberalisation.[19] The phase during late 1970s to 2000s also witnessed the establishment of the State Administration of Traditional Chinese Medicine (SATCM) (1985) to coordinate national and international activities of TCM, increase in TCM teaching and training capacity, increase in R&D spending and China's introduction of the concept of "*internationalisation of TCM*" in 1996. Since the late 2000s with the objective of a wider outreach, quality assurance for international market penetration has been one of the primary focus.

1.2 Plans and Programmes

Programmes and plans outline the major objectives envisioned for a sector/industry in China, in this case TCM. Though not binding, these define development priorities of policy making on TCM, and guide TCM related laws and administration. Broadly, following are the main Plans/ Programmes for TCM:

In Five-Year Plans, especially since the 10th Five-Year Plan (2001-2005), a series of guidelines and policies have been formulated to promote development of TCM. The 10th Five-Year Plan has also facilitated application of new technology for TCM manufacture/production.

In the 11th Five Year Plan of the National Economic and Social Development of China in 2006 the TCM industry was selected as one of the strategic emerging industries. This was the first time modernisation and standardisation of TCM industry was emphasised in a Five Year Plan and the first selective policy for the sector at the national level. The 12th Five-Year Plan (2011-2015) also emphasises on government treating TCM at par with modern medicine, increased coverage of TCM services, training more TCM practitioners, increasing R&D funding and more international collaboration. It also proposes to strengthen development of legal system on standardisation and information communication on TCM.

The National *Medium-and Long-Term* Programme for *Science and Technology Development* (2006-2020)[20] was the first long term national innovation policy document and TCM sector was selected as one of the key and emerging knowledge intensive sectors under the Plan. It outlines innovation, modernisation, and internationalisation of TCM as major goals. Modernisation of TCM is envisioned through standards development, manufacturing technology, and research and development by utilising global scientific and technological resources.

The *Innovation and Development Planning Outline for Traditional Chinese Medicine (2006-2020)* [21]calls for a diversified and multichannel investment system, which can be formed, among others, by international cooperation. The document also proposes to enhance the standard system construction of TCM hospitals.

More recently, the *Strategic Plan on the Development of Traditional Chinese Medicine (2016-2030*) makes TCM development a national strategy. Vertical integration of the sector through interventions in agriculture, cultivation, distribution and provision of related services is a part of the Plan. Other priorities include participation in international cooperation and competition, promotion of localisation of TCM services and international education of TCM.

The Ministry of Traditional Chinese Medicine and the State Council Poverty Alleviation Office and other five departments jointly issued the *China Herbal Industry Poverty Alleviation Action Plan (2017-2020)*, where counties with a high level of poverty indicators would benefit from the programme.[22]

1.3 TCM Administration/Governance

Till 2013, hierarchy of TCM governance in descending order included the State Council, the Ministry of Health and the State Administration of Traditional Chinese Medicine (SATCM). After 2013, the National Health and Family Planning Commission replaced the Ministry of Health in hierarchy.[23] Policy documents issued have relevance as per the issuing authority. Hence TCM related documents issued by the State Council would have greater authority than those issued by the SATCM. All provinces, autonomous regions, and municipalities directly under the Central government have also established their respective TCM administrations. The purchase and the export of wild medicinal plant materials are under the provincial governments. Broadly, pharmaceutical products, including TCM share the same regulations. There are 23 departments, centres or ministries responsible for safety assurance of medicines available. Like modern drugs, TCM administration is governed through institutions like the National Medical Products Administration (NMPA), formerly the China Food and Drugs Administration (CFDA), and the National Health and Family Planning Commission.

While a combination of programmes and administrative provisions on TCM has made significant contribution to its growth within and outside the country, regulatory fragmentation has been a challenge.[24] To address these challenges, a uniform regulatory and legal

structure for TCM and modern drugs through the NMPA has been established. It facilitates capacity building of TCM on parameters similar to modern drugs thereby meeting quality standards as per demand in export destinations where quality assurance is based on parameters similar to modern drugs.

State Administration of Traditional Chinese Medicine (SATCM)

The SATCM established in 1985 formulates regulations and good practices relevant to TCM and, seeks opinions by other related agencies like the National Health and Family Planning Commission, companies and public after which the approval is placed before the Legislative Affairs Office of State Council (LAOSC). LAOSC publishes the final regulation formally, e.g., *Law of the People's Republic of China on Traditional Chinese Medicine, 2017*. The SATCM has also brought important policy documents guiding TCM related administration. This includes 'Measures for Recording of Chinese Medicine Clinics' in 2017.

National Medical Products Administration

The National Medical Products Administration (NMPA) now regulates drugs and medical devices. It replaces the China Food and Drug Administration (CFDA), which also had jurisdiction over food safety and reported to the State Council. The NMPA is now part of the State Administration for Market Regulation (SAMR). The SAMR, established in 2018, itself has been formed after merging State Administration for Industry & Commerce, General Administration of Quality Supervision and the CFDA.

The NMPA's responsibilities include drafting laws and regulations for drugs, medical devices, and cosmetics, as well as establishing medical device standards and classification systems. These changes are designed to enable focus on drugs with the aim of raising drug standards to international standards. NMPA is responsible for drug registration (including TCM), supervision and administration.

NMPA's affiliated institutions include National Institutes for Drug Control, Chinese Pharmacopoeia Commission, Centre for Drug Evaluation, National Committee on the Assessment of the Protected Traditional Chinese Medicinal Products, Centre for Complaints and Report, Centre for Drug Re evaluation (National Centre for ADR Monitoring), China Centre for Food and Drug International Exchange and Centre for Food and Drug Inspection.

The Drug Administration Law 2001

The legal provisions on TCM are mainly provided under the Drug Administration Law 2001, which regulates all pharmaceutical products. Under the umbrella of the Drug Administration law 2001, are some of the major regulations which include:

- Regulation on Protection of Wild Medicinal Resources, 1987.
- Regulations on Protection of Traditional Chinese Medicines, 1993
- Regulation of the People's Republic of China on Traditional Chinese Medicines, 2003: This was the first regulation addressed specifically to TCM
- Regulations for Implementation of the Drug Administration Law 2002

The process of amending Drug Administration Law, 2001 is ongoing.

Law of the People's Republic of China on Traditional Chinese Medicine, 2017[25]

The Law of the People's Republic of China on Traditional Chinese Medicine, 2017 is the latest legislation for TCM. It focuses on quality control of TCM practitioners and medical services in general and protection of TCM as 'state secrets'. The law covers medical services; protection and development of Chinese medicine; education of professional talent; scientific research and guides policies on TCM.

Apart from the above mentioned laws and regulations, there are other regulations and programmes meant to address specific issues related to TCM. In addition, provincial governments have their own regulations. These laws impact various dimensions of TCM system such as education, healthcare delivery, industrialisation, internationalisation and quality administration. These aspects are discussed in subsequent chapters.

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I

TCM Governance in China: Overview of Policies, Laws and Regulations

1.1 Introduction

TCM has received strong policy support ever since the establishment of the People's Republic of China in 1949. The objective of developing TCM and facilitating its growth has been expressed in declarations by all successive state leaders and policy makers. Policies on TCM have passed through several phases.[1] In the period following the establishment of the People's Republic of China in 1949 to 1960s, policy initiatives on TCM included formation of a TCM department in the Ministry of Health, new TCM academies, institutes, recording of Chinese *material-medica* in Chinese Pharmacopoeia and the development of acupuncture and moxibustion. Between 1954 and 1960, China's ten most prestigious TCM universities and its national TCM academy were established.[2] Following economic liberalisation in the late 1970s, integration of TCM with modern medicine became a new priority. TCM hospitals also received a major boost during this time. In the year 1982 the Chinese constitution promulgated that TCM be given full recognition through Article 21 which states that,

"*The State develops medical and health services, promotes modern medicine and traditional Chinese medicine, encourages and supports the setting up of various medical and health facilities by the rural economic collectives, State enterprises and institutions and neighbourhood organizations, and promotes health and sanitation activities of a mass character, all for the protection of the people's health*".[3]

Also, in 1992, the regulations on protection of different types of TCM were issued. From the meagre tally of 184 in 1977, the number of TCM hospitals increased to 3015 in 2013, an increase of 93.9 per cent after economic liberalisation.[4] The phase during late 1970s to 2000s also witnessed the establishment of the State Administration of Traditional Chinese Medicine (SATCM) (1985) to coordinate national and international activities of TCM, increase in TCM teaching and training capacity, increase in R&D spending and China's introduction of the concept of "*internationalisation of TCM*" in 1996. Since the late 2000s with the objective of a wider outreach, quality assurance for international market penetration has been one of the primary focus.

1.2 Plans and Programmes

Programmes and plans outline the major objectives envisioned for a sector/industry in China, in this case TCM. Though not binding, these define development priorities of policy making on TCM, and guide TCM related laws and administration. Broadly, following are the main Plans/ Programmes for TCM:

In Five-Year Plans, especially since the 10th Five-Year Plan (2001-2005), a series of guidelines and policies have been formulated to promote development of TCM. The 10th Five-Year Plan has also facilitated application of new technology for TCM manufacture/production. In the 11th Five Year Plan of the National Economic and Social Development of China in 2006 the TCM industry was selected as one of the strategic emerging industries. This was the first time modernisation and standardisation of TCM industry was emphasised in a Five Year Plan and the first selective policy for the sector at the national level. The 12th Five-Year Plan (2011-2015) also emphasises on government treating TCM at par with modern medicine, increased coverage of TCM services, training more TCM practitioners, increasing R&D funding and more international collaboration. It also proposes to strengthen development of legal system on standardisation and information communication on TCM.

The National *Medium-and Long-Term* Programme for *Science and Technology Development* (2006-2020)[5] was the first long term national innovation policy document and TCM sector was selected as one of the key and emerging knowledge intensive sectors under the Plan. It outlines innovation, modernisation, and internationalisation of TCM as major goals. Modernisation of TCM is envisioned through standards development, manufacturing technology, and research and development by utilising global scientific and technological resources.

The *Innovation and Development Planning Outline for Traditional Chinese Medicine (2006-2020)* [6]calls for a diversified and multichannel investment system, which can be formed, among others, by international cooperation. The document also proposes to enhance the standard system construction of TCM hospitals.

More recently, the *Strategic Plan on the Development of Traditional Chinese Medicine (2016-2030*) makes TCM development a national strategy. Vertical integration of the sector through interventions in agriculture, cultivation, distribution and provision of related services is a part of the Plan. Other priorities include participation in international cooperation and competition, promotion of localisation of TCM services and international education of TCM.

The Ministry of Traditional Chinese Medicine and the State Council Poverty Alleviation Office and other five departments jointly issued the *China Herbal Industry Poverty Alleviation Action Plan (2017-2020)*, where counties with a high level of poverty indicators would benefit from the programme.[7]

1.3 TCM Administration/Governance

Till 2013, hierarchy of TCM governance in descending order included the State Council, the Ministry of Health and the State Administration of Traditional Chinese Medicine (SATCM). After 2013, the National Health and Family Planning Commission replaced the Ministry of Health in hierarchy.[8] Policy documents issued have relevance as per the issuing authority. Hence TCM related documents issued by the State Council would have greater authority than those issued by the SATCM. All provinces, autonomous regions, and municipalities directly under the Central government have also established their respective TCM administrations. The purchase and the export of wild medicinal plant materials are under the provincial governments. Broadly, pharmaceutical products, including TCM share the same regulations. There are 23 departments, centres or ministries responsible for safety assurance of medicines available. Like modern drugs, TCM administration is governed through institutions like the National Medical Products Administration (NMPA), formerly the China Food and Drugs Administration (CFDA), and the National Health and Family Planning Commission.

While a combination of programmes and administrative provisions on TCM has made significant contribution to its growth within and outside the country, regulatory fragmentation has been a challenge.[9] To address these challenges, a uniform regulatory and legal structure for TCM and modern drugs through the NMPA has been established. It facilitates capacity building of TCM on parameters similar to modern drugs thereby meeting quality standards as per demand in export destinations where quality assurance is based on parameters similar to modern drugs.

State Administration of Traditional Chinese Medicine (SATCM)

The SATCM established in 1985 formulates regulations and good practices relevant to TCM and, seeks opinions by other related agencies like the National Health and Family Planning Commission, companies and public after which the approval is placed before the Legislative Affairs Office of State Council (LAOSC). LAOSC publishes the final regulation formally, e.g., *Law of the People's Republic of China on Traditional Chinese Medicine, 2017*. The SATCM has also brought important policy documents guiding TCM related administration. This includes 'Measures for Recording of Chinese Medicine Clinics' in 2017.

National Medical Products Administration

The National Medical Products Administration (NMPA) now regulates drugs and medical devices. It replaces the China Food and Drug Administration (CFDA), which also had jurisdiction over food safety and reported to the State Council. The NMPA is now part of the State Administration for Market Regulation (SAMR). The SAMR, established in 2018, itself has been formed after merging State Administration for Industry & Commerce, General Administration of Quality Supervision and the CFDA.

The NMPA's responsibilities include drafting laws and regulations for drugs, medical devices, and cosmetics, as well as establishing medical device standards and classification systems. These changes are designed to enable focus on drugs with the aim of raising drug standards to international standards. NMPA is responsible for drug registration (including TCM), supervision and administration.

NMPA's affiliated institutions include National Institutes for Drug Control, Chinese Pharmacopoeia Commission, Centre for Drug Evaluation, National Committee on the Assessment of the Protected Traditional Chinese Medicinal Products, Centre for Complaints and Report, Centre for Drug Re evaluation (National Centre for ADR Monitoring), China Centre for Food and Drug International Exchange and Centre for Food and Drug Inspection.

The Drug Administration Law 2001

The legal provisions on TCM are mainly provided under the Drug Administration Law 2001, which regulates all pharmaceutical products. Under the umbrella of the Drug Administration law 2001, are some of the major regulations which include:

- Regulation on Protection of Wild Medicinal Resources, 1987.
- Regulations on Protection of Traditional Chinese Medicines, 1993
- Regulation of the People's Republic of China on Traditional Chinese Medicines, 2003: This was the first regulation addressed specifically to TCM
- Regulations for Implementation of the Drug Administration Law 2002
- The process of amending Drug Administration Law, 2001 is ongoing.

Law of the People's Republic of China on Traditional Chinese Medicine, 2017[10]

The Law of the People's Republic of China on Traditional Chinese Medicine, 2017 is the latest legislation for TCM. It focuses on quality control of TCM practitioners and medical services in

general and protection of TCM as 'state secrets'. The law covers medical services; protection and development of Chinese medicine; education of professional talent; scientific research and guides policies on TCM.

Apart from the above mentioned laws and regulations, there are other regulations and programmes meant to address specific issues related to TCM. In addition, provincial governments have their own regulations. These laws impact various dimensions of TCM system such as education, healthcare delivery, industrialisation, internationalisation and quality administration. These aspects are discussed in subsequent chapters.

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II

TCM in Healthcare System

2.1 Introduction

In recent years, with a growing economy and continuous medical reforms, China's healthcare systems has been in the process of rapid expansion with significant improvement in medical services. Life expectancy has reached 76.4 years, an average higher than some high income countries.[1] Total national health expenditure exceeded 5 trillion Yuan in 2017, accounting for 6.2 per cent of the GDP.[2] This number is expected to reach 16 trillion Yuan by 2030, according to Healthy China 2030 Plan Outline.[3]The growing role of TCM in healthcare has been driven by the support for TCM in health policies, especially since 2009, with increasing public expenditure in health and a growing interest in alternative medicines. Utilisation of TCM during the SARS crisis in 2003[4] and the treatment of H1N1 influenza in 2009[5] further strengthened TCM's influence in healthcare delivery.

2.2 Healthcare Governance: Overview of Heath System

Healthcare governance in China is under the National Health and Family Planning Commission (NHFPC), below which is the State Administration of Traditional Chinese Medicine (SATCM). Other departments of the State Council also assume relevant responsibilities such as the National Development and Reform Commission (NDRC), Ministry of Civil Affairs (MOCA), Ministry of Finance (MOF), and the Ministry of Human Resources and Social Security (MOHRSS). Though healthcare administration has been decentralized among Bureaus of Health in 31 provinces/autonomous regions (provincial health bureau, prefecture/ municipal health bureau and county health bureau are main health authorities at each level[6]) Several waves of reform have emphasised on streamlined administration and decentralisation though the central government is still the leading force in lawmaking and decision-making.[7] Directed by the principles formulated by the central government, local governments at various levels issue and execute plans and decisions within their jurisdiction. Health planning in China is divided into two major sections - health development planning and specific health planning[8] (i.e., human resource planning and disease control planning). The health service delivery system consists of the public health system and the medical service delivery system. The public health delivery system is composed of disease prevention and control institutions, maternal and child health (MCH) institutions, health education institutions, health information institutions and health supervision and management institutions, among others. The medical

service delivery system includes hospitals at provincial, city and county levels, as well as grassroots health institutions. The rural health service system includes three levels: county level, township level and village level. County level facilities are hospitals, TCM clinics, and maternity and children's hospitals. Basic healthcare centres and village clinics provide the health services at both township and village levels. In the urban areas, hospitals are the centre of patient care services and are organised into a three-layered structure. Third level hospitals are run directly by the central authorities, each with more than 500 beds. These provide tertiary care. These hospitals are usually equipped with advanced medical staff and equipment. Second level hospitals have 100-–500 beds and provide full healthcare services to a district. First level hospitals provide the most basic healthcare services of prevention, sanitation and essential medical services. There are specialised sanatoriums also. Medical pluralism exists within state-run hospitals, universities, and clinics in which modern medicine and TCM are practiced in parallel. Under the SATCM several notifications serve as guiding documents for TCM governance.

2.3 Healthcare Reforms: Role of TCM

At the time of China's move towards a market economy in the late 1970s, public health institutions through state owned hospitals, clinics, enterprises and cooperatives had achieved impressive health outcomes.[9] Several health insurance schemes were in existence and the role of 'barefoot doctors', i.e., rural medical personnel, who integrated western and TCM and provided primary healthcare under the directions of the state, was significant.[10] After 1978, economic reforms leading to privatisation of industry and agriculture undermined the public health insurance system and health delivery system.[11]

Unaffordable basic health services, high out of pocket health expenditures and increasing disparity in health status led to the launch of *Healthcare System Reform* in 2009 by the State Council. The Reforms have been rolled out in three phases. The first phase from 2009 to 2012 included five priority target areas, namely, (i) to accelerate the establishment of a basic health insurance system, (ii) to establish a national essential medicines system, (iii) to strengthen primary healthcare services, (iv) to improve access to fundamental public health services, and, (v) to promote public hospital service reform.[12] Reform in TCM healthcare delivery institutions is a part of this agenda.

The second phase (2012-2015) began with the 12th five year plan for health reforms. Apart from the five targeted areas mentioned above, the agenda focussed on public hospital reforms, including those of county hospitals. Further, a national basic public health services plan issued on June 5, 2013, revised in 2015, specifies several targets to be met by the end of 2015, which included covering 40 per cent of the population with TCM based health management offerings such as providing regular TCM-based consultation.[13]

With the beginning of the third phase of reforms in 2015, the *National Planning Guideline for the Healthcare Service System (2015-2020) (the Guideline)* targeted key areas for development by 2020.[14] This included establishment of TCM hospitals at the county and municipal levels.

In October 2016, the "*Healthy China 2030*" blueprint was approved. It includes 29 chapters covering public health services, environment management, the Chinese medical industry, and food and drug safety.[15]

Other healthcare reform programmes specifically targeting TCM include the *Innovation Development Program of Traditional Chinese Medicine (2006-2020)* to enhance the standard in construction of TCM hospitals.[16]

In February 2016, the State Council issued *Outline of Strategic Planning for the Development of Traditional Chinese Medicine (2016-2030)* under

which the TCM institutions are encouraged to set up hospitals overseas.

In May 2016, the State Council also issued *Development Plan of Chinese Medicine Health Service (2015-2020)*, which aims to fully establish the health service system of TCM and utilise the health service of TCM as an important force to promote the economic and social development.

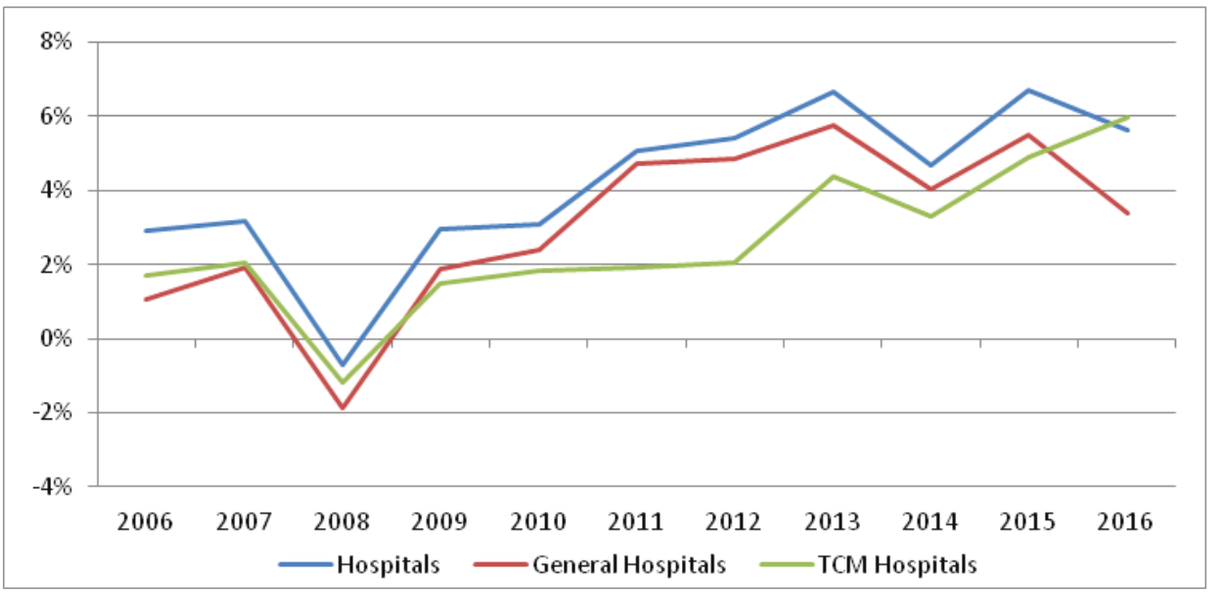
2.4 TCM Hospitals: Key Features

Since 1978, following economic liberalisation and reforms in TCM sector the number of TCM hospitals have grown significantly. Between 1977 and 2017 TCM hospitals grew from 184 to 3695.[17] The number of beds has increased from around 20,000 in 1975 to around 818,216 in 2018.[18,19] The growth rate in the number of beds has surpassed the growth rate of TCM hospitals indicating the priority to expand the scale of working hospitals rather than number of hospitals. Moreover, in recent years, the growth rates of TCM hospitals have surpassed that of general hospitals (Figure 2.1).

Figure 2.2 shows the trajectory of patient visits in TCM hospitals and number of inpatients. The graph shows a steady increase in both the indicators reflecting growing usage of TCM system in China. In the last ten years, the number of visits to TCM hospitals has nearly doubled from 275 million person times to 578 million person times. The inpatient visit has grown by nearly 180 per cent. These numbers reflect the significance of TCM in Chinese health care system.

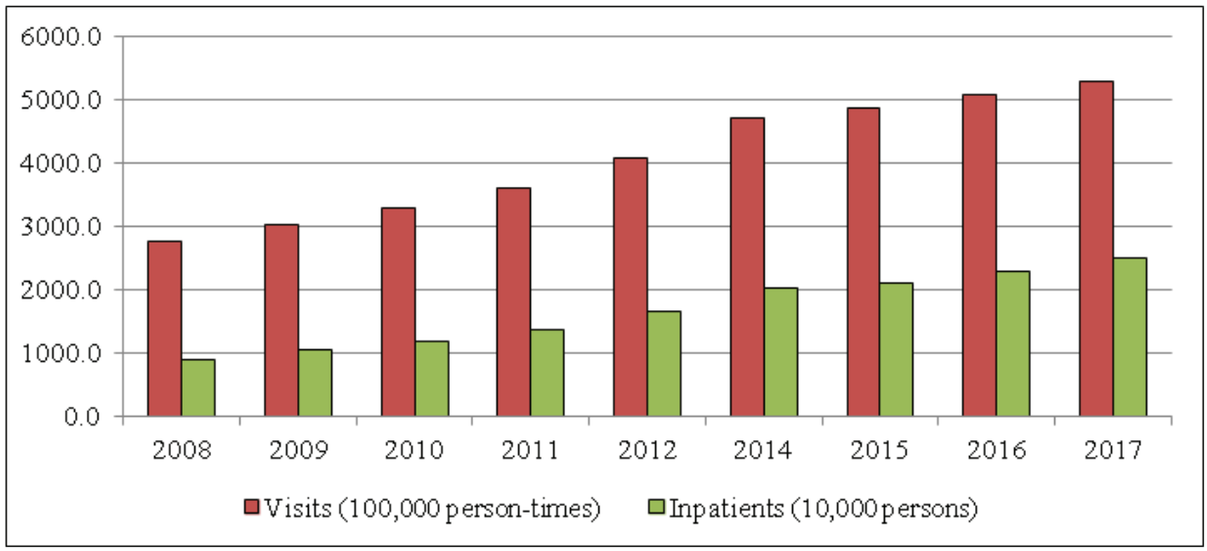
Table 2.1 shows the general statistics of hospitals in China, categorised as General Hospitals, TCM hospitals and Integrated TCM & Western Medicine Hospitals for the year 2017. However, there are other types of hospitals such as nationalities hospitals, specialised hospitals and nursing hospitals. Although the scale of operations of TCM hospitals may seem small when compared to general hospitals, their value in Chinese healthcare delivery system is quite significant. Hence, while service utilisation of general hospitals is greater than TCM hospitals (in 2017, the number of inpatient visits to general hospitals was nearly 6 times than that of TCM hospitals) in 2017 the average daily visits to TCM doctors (7.45 person time) surpassed the

Figure 2.1: YoY Growth Rate of Number of Hospitals in China



Source: Chinese Statistical Yearbook, 2017.

Figure 2.2: Total Visits and Inpatients in TCM hospitals Year Wise



* ***Note:*** data for Time period 2013 is unavailable.

Source: China Statistical Yearbook, 2017.

Table 2.1: TCM- and Western Medicine Hospital Patient Data for Year 2017

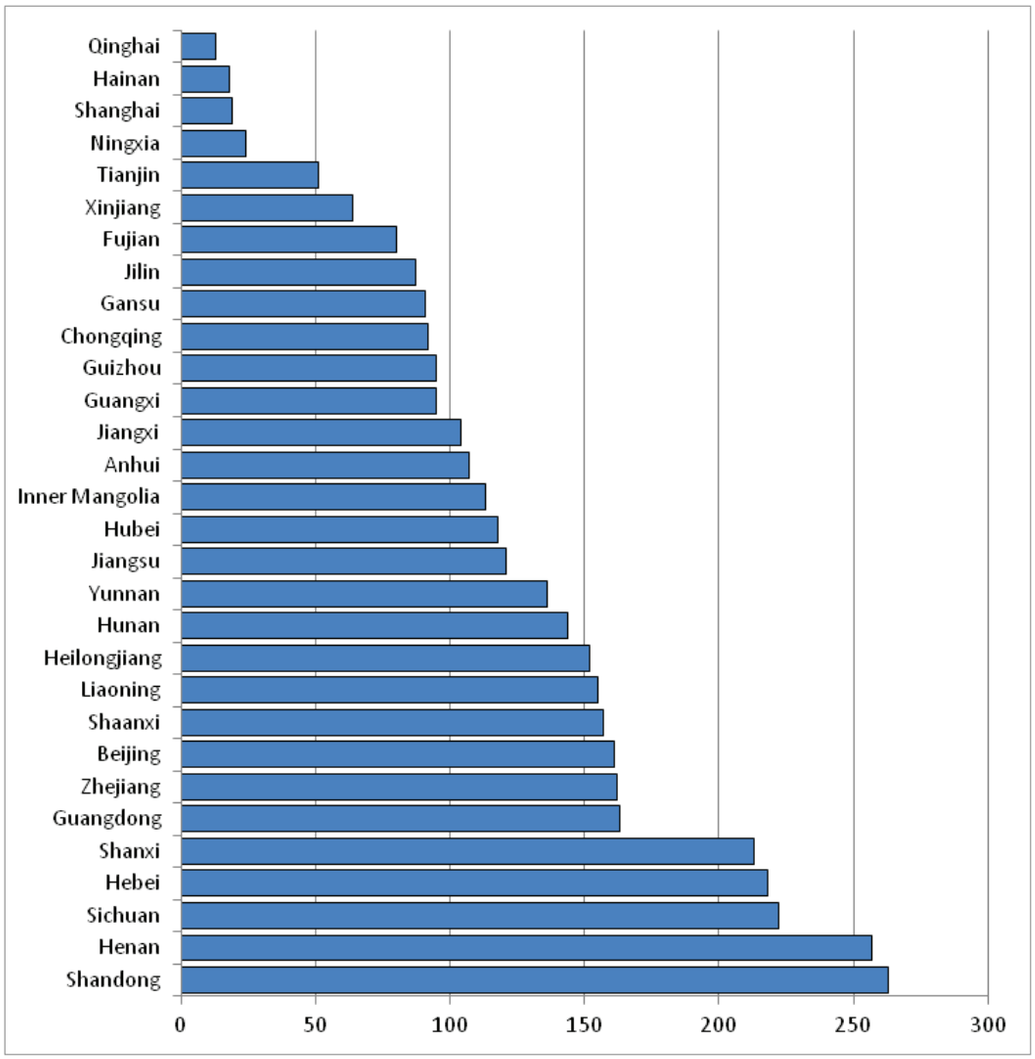
Variable	Total	General Hospitals	TCM Hospitals	Integrated TCM & Western Medicine Hospitals
Visits (10,000 person-times)	818311	250229	52849	6363
Inpatients (10,000 persons)	24436	14360	2493	261
Daily Visits Each Doctor (person-time)	8.16	7.26	7.45	7.12
Days of Total Beds Actually Opened (100,000 day)	274490	145863	28631	3404
Average Beds Opened (bed)	752	400	78	
Turnover of Beds (time)	32.3	35.8	31.6	27.9
Working Days of Beds (day)	291.0	314	310.3	294.6
Utilization Rate of Beds (%)	79.7	86	85	80.7
Average Stay Days in Hospital (day)	8.6	8.6	9.6	10.3

Source: China Statistical Yearbook, 2018.

same for western medicine doctors (7.26 person time), implying the perception, acceptability and reliability of TCM among Chinese patients. Even the utilisation rate of beds of TCM hospitals (at 85 per cent) is comparable to that of general hospitals (86 per cent). The average length of stay in hospitals (ALOS) is often used as an indicator of efficiency, where a shorter stay will reduce the cost per patient discharged and shift care from inpatient to less expensive post-acute settings. Here, general hospitals fare better as compared to TCM hospitals (Table 2.1) implying the increased costs associated with TCM treatments.

Figure 2.3 shows the provincial distribution of TCM hospitals across China for the year 2017. The geographic spread of TCM hospitals are in proportion to the regional population

Figure 2.3: Number of Healthcare Institutions Specialising in TCM Services, 2017



Source: China Statistical Yearbook, 2017.

number in general. Guangdong province has China's largest population number, accounting for about 7.8 per cent of total. It is also one of China's most developed regions. In 2017, about 4.4 per cent of total TCM hospitals were in Guangdong province. With large populations, Henan and Shandong provinces also have relatively more TCM hospitals than other provinces. There are fewer TCM hospitals in West China for reasons including smaller populations, relatively underdeveloped economies, and lower income levels though the government has increased its focus on China's western regions in recent years.

For the TCM hospital industry, a growing number of patients have ensured that revenue and profitability increases. Profitability has risen from 0.9 per cent in 2007 to an estimated 5.4 per cent in 2018.[20]

However, FDI in TCM hospitals is not permitted. In 2017, *Catalogue for Guidance of Foreign Investment (2017 version)* was issued by the National Development and Reform Commission and the Ministry of Commerce[21]

Box 1: Sichuan TCM Hospital

Sichuan Province Traditional Chinese Medicine Hospital, affiliated with the Chengdu University of Traditional Chinese Medicine is the most comprehensive TCM hospital in the southwest region of China. Sichuan TCM hospital was established in 1957 and has 2,000 beds and 1,000 employees. Currently, the hospital has 30 clinical departments, nine medical technology departments and eight TCM inpatient areas. It also provides some Western medicine service for the patients. As an important foreign communication base of TCM hospitals in Sichuan province, the hospital has established diabetes treatment centres in Malaysia, Montenegro and Germany.

Source: Based on field visit to Sichuan TCM Hospitals.

Box 2: Sichuan Tian Xiang Orthopedics Hospital, Chengdu, Sichuan

It is a private TCM hospital that specialises in Traditional Mongolian Medicine.1 Mongolian medicine system mainly specialises in orthopaedics because of Mongolian history of experience with war related injuries. The hospital specialises in treatment injures and orthopaedic complications for artists and sports persons. Though TCM is the primary service offered, modern medicine related services are offered too. For example, in emergency services, modern medicine services are required. However, modern medicines account for only 10 per cent of total services.

There are approximately 70-80 doctors, 80 nurses and 20 paramedics. All doctors are qualified and licensed. Sixty per cent are TCM personnel while the rest are modern. The patient to nurse ratio is 1:0.4. All paramedics are regulated by state license authority. The hospital receives around 300 inpatients per month and 200 outpatients per day. The hospital has 250 beds.

Recent policy focus on support for minority medicine and private hospitals has ensured state support for this hospital.

Source: Based on field visit to Sichuan Tian Xiang Orthopedics Hospital.

Sichuan Tian Xiang Orthopedics Hospital, Chengdu, Sichuan

where the state restricts foreign investment in medical institutions. The industry is mainly dominated by public medical institutions. In 2018, state-owned TCM hospitals are estimated to account for 71.2 percent of total.[22] Although national policies have encouraged developing private hospitals in recent years, private hospitals' scale and service quality are still lower than public traditional Chinese medicine hospitals.

TCM hospitals have been offering comprehensive and diversified medical services since the 1970s. The "*Integrating Medical Services of both TCM and WM*" policy in 1970s brought modern medicine into TCM hospital system.[23] Further reforms like the "*Basic Standards for Medical Institutions*" by the Ministry of Health in 1994 explicitly required 'first class' (Grade A) TCM hospitals to be equipped with adequate Western Medicine instruments.[24] Therefore,

besides the traditional medicine devices, some Western diagnosis and treatment devices are also introduced. Rising demand, China's move towards a market economy and pressures from Western Medicine has also resulted in TCM hospitals providing both TCM and Western Medicine in both inpatient and outpatient medical services.

Hospitals in China are segmented by grade based on an overall evaluation of medical technology adoption, medical equipment, patient safety, hospital management, etc. There are three main hospital grades (A, B, and C).[25] Competition among TCM hospitals is often based on hospital grade. In general, higher-grade hospitals have more experienced doctors, better accommodations, better reputations, and attract a greater number of patients.[26]

The top five diseases for admission to TCM hospitals in 2008 were: cerebrovascular accident, intervertebral disc displacement, haemorrhoids, ischemic heart disease and hypertension.[27] Gynaecological and Orthopaedic treatments are also sought after.

2.5 Key Policy Initiatives for TCM Hospitals

The government has increased the financial allocation to TCM hospitals, from USD 2.3 billion in 2012 to USD 4.15 billion in 2017, an annual growth of 12.5 per cent over the period.[29]

In 2016, the National Development and Reform Commission released the *National Health Security Construction Plan*. In order to improve the level of medical service in TCM hospitals, increase in financial support for 90 major TCM hospitals and 10 provincial TCM research institutions to develop medical innovation capability was announced.[30]

To improve quality of services and ensure subscription to regulations the following plan and programmes have been relevant:

Box 3: Chengdu Jinniu Erma Clinic Qiang Medical Centre

The is a small licensed clinic that practices Qiang medicine, an ethnic minority medicine categorised by the SATCM. According to Dr Fushou Yang, Head, *Chengdu Jinniu Erma Clinic Qiang Medical Center,* Qiang medicine dates back to BC 28000 - BC 10000 years (*sic*) and developed in Tibetan mountainous area. Pharmacy has been built over time. The raw material for the system requires high altitude. There are 11 Clinics of Qiang medicine in Sichuan.

This clinic has a treatment room, a pharmacy and around four beds. It claims to have treated patients suffering from blood cancer and bone cancer. Dr Fushou Yang, the head of the clinic, is a member of the Board of the TCM Committee in Chengdu. It receives approximately 30 patients per day. Major treatments offered in such clinics include orthopaedic services, internal medicine, paediatrics and gynaecology though Qiang medicine specializes in orthopaedics and internal medicine. Chiang Qiang doctors are taught by Qiang medicine teachers and do not have TCM University education. The standards for this system of medicine are being developed. Before 2017, such clinics could be established under a licensed TCM doctor. After 2017 following special policy directives for minority systems, regulations prescribe TCM certification to start a clinic.

The clinic collaborates with institutions like South West Medical University for technical support and has been receiving support from the government since 2017. They also receive support from the Bureau of Sanitation in Chengdu. At present, more than 200 doctors practice Qiang medicine. The clinic is also used for educational purposes. They have collaborations with other hospitals and educational institutions and universities.

Qiang medicine is mainly practised in Sichuan though two hospitals operate in Shaanxi province. A hospital in Sichuan is under construction and is being built through State support. This hospital is a combination of Qiang medicine and TCM.

Source: Based on visit to Chengdu Jinniu Erma Clinic Qiang Medical Centre.

TCM hospitals are required to comply with the "*Traditional Chinese Medicine Institution Setting Standard*" established by the State Council and with local health planning. The Ministry of Health is the highest institution in the healthcare sector in China, and it has established several series of health regulations. TCM hospitals must comply with conditions of participation, licensing, and construction requirements. Regional TCM hospitals must also comply with relevant local regulations.

In 2008, *TCM Hospitals Administrative Evaluation Guidelines (2008)* was revised. It put forward detailed regulations on hospital management, medical quality control, hospital safety, hospital performance and hospital evaluation.

In March 2012, *Traditional Chinese Medicine Industry Scientific Research Project Management Interim Procedures* was issued by the SATCM. It further standardised organising procedures and improved fund application efficiency.

Digital technology is being promoted for better service standards in TCM. In December 2017, SATCM launched *Guidance for Promoting Application of Internet Technology in Traditional Chinese Medicine Hospitals*. It encourages TCM hospitals to use digital technology to innovate and increase efficiency of medical services. In addition, the government encourages TCM hospitals to provide remote consultation and imaging diagnosis services to basic level TCM hospitals and healthcare institutions by using internet and intelligent technology equipment. This is beneficial to the development of primary level TCM hospitals.

SATCM in 2007 introduced the "*Guide for Evaluating TCM Characteristics of TCM Hospital,"* requiring that certified TCM staff (doctors and pharmacists) must account for more than 60 per cent of total medical staff in TCM hospitals.[31]

In 2010, *Opinions on Further Encouraging and Guiding Social Capital to Establish Medical Institutions* was issued by the State Council. As a result, the proportion of private TCM institutions has increased from 10.8 per cent in 2009 to 20.5 per cent in 2018.[32] Although in recent years national policies have encouraged private hospitals, private hospitals' scale and service quality are still lower than those of public TCM hospitals.

To promote the development of Traditional Chinese Medicine, local governments also formulate their own regulations. For example, in December 2009, the "*Sichuan Traditional Chinese Medicine Regulations*" was drafted. In 2014, Shandong province also drafted series of policy to promote the comprehensive reform of public traditional Chinese medicine hospitals.

2.6 TCM in Rural Health Delivery Systems: Regulating TCM Clinics

As mentioned above, the rural healthcare delivery exists at the county, township and village levels with corresponding facilities in TCM clinics and primary health centres offering TCM services apart from hospitals at the county level offering TCM services. Though health clinics in China may include enterprises, nursing homes, TCM clinics, village clinics and clinic departments in hospitals, over 70 per cent clinics are small village clinics. TCM clinics play an important role in health delivery in rural areas though modern medicine clinics are more preferred among rural population.

Clinics of minority medicine have also been encouraged. Challenges associated with standards and certifications of minority medicine without adequate codified texts exist. Regulations for certification of such practitioners are being designed. To ensure quality of TCM medical professionals in clinics new regulations have been underway. Under the latest policy document issued by the National Health and Family Planning Commission, '*Interim Measures for the Administration of Recording of Chinese Medicine Clinics* (2017)', the SATCM is responsible for the administration of the TCM clinics. Local authorities above the county

level will be responsible for supervision and administration of TCM clinics within their jurisdiction. For those in charge of the clinic or are clinic owners, new regulations require them to possess:

- 'Medical qualification certificate' on TCM, and
- Practice for at least three years in medical, preventive or healthcare institutions, or have a 'Chinese medicine physician qualification certificate'.[33]

Penalties including revocation of permission to practice in case of inconsistency in recording details and practice have also been provided for.

However, in keeping with the need to expand TCM clinics, standards for setting up TCM clinics have been relaxed in December, 2017.[34] Under the Interim Measures:

- TCM clinics can choose to offer solely TCM medical treatment and services or a combination of TCM and western medicine.
- Clinics that provide both TCM and western medicine are to prioritize TCM, using it in at least 85 per cent of their treatments.
- These dual function clinics should cover a total of more than 40 square metres and provide at least 10 square metres per practitioner on average.[35]

The Interim Measures require fewer years of on-the-job training before practitioners can become licensed to work in the clinics.

2.7 TCM Pharmacies

The '*Licensed Pharmacist Examination Implementation Measures*' issued by the China Food and Drug Administration (CFDA), provides for two types of pharmacists legally: TCM pharmacists and general pharmacists. TCM pharmacists are allowed to practice only in TCM whereas general pharmacists only in Western Medicine.[36] The doctors and licensed pharmacists alone can provide prescriptions to patients, and only with prescriptions can the prescription drugs be dispensed. Separate prescriptions are required for TCM patent medicines, TCM decoctions, and modern medicine. Drug retailing enterprises operating across provinces are required to obtain Good Selling Practice Certifications and each of the stores is to have at least two pharmacists – one for western medicine and one for TCM.

2.8 Challenges

One of the key challenges in TCM healthcare delivery despite substantial progress is the quality of TCM workforce both among doctors in village clinics and community health centres. TCM hospitals too suffer from a shortage of qualified TCM medical staff.

2.9 Conclusion

TCM is well extended in the general health care system. While modern medicine is popular, TCM also being promoted to reach parity in acceptance with modern medicine. An admirable feature of the Chinese healthcare system is the availability of both the systems under the same roof in many establishments and the patients have the choice to opt according to preference. TCM healthcare delivery has also improved in quality over the years.

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Sichuan TCM Hospital


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III

Medical Education

3.1 Introduction

TCM sector is undergoing rapid transformation. The reforms in TCM education have aimed to address the larger policy goal of national and international expansion. The Chinese Ministry of Education has recently issued a Regulation entitled "Reforms of Teaching Contents and Curricula of the Higher Education System in the 21st Century", 15 regulations of which are on TCM. Based on that, a number of reforms were carried out in the curriculum of TCM. Curriculum development is not restricted to TCM clinical studies. Interdisciplinary curricula have been created and national performance grades have been introduced. At the same time several versions of TCM textbooks are now used in universities. These policies are aimed at producing coherent and comprehensive education system in TCM.

3.2 Chinese Medical Education

According to 2013 data from the SATCM, 45 TCM tertiary institutions and another 215 tertiary institutions provide TCM programmes/majors in mainland China. These tertiary institutions include modern medical education institutions that offer TCM majors as well. Overall, China has adopted its medical education structure mainly from the British system. For medical training, high school graduates can choose 3-year programme in technical schools, 5-year programme as undergraduates, 7-year programme as post-graduates or 8-year programme as doctors of clinical specialty in colleges. Upon graduation, the graduates were qualified to work in the hospitals under supervision. After at least one-year practice, the graduates are allowed permission to take the National Medical Licensing Examination (NMLE) for physician certification. Residency training has been implemented nationwide in Chinese hospitals in 2016. Besides medical education system has been undergoing reforms since 2016. This includes a 4 plus 4 year degree programme that will encourage promotion of meritorious students.

3.3 TCM Education

More than 700,000 students, including 5510 international students, are enrolled for TCM education.[1] Medical education in TCM is broadly categorised into two:

- Chinese Medicine: This includes Fundamental Courses of Chinese medicine, Basic Theories of Chinese Medicine, Chinese *Materia-Medica*, Formulae of Chinese Medicine and Diagnostics of Chinese Medicine, and the classics of TCM.
- Acupuncture, Moxibustion, Tuina: They

include theories of Acupuncture and Moxibustion, Meridians and Acupoints, Selective Readings of Acupuncture Classics, and Acupuncture, Theories of Different Schools, Techniques of Acupuncture and Moxibustion, Therapeutics of Acupuncture and Moxibustion, and Medical Qigong.

Subjects of western medicine have been included in the curricula of TCM universities. Chinese university education is broadly divided into three levels: bachelors, masters and PhD levels. After the National Admission Examination, the admitted undergraduate students undergo five years of training with 5,000 hours of study.[2] This may be followed by graduate studies for three years and post graduate studies for three years. Undergraduate TCM studies are divided into majors that may include:

- TCM (this includes training clinicians in herbal therapy)
- Acupuncture manual therapy, and
- Chinese pharmacology therapy.

After a master's degree, students who pass the National Doctor Entrance Examination may enter a medical university or institute to pursue a doctorate. While the Doctorate of Medicine (DM) is a research degree attained after three years of study (including six months of curriculum study and 2.5 year medical research) the Doctor of Clinical Medicine (DCM) is a professional degree. The latter is awarded after successful completion of a three year study that includes six month curriculum study, 1.5 year clinical training in a hospital and one year medical research. According to the National Health and Family Planning Commission (NHFPC) Development Report on the Formal Training of Resident Doctors in China, 2014, all 5-year medical graduates must undergo three years of residency training in the "5+3" standard to meet the minimum requirement to practice as physicians. This state-led effort to expand clinical training converges with medical schools pursuing reforms in bringing multi-specialty clinical education into earlier stages of biomedical training.[3] Hence the study period for DCM is usually 8 to 14 years.

In addition to the five year undergraduate medical curriculum, some medical universities offer seven year programmes in clinical medicine leading directly to Masters of Clinical Medicine (MCM). More than 40 schools have both five years and seven years programmes.[4] To nurture greater talent, the top 12 leading medical schools have been authorised by the Ministry of Education to develop a dedicated 8-year programme leading to DCM. Yearly enrolment in these schools is limited to 1,300 only.[5]

TCM education programmes are also evolving with several new models being adopted. Following are some examples:

- In 2007, Beijing University of Chinese Medicine adopted a "TCM education reform experimental program." Students were admitted to this programme by an independent student recruitment process that selected applicants from families of TCM practitioners instead of through a college entrance examination.[6] Once enrolled, students were assigned to different supervisors. This programme is a combination of institutional education, master-apprentice education, and father-son education models[7].
- In 2011, Beijing University of Chinese Medicine started a 9-year Chinese medicine programme called the "*Qihuang* Program." This is a combined undergraduate and doctoral programme. During the first five years, students are trained according to an undergraduate teaching plan. In the fourth year, an entrance examination is held to enrol eligible students directly into the subsequent doctoral programme.
- In 2015, Beijing University of Chinese Medicine implemented new cultivation models of programs towards non-Chinese

Medicine majors. For instance, the new Chinese *Materia Medica* programme, called the "*Shizhen Guoyao* Program", is an 8-year integral programme comprising both domestic and international training and combining bachelor's and doctoral degrees.

- Other new programmes include the 'Excellent Pharmacist of Chinese Medicine Program" which is a 6-year combined bachelor's and master's degree and aims to produce highly qualified professionals who have specialized skills in Chinese *material-medica* and integrated pharmaceutical care.

***TCM Nursing*:** The Ministry of Education introduced in 2010 the *Standards for Establishment of Undergraduate Nursing Programme* and *Basic Requirements for Teaching in Undergraduate Nursing Programme*, which have promoted establishment and development of nursing programmes in medical colleges and universities in China with a basic guideline for training of nursing professionals. In 2013, the Nursing Education Steering Committee under the Ministry of Education formulated relevant standards for TCM nursing programmes in collaboration with TCM colleges and universities including standardising the curriculum and clinical practice of nursing programmes in colleges and universities[8] (Hao, Jiang, and Gu, 2017). *The Outline of the Development Plan of Nursing Career in China (2011–2015)* also emphasises on TCM nursing development through improved nursing standards and application of TCM nursing techniques in clinical practices.

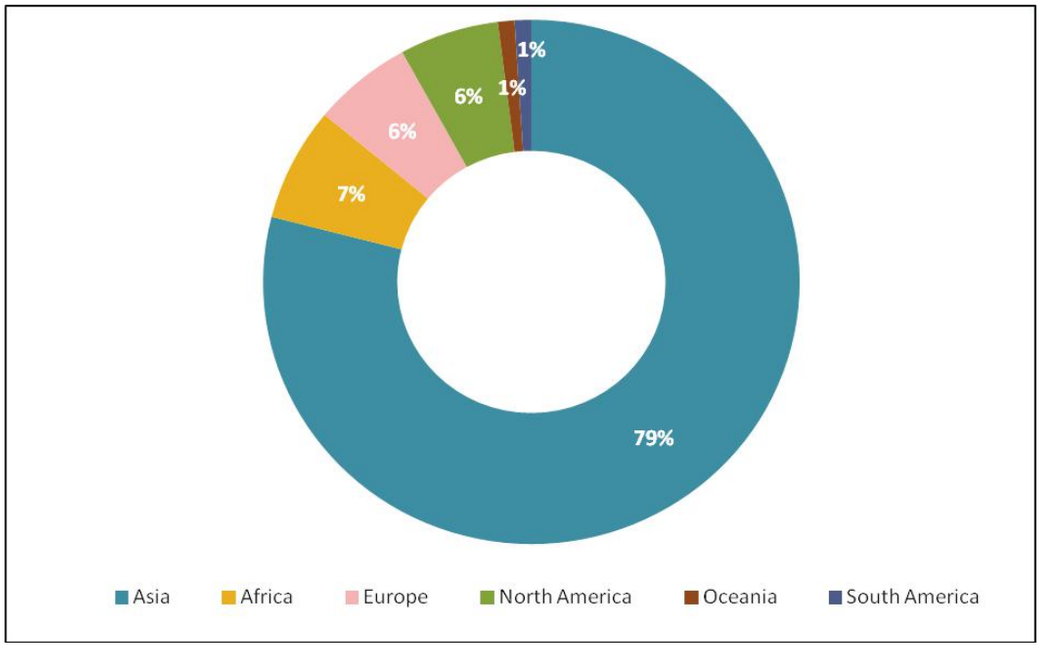
***TCM Pharmacist*:** The new Chinese *materia medica* education programme, called the "Excellent Pharmacists of Chinese Medicine Program," is a 6-year combined bachelor's and master's degree and aims to produce highly qualified professionals who have specialised skills in Chinese *materia-medica.*

3.4 Distinctive Features of TCM Education

***TCM as a part of modern medicine education curriculum*:** TCM education is a mandatory part of mainstream medical education in China**.** The Chinese Ministry of Health stipulates that medical education institutions must provide nationally standardized courses in TCM.

Integration of humanities, social and natural sciences: TCM universities do not restrict to teaching TCM. There are compulsory courses such as a basic course in humanities and social sciences, foreign languages, sports units, information sciences, basic courses in TCM, basic courses in clinical TCM, basic courses in western medicine, clinical courses for TCM and clinical courses for western medicine. Courses on management, trade, accounting and governance are intended to train professionals to meet the needs of all TCM allied industries. At the same time professional courses are structured by taking cognisance that TCM is different from modern medicine. For example, in western medical hospitals which are highly dependent on medical equipments for diagnostics, procedures, etc., accounting for fixed costs particularly in medical equipments becomes very important. In TCM hospitals the practitioners' medical experience is traditionally more important than devices, the accounting should be concentrated on human costs. Additionally, the revenue costs of modern pharmaceuticals and TCM medicines (herbal concoctions) are different because the latter is used in larger amounts.[9] Many TCM universities like the Chengdu University of TCM offer well rounded non-medical disciplines apart from TCM medical education. These include disciplines such as business management, economics, trade, language, engineering, etc. The uniqueness of this approach is the inclusion of TCM education as compulsory subject in selected semesters. The benefit of this model is

Figure 3.1: International TCM students in China by region (2015)



Source: Zheng and Lee, 2016.

that it prepares a workforce in management of TCM sector that could include business, trade, marketing, production, etc.

TCM for international students: Higher education of TCM has already begun its process of internationalisation. More than 3,000 foreign students are enrolled in TCM courses, representing the largest part of exchange students. For students who have not previously studied Chinese, an English version of the textbooks is offered. Separate classes taught by specially trained bilingual teachers; if necessary, a translator is consulted. Most of these students specialise in acupuncture and massage therapies.

Majority of the international students pursuing TCM courses in China are from Asia, followed by Africa (See Figure 3.1).

Collaboration with foreign universities

Many TCM universities have developed transnational programs for TCM. For example, the Florida based Atlantic Institute of Oriental Medicine, has a scheme under which acupuncture students can study one additional year at Shanghai University of Traditional Chinese Medicine[10]. Chinese universities have also set up campuses outside China, specialising in TCM education. For example, the Chengdu University of Traditional Chinese Medicine

Box 1: Chengdu University of Traditional Chinese Medicine

CUTCM is one of the early universities and one of the key universities. Besides the leading courses in TCM, it offers courses in engineering, business management, literature and agricultural sciences, etc. The teaching Hospital of CUTCM is one of the premier hospitals and is a national model TCM hospital. With over 500 professor and associate professors, 88 tutors for doctors and 283 tutors for masters, the University houses around 10,000 students. Non-medical students pursuing other disciplines are required to mandatorily undergo two semesters of TCM related courses. Many students opting for medical and non-medical courses aim at the career in the TCM.

Source: Authors' visit to Chengdu University of Traditional Chinese Medicine

(CUTCM) in collaboration with Universidade de Evora has set up an overseas TCM campus in Portugal.[11] TCM education in other countries is discussed in Chapter-8, 'Internationalisation'.

3.5 Conclusion

TCM education in China is not isolated from general medical education. All medical education exposes students to both TCM and modern medicine. This helps develop in the students an understanding of the other system. Big TCM universities are universities offering courses in both medical and non-medical subjects. These include trade, management, humanities, social sciences, etc. This contributes to promotion and facilitation of entrepreneurship in TCM related industries.

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IV

TCM Manufacturing Industry

4.1 Introduction

The TCM industry constitutes a significant proportion of Chinese pharmaceutical industry. Out of total 7,541 pharmaceutical enterprises in China, about 1640 enterprises were TCM industry enterprises in 2016 (see Table 4.2). Domestic demand for industry products has increased from USD 21.20 billion in 2013 to an estimated USD 36.47 billion in 2018. Although revenue and profit have been growing steadily, the scale of industry enterprises is small with a small number of enterprises dominating total industry revenue. The demand for TCM products is mainly from hospitals and drug stores where hospitals play a dominant role. Policy emphasis has been towards higher standards. This is expected to create greater maturity of the industry, thereby weeding out smaller non-performing units and giving way to more competitive units.

4.2 Regulations

Institutional Framework

In order to manufacture drugs in China, a manufacturer must receive a Drug Manufacturing Certificate, which is granted by the relevant provincial or local authority, following the guidance provided by the Good Manufacturing Practice (GMP) legislation at the Central level. There is some overlap between GMP manufacturing certifications and the drug approval process, as GMP certification is product specific, but cannot be granted without a drug approval, which can only be given with a drug manufacturing license. Overall there is a three-step process: a new facility must be approved after passing facility inspections, whereupon it will receive a drug manufacturer license: then, it can initiate the drug registration approval process lasting at least nine months, following which it may receive a provisional approval. Following this, there must be application for and approval of GMP certification. The time period between completing construction of a new manufacturing facility and placing a good on the market often takes 12 to 18 months[1].

Registration

The China Food and Drug Administration (CDFA) is responsible for registering new TCM drugs and in principle they are to undergo similar technical evaluations as western medicines, including data on effectiveness and safety. Article 31 of Drug Administration Law (DAL) and Article 40 of Regulations for Implementation of DAL are the main provisions for registering TCM.TCM preparations with proven history of use are exempted from some of these requirements. Those seeking market

authorisation for TCM preparations apply for one of nine categories (Table 4.1). In 2017 the CFDA approved 394 registration applications for marketing drugs which included 2 TCM drugs.[2]

Table 4.1: Registration Categories for TCM Drugs Seeking Market Authorization

Category	Description	Notes
1	Active ingredients and their preparations extracted from plants, animals, minerals or other substances which have not been marketed in China	Drugs in this category include artemisinin for malaria and arsenic trioxide for the treatment of leukaemia.
2	Newly discovered crude drugs and their preparations	Includes drugs not yet recognized as medicines of any national, provincial or autonomous region, or municipal jurisdiction; few TCMs are registered under this category.
3	New substitutes of existing Chinese drugs	Involves replacing crude drugs in TCM preparations that are toxic or are in danger of extinction; few TCMs are registered under this category.
4	New medicinal parts of existing crude drugs or their preparations	Requires using different parts of traditional TCM products (e.g. the rhizomes and rootlets of *Panax notoginseng*) in addition to the traditionally used roots; few TCMs are registered under this category.
5	Active fractions and their preparations extracted from plants, animals, minerals or other substances that have not been marketed in China	The pharmacologically active components must make up more than 50 per cent of extracts; although these are simpler than complex TCM preparations, these are still mixtures of chemicals, which may require multi-component quality control and pharmacokinetic testing.
6	Preparations of TCM formulas and natural medicine formulas that have not been marketed in China	Some medicines under this category are considered safe and efficacious because of a long history of use and can bypass phase I and II clinical studies; other medicines under this category include mixtures of chemical medicines and have more strict testing requirements.
7	Preparations with altered mode of drug delivery of marketed Chinese medicines and natural medicine products	Categories 7, 8 and 9 are for products that are already on the market but with a change in mode of administration (category 7), change in dosage (category 8) or no change at all (category 9).
8	Preparations with altered dosage form of drug delivery of marketed Chinese medicines and natural medicine products	
9	Generics	

Source: Wu, Hou, Long, Yang, Liang, and Guo (2014).

4.3 Manufacturing, Distribution and Supply

TCM manufacturing includes processed medicinal plants (*Zongyaoyinpian*) sliced, stored and distributed with the support of modern technologies, production of TCM prescriptions medicines, i.e., patent TCM drugs (*Zongcgengyao)* and production of other TCM healthcare products. Patent TCM drugs or *Zongcgengyao* mainly consist of products – pills or concentrated powered extracts – used for the prevention or treatment of diseases. A proprietary medicinal product is "any ready-prepared medicinal product placed in the market under a special name and in a special pack".[3] It is normally still in protection period based on patent law. Therefore, it is also called patent medicinal product. Additionally, TCM manufacturing includes other related activities, such as the production of TCM-specific medical devices, auxiliary materials production, packaging, etc (Tommaso, Marco, Huang, Yue and Chiara, 2018). Another classification of TCM based on the nature of raw materials used, is the classification into herbal medicine, animal medicine and mineral medicine.[4]

For producers drug manufacturing licence and GMP certificate are required while for distributors' drug supply licence and GSP certificate are required. Further, for *Zongyaocai,* i.e. medicinal plants, GAP Rules apply though GAP certificate is not compulsory. For decoction pieces and prepared slices, i.e., *Zongyaoyinpian*, a licence and GMP certificate are necessary. For TCM drug preparations, i.e., *Zongcgengyao,* a licence and GMP certificate are necessary. The drug supply licence is applicable to all TCM drug wholesalers and drug retailers. Raw materials are supplied through town and country fairs and under the 17 markets designated for crude drugs. Articles 14 and 21 of the DAL regulate drug supply licence and GSP certificate.[5]

Supply Chain

Key buyers of TCM products include TCM patent drug manufacturers using TCM decoctions, pharmacies and drug stores as the key retailers of prescription and over the counter products, general hospitals as the key distributors of prescription and OTC products of the industry, TCM hospitals as the key distributors of TCM *Zongyaoyinpian* and health clinics as the key distributors of prescription and OTC products produced by the industry. The major suppliers of the industry include TCM herb growing industry and manufacturers of medical supplies such as materials and packaging of medicinal products.[6]

4.4 International Trade

Traditional Medicine products in China offer several categories of products such as food supplements, nutrition supplements, herbal medicinal products, medical devices, and traditional medicine. In the Asian regions, Japan, Hong Kong and South Korea are the major export destination of TCM drugs and medicinal plants. Table 4.2 shows export statistics for 21 major herbal products from China. The products have been selected on the basis of methodology adopted by a Research Study on 'Enhancing Indian Exports of Pharmaceutical Products to China[7]. This study was commissioned by Department of Commerce, Ministry of Commerce and Industry, Government of India.

The table shows that the majority of exports of herbal medicines from China are dominated by just a few important herbs. *Venenum Bufonis*, a major TCM herb used as pain reliever dominates the export market. The major markets for the products given in Table 4.2 are Hong Kong, US, Japan, France and Germany. Among them, Hong Kong alone accounts for around one fourth of the total exports from China, followed by US accounting for around 8 per cent (See Table 4.3).

Table 4.2: Export of 22 Chinese Proprietary (Herbal) Medicines from China in 2017 (Million USD)

HS Code	Commodity Name	Export
30019010	Venenum Bufonis	787.5072
12119031	Fructus Lycii	101.7993
12119029	Poria	29.2055
12119016	Cordyceps Sinensis	27.7653
12119019	Rhizoma Pinellia	27.40423
28273920	Barium Chleride	25.46958
12119023	Radix Astragali	20.64558
12119026	Radix Rehmanniae	19.68077
12119018	Rhizoma Ligustici	17.76286
12119025	Rhizoma Atractylodis Macrocephalae	16.69378
12119036	Liquorice Roots	15.92551
12119021	Radix Paeoniae Lactiflorae	14.76774
12119037	Radix Astragali	13.16808
12119028	Cortex Eucommiae	11.03246
12119024	Rhubarb	9.390737
12119017	Bulbs of FritilariaeThunbergii	7.366715
28273910	Lithium Chloride	5.747414
12119022	Rhizoma Gastrodiae	3.090106
12119027	FlosSophorae	3.008663
12119032	Bantaroi Seeds	2.578192
25309010	Mineral Medicinal Substances	2.458548
12119034	Adenophora Axilliflora	2.226219
12119035	Southernwood	0.061107
Total		**1164.756**

Source: China Custom Statistics Query Platform.

Table 4.4 shows the major importers of top five medicines given in Table 4.2. As the table suggests, the Asian markets are the most preferred destinations of the proprietary medicines being exported from China. Hong Kong remained the largest importer of top four medicines, though Japan is the largest importer of Rhizoma Pinellia. Among the western nations, United States imported a lot of these medicines in large quantities, followed by Germany.

All of the above MAPs are commonly used for their various medicinal properties. For example, *Poria* (a fungus) is widely used in Asia, and approximately 10 per cent of medicinal preparations in the 2000 Pharmacopoeia of the People's Republic of China contain Poria (fu-ling) (Zhao et al, 2013). Animal studies suggest potential uses as an immunomodulator and anti-inflammatory agent, and in the management of cancer and diabetes. *Cordyceps* is also a very famous TCM herb that is being used a supplement to promote kidney health[8]. *Rhizoma Pinellia* is used for eliminating phlegm, cough and vomiting.[9]

Though TCM's main markets remain in

Table 4.3: Major Export Destination of 22 Chinese Proprietary (Herbal) medicines, 2017

Trading partner	Export	Per cent age of Total Chinese Proprietary (Herbal) Medicine Export
Hong Kong	283.81	24.37%
United States	87.464	7.51%
Japan	86.83	7.46%
France	86.34	7.41%
Germany	76.71	6.59%

Source: China Custom Statistics Query Platform

Table 4.4: The major export destination of the top 5 Chinese Proprietary (Herbal) medicines

HS Code	Commodity Name	Major Trading Partner
30019010	VenenumBufonis	Hong Kong, France, United States, Germany, Italy
12119031	Fructuslycii	Hong Kong, United States, Netherlands, Taiwan, Malaysia
12119029	Poria	Hong Kong, Japan, Korea, Rep., Viet Nam, Taiwan, China
12119016	Cordyceps sinensis	Hong Kong, Macau, Japan, United States, New Zealand
12119019	Rhizomapinellia	Japan, Hong Kong, Viet Nam, Korea, Rep., Taiwan, China

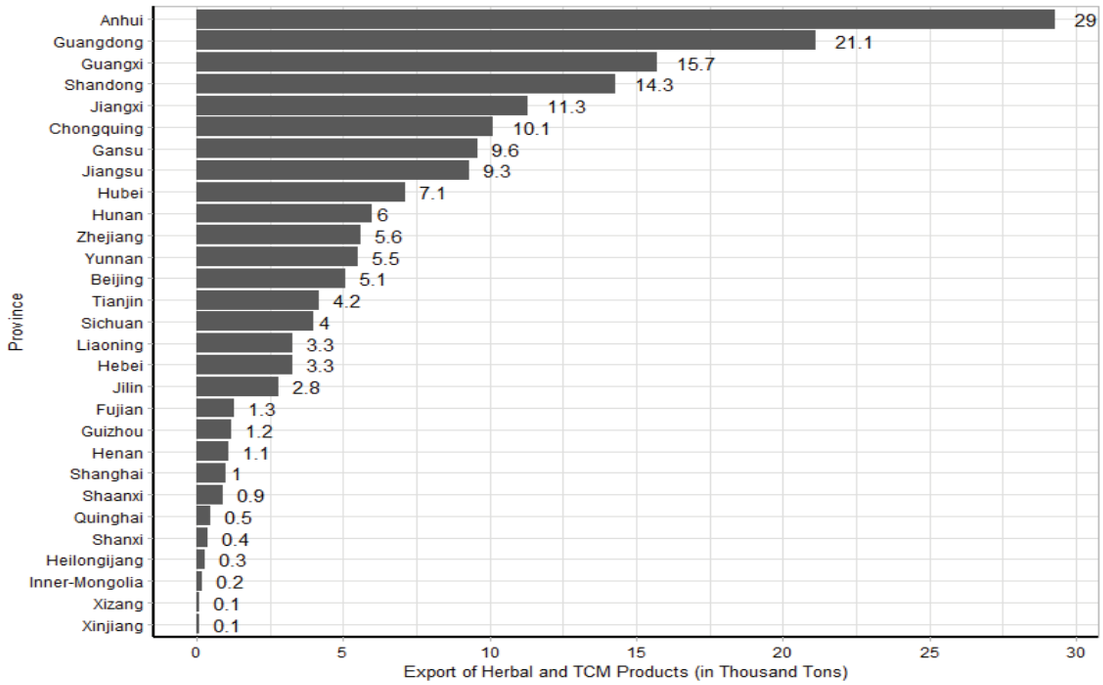
Source: China Custom Statistics Query Platform.

Asia with the major target markets located in Hong Kong, Japan, Malaysia, South Korea and Indonesia countries like the United States is another highly preferred destination of TCM products.[10] In 2016, Japan became the second largest export market after US with an export value of USD 505 million, a 6.62 per cent increase over 2015. Trade in TCM has been dependent on regulatory provisions of the importing destinations. In certain countries such as Russia, Vietnam and Australia, TCM products are sold as pharmaceutical drugs. In many other countries and regions, however, TCMs are approved for sales as health care product, active pharmaceutical ingredient (API), or dietary supplement.[11] In countries like South Korea stringent standards have led issues like heavy metal content and pesticide residues to become a discouraging factor for TCM exports.

During the five years up to 2018, the exports of TCM products have, however, declined at an annual rate of 1.3 per cent.[12]The main reason for this decline is adduced to fall in demand from developed countries.[13] Factors accounting for decreasing exports include EU regulations restricting TCM imports, increased transportation costs, lower global pricing and weak foreign demand.[14]With falling demand from the West, Japan and other East Asian countries are now the major destination of TCM exports from China.

But future demand for TCM medicines is speculated to come from other less developed countries, particularly from Africa and Central Asian countries bordering China. The 'Belt and Road Initiative' is expected to increase exports of TCM exports in the future.[15] This is likely to increase trade with Central Asia and Russia. Further, as the bilateral relations between China and Africa have grown, many Chinese have rehabilitated or moved their businesses to Africa. At present, around 10 million Chinese expatriates work in Africa.[16] This creates a demand for TCM medicines in Africa. Efforts to popularise TCM in Africa is also speculated to

Figure 4.1: Export of Herbal and TCM Products by Province (Year: 2015; Unit: Thousand Tons)



Source: Tommaso et al., 2017

increase exports of TCM even though in value terms, it is still not a major contributor to TCM exports from China.

Imports have also been decreasing over the period of five years up to 2018 at an annual rate of 5.6 per cent. Imported products are mainly higher quality products like *panaxquinquefolius, rhizome gastrodiae, radix notoginseng* and *radix pseudostellariae*.[17] Low levels of imports are mainly due to the presence of domestic TCM manufacturing industry that meets domestic demand.

Major Export Hubs

Till 2015, Anhui Province has been the largest exporter of TCM products from China, with exports from Xinjiang being the least (Figure 4.1). It is followed by Guangdong and Guanxi. As evident, the eastern regions of China have been export hubs. Eastern provinces have traditionally been more developed economically and industrially. Guangdong and Guanxi are coastal provinces, have been industrial bases with export processing bases. Anhui, despite being landlocked, has been a leading province owing to its economic development, natural resource base, educational and research leadership and important constituent part of the Yangtze River Economic Belt and the Yangtze River Delta city cluster, an important hinterland province and transport hub for the Belt and Road Initiative, and one of the most innovative and opening regions in China.

4.5 Major Manufacturing Hubs

Business locations of TCM industry are mainly concentrated in Eastern China, followed by Central and South East China. TCM manufacturing industry in China is largely concentrated in Jilin (accounting for 12.4 per cent of industry revenue), Liaoning (11.6 per cent), Sichuan (12.8 per cent) and Shandong (8.0 per cent).[18] Reasons for concentration of industry in these regions include the regional economic

development in Eastern China in general and also due to the abundance of Chinese medicinal plant resources there. However, a greater policy focus towards capacity building of the western Chinese provinces is in the process. The 'Belt and Road initiative' targeting neighbours in the western Chinese borders aims at attracting international medicinal tourists from these countries to the western provinces. In the long run this is intended to boost the TCM industry in the western provinces too.

4.6 Industry Performance

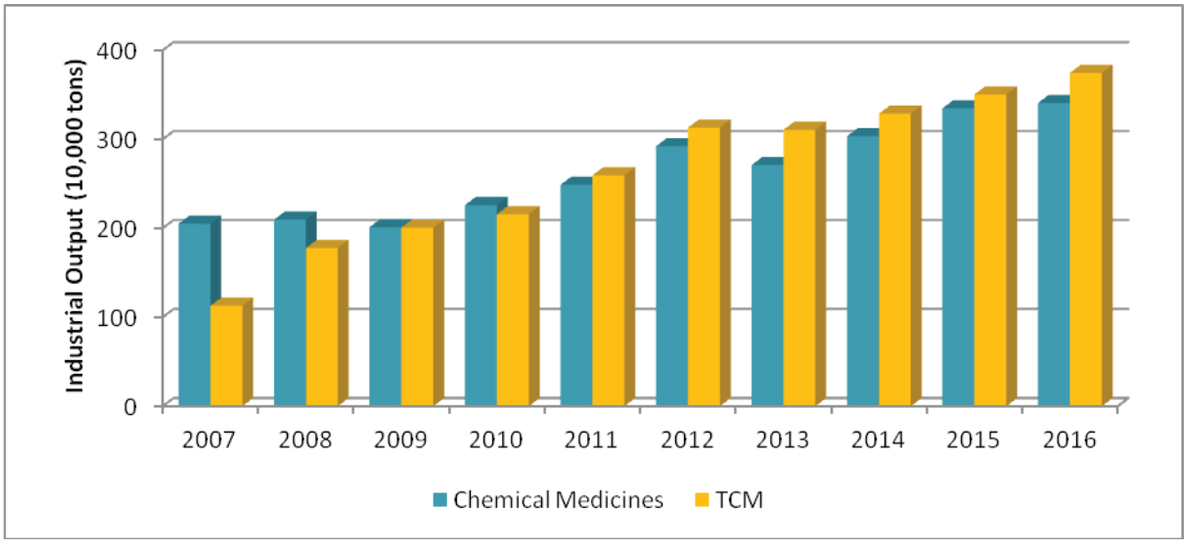
At present capital intensity is medium, owing to spending on distribution and sales related capital requirements. The level of technology use is also medium. Regulatory and policy support as well as financial assistance for TCM industry is high.

In 2016 the total industrial output of TCM pharmaceutical industry was 37.46 thousand tons, almost 10 per cent above the industrial output of chemical medicines (Figure 4.2). Between 2007 and 2016 industrial output of TCM has grown by 231.83 per cent.[19] The output value of TCM products has increased almost nine-fold from 84 to 708 billion Yuan between 2003 and 2014.[20]

Its share in the pharmaceutical sector as a whole too has increased while western medicine production has grown at a slower pace. While the number of TCM firms has been lower than chemical medicine, it has grown by 5.8 per cent during 2010 to 2016. On the other hand the number of chemical medicine firms has declined from 2,525 in 2010 to 2,421 in 2016, a decrease of 4.12 per cent (Table 4.5).

The total profits of TCM finished products as a percentage of manufacture of medicines between 2010 and 2016 has also increased from 23 per cent to 25 per cent as compared to the pharmaceutical industry where percentage share of profits has come down from 50 per cent to 46 per cent (Table 4.6). Within TCM products, patent medicines have shown more contribution to industrial output accounting for almost 567 billion Yuan in 2014 as compared to decoction or *Zongyaoyinpian*, which contributed 141.5 billion Yuan in the same year. But lately decoction pieces account for an increased share following their faster growth.[21] Over all, the TCM market segment has consistently

Figure 4.2: Industrial output of TCM and Chemical Medicines (in 10,000 tons)



Source: China Statistical Year Book, 2017.

Table 4.5: Number of TCM firms vis-a- vis other Pharmaceutical firms in China

Year	Manufacture of Biological Medicine	Manufacture of Chemical Medicine	Manufacture of Finished TCM Medicine	Manufacture of Medicines
2010	862	2525	1550	7039
2011	731	2172	1398	5926
2012	821	2274	1493	6387
2013	889	2366	1555	6839
2014	934	2371	1592	7108
2015	975	2416	1622	7392
2016	959	2421	1640	7541

Source: Compilation of data from China Statistical Yearbooks

Table 4.6 : Profits of TCM industry *vis-a- vis* other Pharmaceutical Industries in China (in Million Yuan)

Year	Manufacture of Biological Medicine	Manufacture of Chemical Medicine	Manufacture of Finished TCM Medicine	Manufacture of Medicines
2010	17850.92	66752.52	30536.87	133109.39
2011	22442.97	72702.71	40550.74	160602.42
2012	27342.62	83808.70	47163.87	186589.42
2013	29613.66	93601.39	56262.20	213270.63
2014	33335.87	106423.34	61909.99	238246.60
2015	39038.31	119733.24	69695.16	271734.93
2016	41970.02	144186.95	76579.00	311499.50

Source: Compilation of China Statistical Yearbooks

outperformed Western medical sales since 2008 in terms of growth rate.

The profitability of TCM firms has also been increasing over time. Table 4.6 gives the average profits made by different pharmaceutical firms in China. The average profit of TCM firms has increased from 19.7 million Yuan in 46.7 million Yuan in 2016, a rise of 137 per cent (see Table 4.7). Modern Medicine enterprises still make a higher profit on an average, when compared to TCM enterprises. But the growth in profits (around 125 per cent) is lower than that of TCM enterprises.

The profits of TCM *Zongcgengyao* as a percentage of the total profits of the pharmaceutical industry increased from 23 per cent to 25 per cent between 2010 and 2016 (see Figure 4.3). On the other hand, the percentage share of profits of the Chemical Medicine industry has come down from 50 per cent to 46 per cent during the same period (see Figure 4.3).

4.7 Policy Assistance to TCM Manufacturing

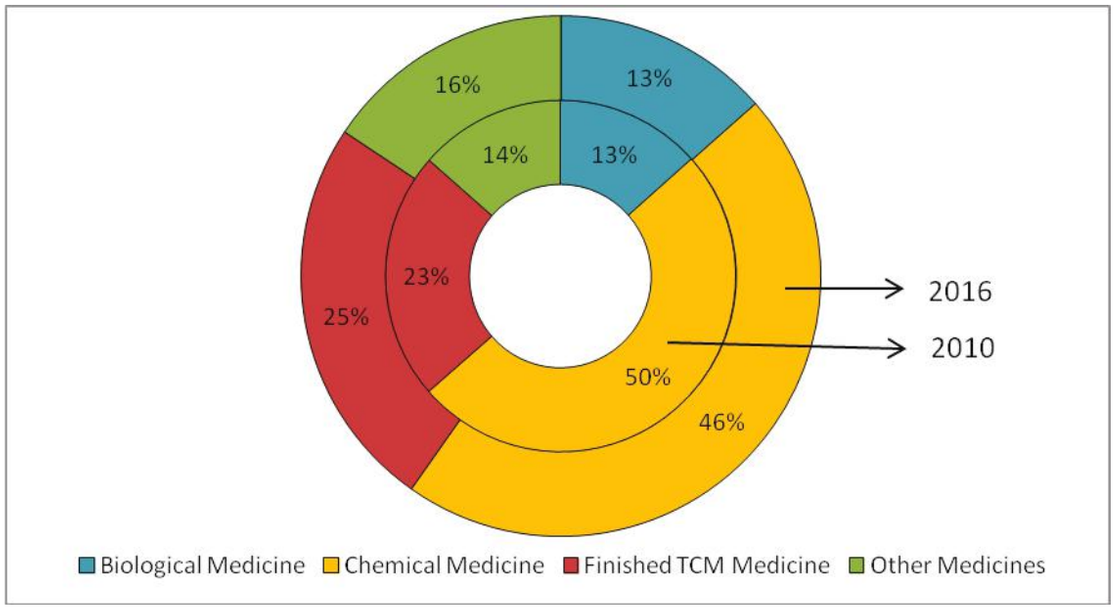
The TCM manufacturing industry in China is highly assisted by the central government in a number of ways, including by the provision of favourable taxation policies, administrative protection, large investments in the research and development of TCM, support from Chinese medicine institutions, traditional Chinese medicine training, and the establishment of

Table 4.7: Average Profit of Medicinal Industries in 10,000 Yuan

Year	Manufacture of Biological Medicine	Manufacture of Chemical Medicine	Manufacture of Finished TCM Medicine	Manufacture of Medicines
2010	2070.87	2643.66	1970.12	1891.03
2011	3070.17	3347.27	2900.62	2710.13
2012	3330.40	3685.52	3159.00	2921.39
2013	3331.12	3956.10	3618.15	3118.45
2014	3569.15	4488.54	3888.89	3351.81
2015	4003.92	4955.85	4296.87	3676.07
2016	4376.43	5955.68	4669.45	4130.745

Source: Compilation of China Statistical Yearbooks

Figure 4.3: Distribution of percentage share of profits of different pharmaceutical industries in China, 2010 and 2016



Standard Specifications for Chinese medicine. The National Essential Medicine System incorporated more than 100 TCM Patent medicines into the Essential Medicine List. Medical practitioners are required to prescribe medicine in the list, which has increased demand for Chinese patent medicine. Some local governments have issued favourable policies to support the development of enterprises engaged in traditional medicine. For example, Sichuan province formulated its own localised development plan for its traditional Chinese medicine industry. The support was manifested in funding for R&D, loans, patent declaration and for herb plantations.

The 13th Five-Year Plan (2016-2020) supports R&D in TCM and health service technology, with a focus on Chinese patent drug quality and optimize traditional Chinese medicine health services. On 26 February, 2016, the State Council issued *Outlines on Chinese Medicine and Drugs Development Strategies and Plans (2016-2030)*, which settled the development direction and key works of the Chinese medicine industry. On 25 October, 2016, the State Council issued the *Healthy China 2030 Planning Outline*, which emphasises "healthy China" strategies including the use of TCM. On 29 December, 2016, the Ministry of Commerce issued the *Industry Development Plan on National Medicine and Drugs Circulation*, which plans to develop large manufacturing and distribution networks backed with data and information services to reduce the demand-supply gap of medicines. From 2018 May, the tariffs of 28 types of Chinese patent drugs were set as zero. These include many anticancer drugs.

4.8 Challenges

TCM industry has witnessed substantial growth in the recent times to become a high tech industry in China. The pharmaceutical sector has also been undergoing reforms. From the year 2003, policy support for development of TCM industry has included modernisation of TCM, Good agricultural practice (GAP) bases, and support for large and medium enterprises.

Yet challenges remain. As with western medicine, there is significant market fragmentation with manufacturers both registered and unregistered. This contributes to challenges in quality control and regulatory burden faced by CDFA. The government has introduced GAP, GLP, GMP but implementation is often difficult. Standards for the ingredients in

Box: Chongqing Taiji Industry (Group) Co. Ltd.[25]

ChongqChongqing Taiji Industry (Group) (CTI) was incorporated in 1993 and is listed on the Shanghai Stock Exchange. CTI has 39 holding subsidiaries and is mainly engaged in manufacturing Chinese patent medicine and western medicine, processing and marketing of healthcare related products, medical equipment sales and the cultivation of Chinese herbs. CTI has strong research capabilities with five R&D centres and research programs including:

- Taiji Pharmaceutical Research Institute
- Chongqing Research Institute of Chinese Medicine
- Taiji Academic Workstation

The company has introduced advanced production techniques and lines from Japan, Germany, Canada and Italy, which has enabled higher profitability. It is among top ten Chinese pharmaceutical companies. Counted among top TCM patent medicine producers, the Group's total sales are RMB 37.6 billion in 2018.The Group also possesses its own medicinal plant cultivation base that is GAP subscribed.

The main factory of the group is in Chongqing which goes back to 1881.Production process is entirely automated with granule production capacity of 2,500 kgs. The plant also has a capacity of producing 180,000 tablets per hour following an end-to-end production. The Group has a big production facility at Fuling, Chongqing which can produce 6,000 bottles of tonic syrup per day.

The Group has managed to register their bestselling TCM product *Huo Xiang Zheng Qi Ye* in Bangladesh, Pakistan, South East Asia (Indonesia, Singapore) and Canada and UAE These are mainly registered as Traditional Medicine or TCM. However, Registration in EU, US and India has been a challenge. Their distribution network in other countries is mainly though the Chinese embassy, online contacts and local contacts provided through middle men.

Box: Zhong Kang Fu Group[26]

Zhong Kang Fu Group is medium scale enterprise dealing with *Zongyaoyinpian* (Slices) manufacturing. The Group supplies to TCM Patent medicines manufacturers. *Zongyaoyinpian*are also sold as medicines in hospitals and clinics. While raw materials are procured domestically, some herbs are imported from Russia, US and Australia. The enterprise is valued at 500mn Yuan. The policy support to industry by the government is high and includes loans to *Zongyaoyinpian* manufacturers at low interest rates, tax rebates of almost 10 per cent lower than other industries. Tax benefits however depend on various factors including location and product. Besides, provinces like Sichuan have monetary funds to support such enterprises and export promotion related assistance is also provided.

patent medicine and for preparations processes involved in sliced herbal medicines are not clearly delineated. As a result, manufacturers can cut costs by using less effective components in their products.[22]

Despite efforts, modernisation of the sector is still low.[23] Restructuring of the TCM production chain to set up full quality control and traceability system and technological innovation have been demanded and policy efforts have been strongly focused on the same. Independent innovation processes in TCM manufacturing seems to be lagging behind.[24]Adhering to the regulatory provisions on product categorisation standards is a challenge though China has taken great strides in international outreach of TCM.

4.9 Conclusion

TCM products fall under different categories such as medicine, food supplements, herbal products, etc. The regulatory regime varies as per the product description. With policy support, the sector has been able to grow substantially during the last few years. The export of TCM has shown a similar trend. However, in the last few years, export has shown a declining trend owing to fall in demand from developed countries. The Belt and Road Initiative is expected to facilitate export growth of TCM like other sectors.

Taiji Group Chongqing Fuling Pharmaceutical Factory Co

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26. Based on interview with Mr Chough Shan Zhen, Chairman, Zhong Kang Fu Group

V

Medicinal Plants

5.1 Introduction

Growth of TCM industry is highly dependent on sustained supply of raw materials, i.e., medicinal plants/herbs. Till 2015, eighty per cent of TCM raw materials were sourced from the wild.[1] In addition to depleting biological resources by as much as 30 per cent, collection from wild also failed to meet demand for up to 80 per cent of the highly used species. Cultivation has, therefore, been encouraged through several private and public initiatives. In 2016, the cultivated area of Chinese medicinal herbs reached 715.2 million hectares, up 10 per cent from 2015.[2] The percentage of cultivated area where medicinal plants are sown has increased from 0.19 per cent in 1995 to 1.34 per cent in 2016 (Figure 5.1). Today, out of 1,000 species of medicinal plants used by the industry, more than 300 – 400 constitute cultivated varieties. There are 17 designated Chinese herbal medicine markets with modernised transaction management systems. These markets sell Traditional Chinese Medicinal materials. In addition, there are 100 seasonal Chinese herbal medicine markets and thousands of traditional markets. Besides, to ensure raw material quality and supply, many TCM enterprises have established their own medicinal plant growing bases or cooperate with growing bases for supply. By 2015, Good Agricultural Practices (GAP) certification has been obtained by 195 growing bases.[3]

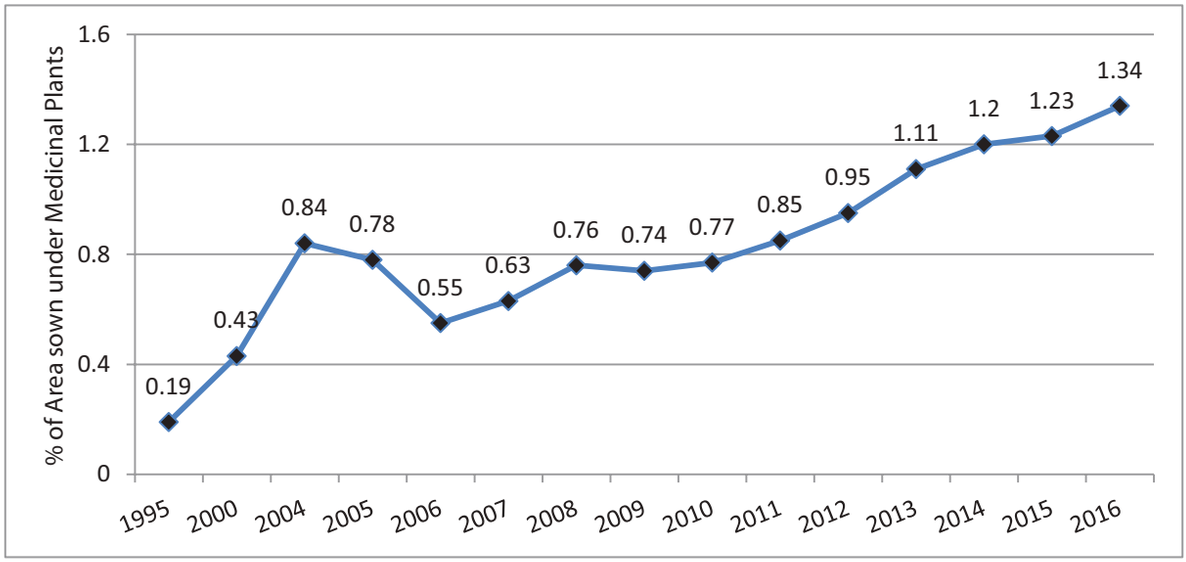
5.2 Regulation of Medicinal Plant Collection and Cultivation Practices

Medicinal plants collected can be categorised as follows:

- Widely used;
- officially used (listed in pharmacopeias); and
- not officially used but is used by local households.

The forest products are processed by collectors following which they are bought by the provincial government. However, of late most of the products are sold to industry enterprises. The collection is regulated by the provincial standards that are detailed and contain many regulations such as on use of fertiliser, method of collection, and standards for processing. Different provinces have different standards. Since provinces vary in the availability of species and genus of plants, the standards applicable are not uniform across provinces. The same species may be regulated

Figure 5.1: Per cent age Share of Cultivated Area Sown Under Medicinal Plants



Source: Elaboration of data from China Statistical Yearbooks, 2005 to 2017.

differently in different provinces.

5.3 Medicinal Plant Cultivation

To meet the growing demand for standard, uniform and quality raw materials, medicinal plant cultivation has been encouraged through policy support. Besides, several large and medium enterprises undertake cultivation of medicinal plants to ensure steady supply of standardised raw materials.

5.4 Major Medicinal Plant Growing Regions

Soil quality and climate are important for TCM medicinal plant cultivation. While soil and climate in some regions in China is unsuitable for TCM medicinal plant species, some regions/ provinces offer optimal growing conditions. Hence industry activities are concentrated in Northeast China, Sichuan and Shandong province. TCM medicinal plant growing industry in China is largely concentrated in Jilin, Liaoning, Sichuan and Shandong as these provinces have soil and climates suitable for growing medicinal plants.

Sichuan province: Sichuan province is one of the largest production bases of Chinese medicinal herbs in China, with four major growing areas in Sichuan Basin and its peripheral mountains, Panxi, northwest plateau and western canyons. Sichuan province has over 5,000 categories of Chinese medicinal herbs, accounting for 75 per cent of China's total.

***Jilin and Liaoning*:** Jilin province is located near the Changbai Mountain, which has appropriate growing conditions for popular Chinese medicinal plants, such as Ginseng. Currently there are about 2,790 categories of known herbs in this area. Liaoning province has the largest amount of rainfall in Northeast China and the climate in Liaoning is suitable for growing Ginseng, Schisandra Chinensis and Codonopsis Pilosula.

5.5 Policy Initiatives/Support for Medicinal Plant Cultivation

The Chinese Medicinal Herb Growing industry is favourably assisted by the Central government in a number of ways, including the provision of favourable taxation policies, administrative

protection, large investment in research and development, support from Chinese medicine institutions, Chinese medicinal herb growing training, and the establishment of Standard Specifications for Chinese medicine. As per recent update of Chinese foreign direct investment (FDI) regulations the joint-venture requirement for cultivation of herbs for TCM production has been removed.[4]

Substantial funds are allocated to support medicinal plant cultivation. The government also supports large scale farming that requires 500-1000 acres farms. These farms are led by enterprises and consist of teams of scientists to monitor the cultivated species for R&D. At the provincial level the funds for these projects are around 1 million Yuan.[5] The funds are allocated by the Central government and are given to Provincial government which in turn directly funds special projects. Fund allocation serves several ends. These include:

- Creating GAP bases.
- R&D and protection of endangered species.
- Employment generation and targeted poverty alleviation.
- The funds are also needed to collect raw materials, processing materials, instruments, seeds, etc.
- Machines for further processing are also needed after the collection process is done.
- Subscription to GMP standards.
- Small scale enterprises are entitled to claim financial support for GAP cultivation of medicinal plants.

Box 4: Planting base operated by Liuli Village, Jiguanshun Township, Chongzhou City, Sichuan[8]

The Cooperative institution/ Committee of Village

The village has an area of 23 sq km. The cultivation project here is supported by central, provincial and county government in the equal ratio. This project comes under the poverty alleviation programs of the government. The farmers offer part of whole of their land for medicinal plant cultivation. Seeds are provided by the centre. Then the cultivation of the medicinal plants is undertaken by local labour trained in species cultivation. The farmers are given a part of the profits. The farmers can sell the plants to this centre or to the industry directly.

Major products of this planting base are *Yunan Polyphylla* (Chong Lou), *Coptis Chinenisi* (Huanglian) and *Bletilla Striata* (Bai Ji) Though GAP standards are voluntary, at these plant bases, standards in ascending order of importance are: Provincial standards, SFDA and Pharmacopeia standards. R&D on the species is undertaken by faculty of Chengdu University of TCM. Some of the plants studied at the base:

Chong Lou (*Yunnan Polyphylla*): This is a major herb cultivated at this base. This is a high value species, endemic to Sichuan province and total revenue generated from cultivation at this base is 10 BN Yuan. It is also an endangered species that is cultivated for propagation and conservation. Twenty species of plants belong to this genus and 17 species can be found at the planting base. It takes a year for the plant to attain maturity. The roots underground can last for five years. Only the roots are used for TCM. The green house is used to collect seeds of this genus. 1000 acres area is devoted only to plant this genus. Some of the species in this genus is extremely endangered. Seventy per cent of all species of this genus is planted in this greenhouse. The scientific research for this genus is done in collaboration with Chengdu University of TCM.

Other herbs like Bai Ji (*Bletilla Striata*) aTCM herb that is used to stop bleeding and help in muscle growth are also grown. The plants grow at the altitude of 100-3200 metres. The County produces 5000 tons annually, out of which 17 per cent is exported to Korea and Japan.

Chong Lu Farms at Liuli Village

China Herbal Industry Poverty Alleviation Action Plan (2017-2020)

Cultivation of medicinal plants is a strategic policy initiative towards livelihood generation and poverty alleviation for several reasons. Traditionally medicinal plant cultivation has been an important part of China's rural poor population income. Each species has biological characteristics determined natural ecological environment factors. Cultivation of plant species endemic to the region would also provide competitive advantage to the farmers. The Ministry of Traditional Chinese Medicine and the State Council Poverty Alleviation Office and other five departments jointly issued the *China Herbal Industry Poverty Alleviation Action Plan (2017-2020)*, where counties with a high level of poverty indicators would benefit from the programme.[6]

Medicinal Plant Cultivation Cooperatives[7]

Cooperatives have been established as a part of the holistic approach to promoting cultivation along with R&D on medicinal plant species. The high demand medicinal plants species receive special R&D attention and research base as well as planting base has been created for these plants with the help of provincial and central governments. There are more than 200 such planting bases in China. Cooperative institution comprises of farmers and the village administration. The Central and provincial governments give funds to these cooperatives. Within a cooperative, the farmers pool their lands together to cultivate medicinal plants. Government offers funds and university offers technology and expertise. The local administration is responsible for leasing land from farmers and cultivation of medicinal plants. Funds for seeds and planting are provided by the village administration.

Designated Markets for Medicinal Plants

Unique to TCM, there are seventeen designated market places for commerce in TCM raw materials. These are collection and distributing centres for Chinese medicinal herbs where farmers, seller and buyers come together. The revenue generated from these markets

Box: Chengdu Lotus Pool Chinese Medicine Professional Market[9]

This market is one of the 17 TCM markets nationally, third largest and the only national market in South Western China. This is also the largest market for *Cordyceps,* used in TCM for Cancer related treatments. There are 2300 shops in the market with 3000 wholesalers. Separate Sections are allotted to sale of raw materials for high demand ingredients and for manufacture of specific medicines. By law, processed raw material for TCM can only be sold in these markets.

The market has its administrative organisation and medical inspection mechanism and infrastructure. At the beginning, the market was supported by central government but now is owned by a private entity. The other 16 markets are also owned by private organisations or a person. The wholesalers rent the shops. A *yinpian* producer can purchase raw materials for himself from this market, from plant bases or from farmers directly. However from farmers it can be bought only as an agricultural product. The prices are not controlled.

The market is supported by seven ministries like ministry of commerce, custom, tax, market, management, etc. This market also provides a platform for the sellers to sell their products to the overseas market. There are four major initiatives to promote export:

- Zero value added tax for export. The minimum value for exports is expected to be one million Yuan. The smaller exporters are expected to collaborate with each other and make the value of the package to one million Yuan.
- Currency exchange from RMB to dollars is supported by banks.
- Given the nature of medicinal plants and quality issues associated with raw materials, quality assurance through certification for herbs being exported from this market is ensured.

The organisation facilitates export and import of TCM products and is the registration centre for exporters.

Chengdu Lotus Pool Chinese Medicine Professional Market


三胶三元堂
三胶三元
东阿阿胶
龟甲胶
鹿角胶
鑫茂药行
湖南爱敬堂制药有限公司


599-2
铁皮石斛


6-1-0049
3

account for 35.3 per cent of total medicinal plant industry revenue. The advantages of such markets include greater regulatory control on standards, traceability of products, ease of doing business for buyers and sellers and export facilitation infrastructure and certifications.

Initiatives at the Provincial level

Some local governments have issued favourable policies to support the development of enterprises engaged in Chinese medicinal herb growing.

5.6 International trade

Unlike TCM manufactured products, export and import of medicinal plants and associated products exports have been growing. Exports grew by 12.6 percent in 2017 to total D1.23 billion, making up 4.8 percent revenue. Major export destinations include Hong Kong, Japan, South Korea, Taiwan, Malaysia, the United States and Germany. Hong Kong, Japan and South Korea have practices of traditional medicine similar to TCM, which promotes industry trade. However, the large domestic market means that most medicinal plants related industries are focused on local trade.

The major sources of imports into China include Canada, Kazakhstan, the United States, Uzbekistan, Ghana and India.

5.7 Conclusion

Medicinal plant cultivation as an alternative to collection practices and as a sustainable supply mechanism has received a major boost under President Xi Jinping. The medicinal Plant Cultivation Cooperatives and the *Poverty Alleviation Plan 2017-2020* are major initiatives at the policy level. These and other focussed initiatives by the manufacturing units have ensured increase in acreage under cultivation of medicinal plants. Further, emphasis on R&D in threatened species crucial for TCM is an important highlight of the TCM promotion policy. These measures have ensured increase in export of medicinal herbs while ensuring supply to the domestic markets. Setting standards at the local, provincial and national level is also an influential factor in the international perception of safety of TCM.

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7. Based on interview with Prof. Yin Hongxiang, Associate Professor, Chengdu University of TCM, Expert in Botanical Plants and Agriculture Research
8. Visit to Liuli Village and interview with Prof. Yin Hongxiang, Associate Professor, Chengdu University of TCM, Expert in Botanical Plants and Agriculture Research
9. Based on visit to Chengdu Lotus Pool Chinese Medicine Professional Market

VI

Quality Assurance and Standards

6.1 Introduction

Quality assurance remains one of the main challenges for TCM's growth. Drug safety concerns arise due to contamination during cultivation, harvesting, handling, processing, storage and distribution. Development of a single pharmacopoeia (that includes TCM and western medicines), pharmaco-vigilance, market surveillance and launch of relevant standards in products and services are important TCM policy initiatives towards quality assurance.

6.2 Chinese Pharmacopoeia

The *Chinese Pharmacopeia* (ChP), compiled by the Chinese Pharmacopeia Commission (ChPC), is the official compendium of national drug standards covering Traditional Chinese and Western medicines. It provides official guidelines on standards of purity, description, test, dosage, precaution, storage and the strength for each drug, and is recognised by WHO as the official pharmacopeia of China. The Commission has 23 specialised committees including four on TCM. The ChPC is responsible for international communication and cooperation on drug standards, and participate in drafting and revision of international drug standards. The harmonisation of pharmacopoeia has provided several benefits to the pharmaceutical and TCM industry, including increased efficiency for access to markets, elimination of redundant testing and ensuring multi-compendial compliance.

6.3 Parmaco-vigilance on TCM: National and International initiatives

According to statistics, TCM accounts for approximately 14 per cent of total adverse drug reaction (ADR) spontaneous reporting data in China.[1]ADR monitoring and reporting has, therefore, assumed significance for safety assurance of TCM. TCM ADR monitoring system identifies and reports drug safety issues. Prior to 1989, the Chinese Ministry of Health (MOH) had established 10 Pilot Monitoring Units across the country; the data collection was mainly via literature survey, and case reports from hospitals and patients.[2] The ADR Monitoring Centre was established in 1989 with responsibility for both types of drugs TCM and modern drugs. In 1998, the Monitoring Centre became a member of the WHO International Drug Monitoring Programme. Through the aid of expanded infrastructure a national network system for ADR monitoring was established in 2003. The number of reports submitted through

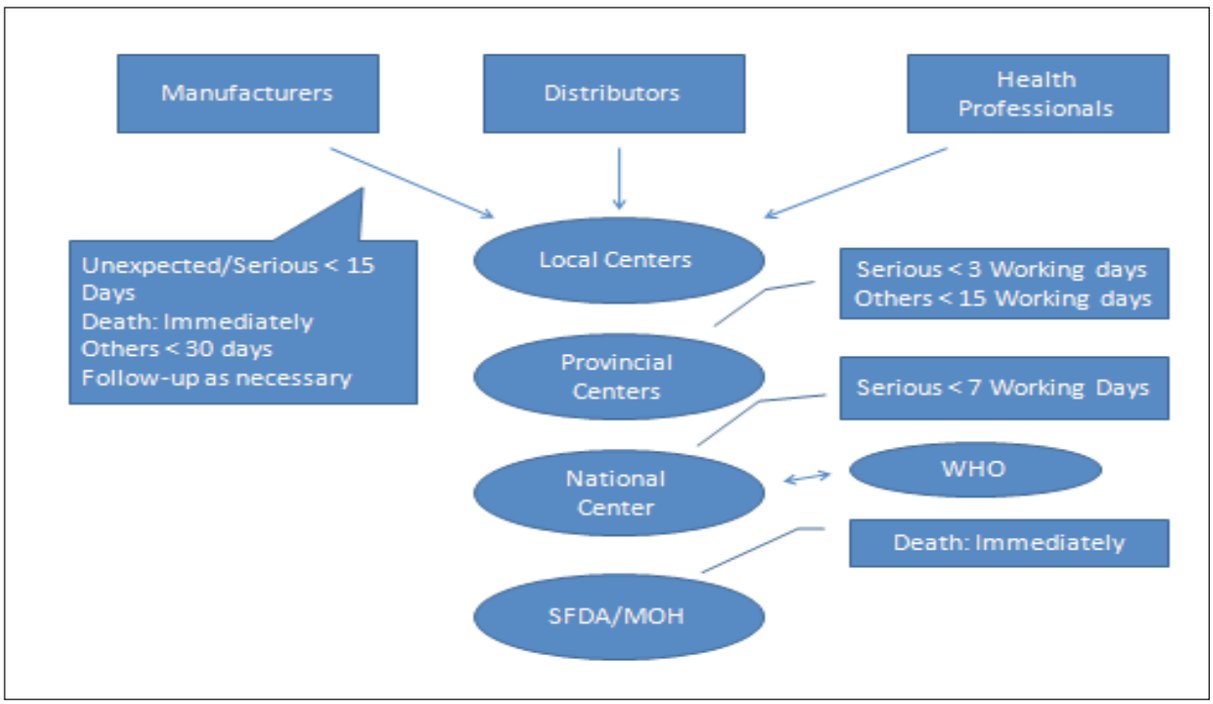
the network reached nearly 10,750,000 in 2016 and has been increasing at a rate of 1 million per year[3]. TCM and western medicine share the same reporting system.

Collaboration with international agencies known for high standards in drug safety is also a strategy adopted towards building safety standards in TCM. Hence the CFDA also collaborates with the United States Food and Drug Administration (US FDA) and the European Medicines Agency (EMA) for inspections and training programmes on ADR reporting. In December 2007, CFDA and US FDA reached agreement to participate in each other's inspections and investigations against counterfeits and substandard drugs.[4] In March 2008, the US Pharmacopeia Convention (USP) and Chinese Pharmacopeia Commission (CPC) signed an MoU with the objective of working together to strengthen the quality of medicines in both the United States and China. This included, among others, planning for joint scientific symposia to facilitate information exchange. Some foreign regulatory authorities (i.e., in addition to the US FDA and EU EMA) perform inspections of pharmaceutical plants in China.[5] In November 2014, CFDA and US FDA also signed an implementing agreement between the two agencies regarding cooperation among regulatory staff.

6.4 Post Marketing Surveillance

In China, policies for drug post marketing surveillance (PMS), known as drug intensive monitoring, are still evolving and the available guidance and overall approach are not as comprehensive as in the United States, European Union, or Japan. However, the basis for intensive monitoring has evolved over the past decade, and provisions for the ideas of post-marketing re-evaluation and re-registration are delineated in China's Food and Drug Administration regulations. The 12th Five Year Plan for the pharmaceutical sector has

Chart 6.1: Reporting Procedure



Source: Zhang et al,.2012.

included combating the production and sale of counterfeit drugs as an objective. As per the Drug Administration Law 2001,[6] production, including dispensing and distribution of counterfeit drugs are prohibited and counterfeit drug includes those where ingredients in the drug are different from those specified by the national drug standards; further, production and distribution of substandard drugs are prohibited.[7] Provisions for Drug Recall 2007, provisions for Drug Advertisement Examination 2007 (by CFDA) and Provisions for reporting, supervising and administration of adverse drug effect 2011 (by NHFPA) are some post market surveillance initiatives. CFDA has the authority to penalise drug advertising violations, to investigate drug-related complaints, and to act against sale of illegal drugs, including making referrals for criminal prosecution. However PMS guidelines are yet to be formed.

6.5 Domestic Standards Development in China

Plans and Programmes

TCM standardisation strategy has broadly been designed to be implemented in a phased manner. During the 11th Five-Year Plan (2006-2010) period, the TCM standard system was overhauled with an emphasis on formulation and revision of basic standards and technical standards. In the 12th Five-Year Plan (2011-2015) *Outline for National Economic and Social Development of the Peoples Republic of China*, "promotion of standardisation and normalisation of TCM" was included as a major objective. The Ministry of Science and Technology has also brought out the *Traditional Chinese Medicine Innovation Development Planning Outline 2006–2020*, in which the standardisation of TCM was set as one priority area. Finally, the *Medium- and Long-Term Development Plan about the Standardisation of Traditional Chinese Medicine* (2011–2020)

Standards Administration

The TCM system of standards consists of four categories of standards. These are (i) basic standards, (ii) technical standards, (iii) management standards, and (iv) working standards.[8] These four categories remain fundamental to any system including ISMs. China has been regularly updating these standards, in all these categories. Further, there are four National Standards (titled GB/GBT), Ministry Standards (titled as JB/JBT YY/YYT, etc), Provincial Standards (titled as DB/DBT), and Enterprises/Industrial standards (over 480).These levels are hierarchical, hence Provincial Standards supersede Enterprise Standards, Professional Standards supersede Provincial Standards, etc. For any given product or service, only one type of Chinese standard will apply. National Standards are often referred to as "GB standards". They are consistent across all of China and are developed for technical requirements. GB standards can be identified as mandatory or voluntary by their prefix code. These may be indicated as

- GB, i.e., Mandatory National Standards
- GB/T, i.e., Voluntary National Standards
- GB/Z, i.e., National Guiding Technical Documents

Similarly, the professional standard code for medicine is YY and for agriculture is NY.

Some standards such as GCP and GSP are mandatory as these are administered under the Drug Administration Law 2001. National standards have mainly included codification of diseases, diagnosis, syndromes and therapeutic methods.

National standards of TCM include:

- Classification and Code of Diseases and ZHENG of Traditional Chinese Medicine (GB/T15657-1995). As China's first national standards for classification of TCM diseases,

it stipulates the classification principles and coding methods of diseases and has the corresponding computer software, promoting the standardisation of TCM clinical diagnosis;

- Clinical Terminology of Traditional Chinese Medical Diagnosis and Treatment –Diseases (GB/T 16751.1-1997);
- Clinical Terminology of Traditional Chinese Medical Diagnosis and Treatment-syndromes(GB/T 16751.2-1997);
- Clinical Terminology of Traditional Chinese Medical Diagnosis and Treatment –Therapeutic Methods (GB/T 16751.3-1997); and
- Basic Theory Terminology of Traditional Chinese Medicine (GB/T 20348-2006)[9]

The first three specify the basic terminology of common diseases, syndromes and therapeutic principles of TCM to improve the quality of TCM and the level of scientific management. The fourth national standard provides basic standard for the terminology of TCM theories such as *yin* and *yang*, five elements, and main and 'collateral channels.[10]

Major TCM Standards

- Acupuncture and Moxibustion standardisation:

  Standards on acupuncture began to be developed from 1980 onwards. There are three national standards in this area,:

  - » Acupuncture needles (GB 2024-1987),
  - » Location of points (GB 12346-1990), and
  - » The nomenclature and location of auricular points (GB/T 13734-1992).
- Eighteen additional national standards for acupuncture and moxibustion were introduced in 2008 and 2009.[11] Industry Standards on acupuncture and moxibustion till 2013 has also included devices and nursing care such as Electrodes for nerve and muscle stimulators (YY 0868-2011), Electro acupuncture therapy device (YY 0780-2010) and Routine & technical operation regulation of nursing care in department of acupuncture and moxibustion (ZYYXH/T 1.12-2006).[12] In addition, there are 5 evidence-based clinical practice guidelines on acupuncture.[13]
- *Good Manufacturing Practices (GMP):* Although inspections with respect to several categories of sensitive products are carried out directly by the CDFA, inspections of manufacturing facilities are carried out principally at the provincial level.[14] For compliance with good manufacturing practice (GMP) standards the provincial governments are mainly responsible for certifying manufacturing facilities, even as these standards framed at the central government level. As of 2016, a total of 2,088 pharmaceutical enterprises manufacturing Chinese patent medicines have been approved under GMP.[15] GMP standards for TCM in China are based on the WHO-GMP Guidelines. GMP regulation was first introduced in 1995, and has undergone several revisions including one in 1998 and 2010.[16]The 1998 GMP attended primarily to quantitative risk management (QRM), such as the items about accuracy of qualitative and quantitative methods. The 2010 GMP standards, compared to the 1998 GMP standards have focussed more on human resource. Hence provisions for the management and supervision of drugs' quality have been enhanced.
- *Good Laboratory Practice for Non-Clinical Laboratory Studies (GLP) and Good Clinical Practice (GCP):* Article 30 of the DAL 2001 regulates GLP and GCP hence these standards are not voluntary.
- *Good Supply Practice for Pharmaceutical Products (GSP):* Overall, Article 16 of the DAL 2001 regulates GSP by distributors. For drug wholesaler and drug retailers, Article 14 provides that the establishment of a drug wholesaler shall be subject to approval of

the local drug regulatory department of the provincial government. Distribution of drugs without a Drug Supply Certificate (DSP) is prohibited. For raw materials such as medicinal plants (referred to as Chinese crude drugs (CCDs)), Article 21 of DAL provides that Chinese crude drugs may be sold at town and country fairs, except those otherwise specified by the State Council. No drugs other than the Chinese crude drugs may be sold at town and country fairs, but drug retailers holding the Drug Supply Certificate may, within the specified business scope, sell such drugs at stores they set up at the fairs. Specific measures for supply and distribution are formulated by the State Council. There are 17 professional markets for Chinese crude drugs.

- *Good Agricultural Practices (GAP)*: GAP standard subscription is an important measure for quality control in medicinal plant cultivation. The safety and consistent quality of TCM herbs provides quality assurance for GLP, GCP, GMP, and GSP of TCM. GAP is, therefore, recognised as a primary requisite to standardise and modernise TCM. GAP for CCDs is intended to control production quality of medicinal plant materials to standardise various crude drug production processes and even the whole process. CFDA issued the Guidelines for Good Agricultural Practice (GAP) of Medicinal Plants and Animals in 2002. Related cultivation base began to be authorised with GAP quality system certification in November, 2003. Since then, medicinal plants have been produced and administered under GAP guidelines. By 2010 a total of 99 bases of GAP for TCM herbs (49 species) were certified by CFDA.[17]They cover 22 provinces/municipalities, and 49 species of TCM herbs are currently cultivated in these GAP bases.[18] Provinces have their own standards and varying levels of implementation.

TCM Services Standards: TCM Nursing

Following the "*Opinions on Deepening the Reform of Medicine and Health*" issued by the State Council in 2009, in 2010 the China's Ministry of Education introduced *Standards for Establishment of Undergraduate Nursing Programs and Basic Requirements for Teaching in Undergraduate Nursing Programs*, as a basic guideline for nursing professionals. In 2013, the Nursing Education Steering Committee under the Ministry of Education formulated relevant standards for TCM nursing programmes in collaboration with TCM colleges and universities, standardising the curriculum and clinical practice of nursing programmes in such colleges and universities, to promote standardised education and training of nursing professionals.[19] The SATCM provided standards which include among others, 18 standards on Nursing Care in TCM.[20]

6.6 International standards on TCM: ISO/TC249

A major thrust of national strategy for TCM is development of international standards. The International Organisation for Standardisation (ISO) is one of the standard organisations that China has reached out to. ISO provides robust, well-established and consensus based international standards that fulfil TCM's international agenda. The ISO founded the Technical Committee for Traditional Chinese Medicine (TC249) in September 2009. The committee includes 20 participating members and 17 observer members. In 2010, the Secretariat of Traditional Chinese Medicine Technical Commission of International Organisation for Standardisation (ISO) (code: ISO/TC249) was established in Shanghai.[21] Five on-going working groups as well as two joint working groups have been established by TC249 to work on the standardisation of different aspects of TCM. Each working group is managed by a convenor(s) and each project within a working group is led by a principal project leader.

Twenty-two international standards have been published by September 2017.[22]

TC249 coordinates with United States Pharmacopoeia, the European Pharmacopoeia and the Chinese Pharmacopeia (which develop herbal monographs), other ISO committees such as those dealing with medical devices, foods, etc. and international groups dealing with medical device regulation. The TC249 secretariat has organised international forums and workshops in the above fields.

Concerted efforts have been made to address challenges for integration of TCM into ISO. This includes application of TCM terminology. TCM theory has been deeply influenced by Chinese traditional philosophies and TCM literature is distinct owing to the lack of unified semantic specifications. International standards are based on western medical terminology. TCM terminology and western medical terminology systems being based on divergent cognition principles has posed challenges in developing and popularising international TCM standards preventing effective understanding and integration into ISO. The Institute of Information on Traditional Chinese Medicine (IITCM), an affiliate of the China Academy of Chinese Medical Sciences (CACMS), jointly worked with more than 10 Chinese medicine research institutes and universities and more than 300 experts over 10 years since 2002 in China to establish a Traditional Chinese Medicine Language System (TCMLS). The TCMLS (originally called UTCMLS) draws on construction principles and the basic architecture of Unified Medical Language System (UMLS).[23] After more than 10 years of application and improvement, the technical specification based on TCMLS, "ISO / TS17938 Health information - Semantic network framework of traditional Chinese Medicine Language System", was accepted and released by the International Organization for Standardization (ISO) in 2018.

6.7 Challenges

Wang *et al.*, 2016 identify the following issues in standardisation of TCM:

- Inadequate awareness among practitioners of the standards,
- Limited coverage of the standards,
- Lack of prompt updating of standards to take care of new technologies and new research,
- Slow development of support system in management, implementation and supervision of standards, and
- Inadequate development of International standardisation.[24]

A major issue with implementation of standards and quality control on TCM is the allocation of regulatory responsibilities between the State and the provinces. Like India, the complexity of the sector requires effective coordination between different implementing agencies at the State and provincial level. The management, implementation, and supervision system of TCM standardisation is still incomplete; surveys and feedbacks of its applicability are also imperfect; shortage of talented professionals in field is also a concern. Further, the heterogeneous nature of many TCM preparations makes quality control a challenge. As with other plant based products, variations in cultivation, climatic conditions may affect final product, hence evolution of uniform standard subscribed product is a challenge.

6.8 Conclusion

Quality and uniformity assurance of TCM has been a focus of the policy framework of TCM. Hence concerted efforts have been made towards pharmaco-vigilance and post market surveillance. Elaborate reporting procedures are expected to bring accountability related assurance to the TCM sector. A single pharmacopoeia including all systems of medicine provides TCM with development

of standards and imposition of laws making it mandatory to subscribe to laboratory and supply practices have been one of the several steps towards ensuring uniformity and quality of TCM products. At the same time China has made significant headways in development of global standards. This initiative is expected to provide accessibility to global markets.

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24. ?

VII

Innovation and R&D in TCM

7.1 Introduction

TCM is now a 'high technology industry', described as one with 'characteristics of high growth' and is a 'strategically leading industry in the national economy, playing an important role in industrial restructuring and transformation of the economic development pattern."[1]The economic growth of China has also contributed to a renewed interest in the application of TCM in R&D for drug discovery and product and service innovations.

China's policy on drug innovation can be described through the three major verticals of:

- Core Intellectual Property Rights (IPR) policy for patent review and approval, protection and administration;
- Drug regulatory policy that includes drug approvals, drug pricing and policies for essential medicines; and
- Other related policies such as scientific and technological inputs, incentives, R&D funding, and research incentives.

7.2 Industry Performance

Table 7.1 presents the basic innovation related parameters of TCM industry from 2007 to 2016. During this period, the innovation related expenditure on TCM has increased substantially. The most dramatic increase was witnessed in 2011. This corresponded with the introduction of new reforms under the 12th Five Year Plan (2011-2015). While the "Key Drug Innovation" Project was launched in 2007, it was during the 12th Five Year Plan that this project was supported with USD 16 billion (approximately) from the central government and USD 49 million (approximately) from local governments.[2] Between 2007 and 2016 investments and expenditure on new product development has grown from 1.77 billion Yuan to 9.66 billion Yuan (Table 7.1), an increase of around 450 per cent. Simultaneously, patent applications on TCM products have also increased from 1,340 in 2007 to 3,487 in 2016, a growth of more than 160 per cent (Table 7.1). The year 2014 saw the highest number of patents filed by TCM firms (5,285). Overall, during 2007 to 2016, TCM firms have filed around 30,850 patents. These numbers clearly reflects that the technological development and innovation in the TCM industry is quite high. These patents also include product and service innovations.

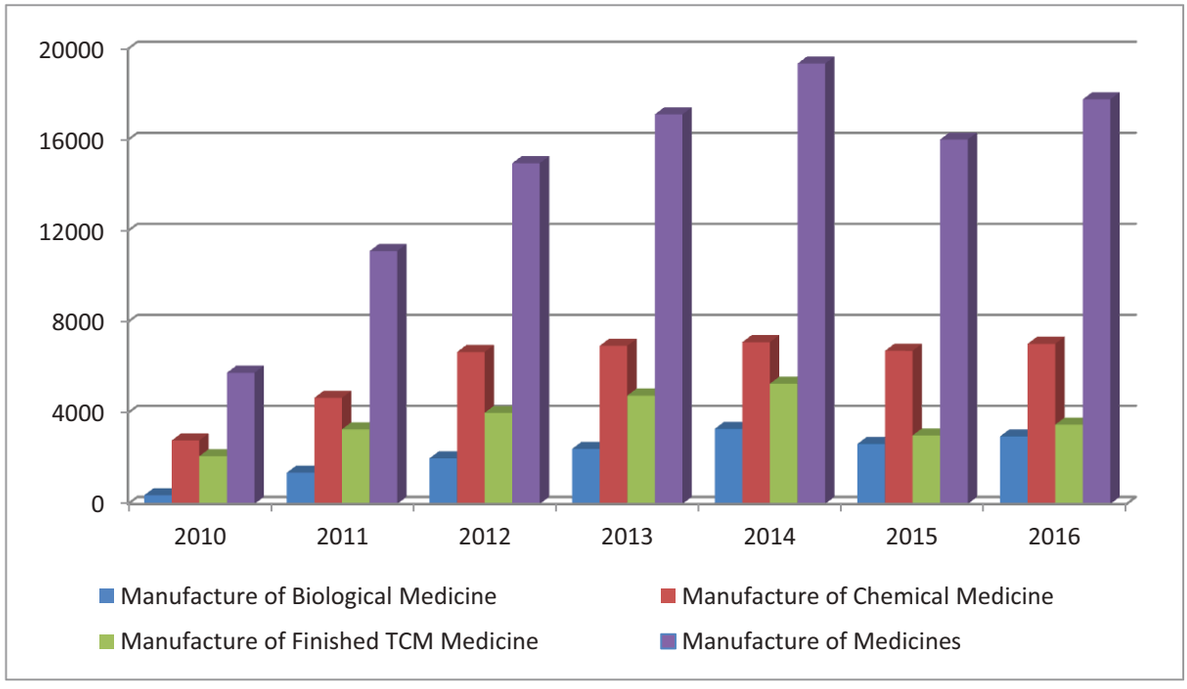
Figure 7.2 reflects how the innovations in the pharmaceutical industry in China have grown in the 21st century. Although the number of patents filed by different pharmaceutical

Table 7.1: Innovation Expenditure and Patent applications by TCM firms (2007-2016)

Year	Expenditure on New Product Development (Billion Yuan)	Sales Revenue of New Products (Billion Yuan)	Number of Patent Applications
2007	1.77	13.66	1340
2008	1.69	17.74	1751
2009	2.1	23.42	1827
2010	2.26	29.44	2098
2011	4.19	47.84	3282
2012	5.75	65.91	4007
2013	7.47	82.96	4762
2014	8.02	101.99	5285
2015	8.05	114.43	3011
2016	9.66	130.38	3487

Source: China Bureau of Statistics 2017.

Figure 7.1: Patent Applications Filed by Different Pharmaceutical Firms, 2010 to 2016



Source: Elaboration of data from China Bureau of Statistics.

industries in China has experienced a steady growth during this decade, the year-on-year rate of growth of the patents filed by these firms has experienced a steady decline (Figure 7.2). This might be indicative of the fact that the IPRs related laws in China are becoming more stringent and, therefore, discouraging spurious patent applications.

By 2016, the total number of patents in force in the pharmaceutical industry has risen

to 24,640. Among these, 6,839 patents in force belong to the TCM industry. The rise in the share of TCM patents in force shows that TCM has contributed significantly to the innovation and R&D in the Chinese pharmaceutical industry.

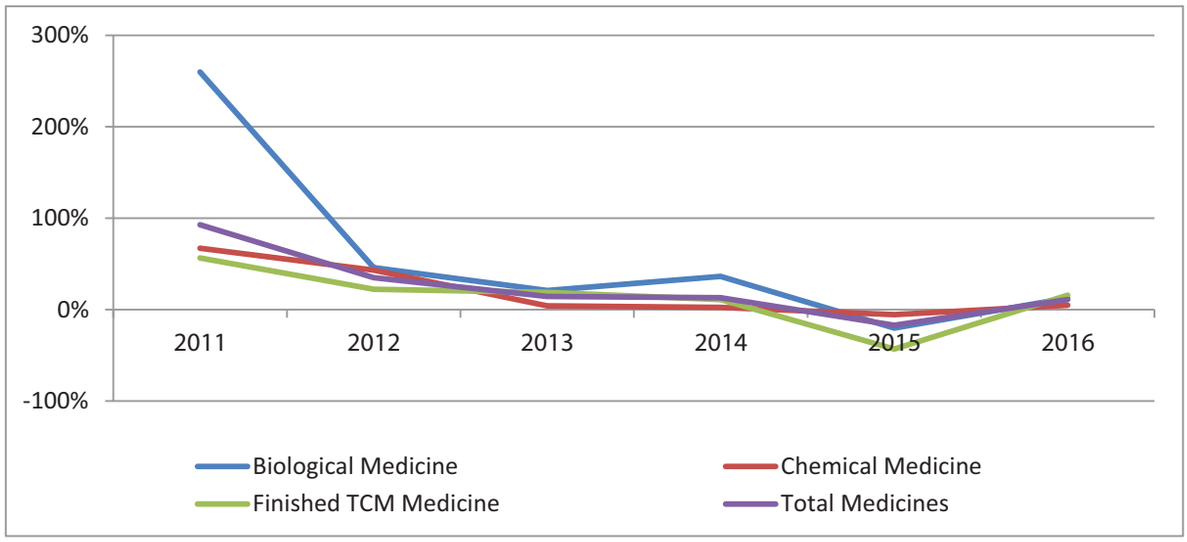
Major contributors to innovation related R&D are 'domestic funded enterprises in large and medium enterprises'.[3] Public institutions, mainly universities, have also played a major role in TCM related innovations.[4] Over 60 national TCM clinical research institutes and programmes for using information and technology systems for R&D exist today.[5] These include 28 province level centres and 65 monitoring stations.[6]

Finally, the role of foreign investors in TCM has become significant. Part of the interest of key pharmaceutical companies into the Chinese market can also be related to the potentials of TCM.[7] Many western countries have set up TCM institutions mainly US, EU, Japan and South Korea which have invested heavily in related research and product development.

7.3 Policies for Innovation and R&D Support

Capacity building for innovation support in TCM has included planning, surveys, education, hospital network and international networks since the 1950s. In the phase between 1950s-1970s policy focus was on building of curriculum of TCM education including China's ten most prestigious TCM universities and its national TCM academy. Several TCM related discoveries date back to this period. These include the Nobel prize awarded medicine innovation of anti-malaria drug artemisinin from *Artemisia annua L.* by Youyou Tu, and other innovations like the isolation of the anti-cancer compound camptothecin from *Camptothecaacuminata Decne*, by Monroe Wall, Mansukh Wani and co-workers[8] and discovery of arsenic trioxide as a new adjuvant treatment for leukaemia.[9]The Ministry of Health organised a number of full-time training courses in the late 1950s where scientists with western medical backgrounds were trained in TCM. From 1983 to 1994, China also conducted a series

Figure 7.2: Growth Rates of Application of Patents Filed by Different Pharmaceutical Firms from 2011 to 2016



Source: Elaboration of data from China Bureau of Statistics.

Table 7.2: Number of patents in force in Chinese Pharmaceutical Industry

Industry	Number of Patents (in Force)					
	2000	2005	2013	2014	2015	2016
Manufacture of Medicines	460	1,134	12,795	16,161	21,563	24,640
Manufacture of Chemical Medicine	165	495	6302	7973	11,448	12,828
Production of Finished Traditional Chinese Herbal Medicine	211	497	4,661	5,513	6,114	6,839
Manufacture of Biological Medicine	37	49	1,197	1,746	2,342	3,265

Source: China Bureau of Statistics 2017

of nationwide surveys on ingredients used in TCM practice across the country. According to the official data published by the SATCM, 11,146 botanical and 1,581 zoological species, as well as 80 minerals were surveyed.[10] These have provided a resource for modern innovation programmes.

Recent Policies, Programmes and Initiatives

Since the late 2000s, along with increased investment in the R&D other areas of support include: :

- Research laboratories at the national and provincial levels
- Open sharing of scientific and technological research and data
- Training and incentives to R&D personnel for TCM based innovation
- Multidisciplinary scientific and technological cooperation
- New regulatory provisions

Registration process of new TCM drugs has been made easier. In 2008, the CFDA published the *Supplementary Provisions for Registration Management on TCMs*. This provided additional guidelines on encouraging TCM innovation through ease of registration. For 'new drugs that may provide remedy for diseases or symptoms not recorded in the nationally approved indications of proprietary TCMs, applicants may request for a special review and approval and preparations based on classic ancient formulae may apply for a manufacturing approval as long as non-clinical safety evaluation data is provided'.[11] In addition the Provisions also support research, development and marketing of compound TCM preparations. TCM was selected as one of the key emerging knowledge intensive sectors under the first long term national innovation policy document '*National Medium and Long Term Science and Technology Plan 2006-2020'*.

Since the Twelfth Five Year Plan launched in 2011, further steps to encourage R&D in TCM have been envisaged. The CFDA now allows drug license holders to sub-contract manufacturing so that R&D institutions can focus solely on high quality R&D innovations rather than investing in their own manufacturing plants.[12]

In 2017, the General Office of the Communist Party of China and General Office of the State Council Printing and Distributing issued "*The Opinion on Deepening the Reform of the Review and Approval System and Encouraging the Innovation of Drugs and Medical Devices*" which focuses on drug innovation. Among the reforms proposed are accelerated approval of drugs and innovations and improved technical review system. The *Opinion* supports innovation in TCM through emphasis on new efficacy, clinical application, simplified approval criteria for TCM derived from classic *materia medica*,

submission of information of market potential of product when applying for registration and utilisation of traditional preparations to develop new forms of medicine.[13]

Focussed talent development programmes like *The National Chinese Medicine Leading Talents Support Program* issued by the SATCM in 2018[14] is designed to meet innovation and development needs of TCM industry. One hundred high-ranking scholars and 10 Chinese medicine chief scientists were to be selected to lead research in TCM as a part of this Programme.

Currently, an evidence based approach is being undertaken to develop new products utilising modern research methodologies in biology and chemistry while trying to retain unique characteristics of TCM. Two cases where curative effects of an active ingredient of TCM have been proven using modern drug development methodologies and clinical trials include arsenic trioxide for the treatment of acute promyelocytic luekemia and artemisinin for the treatment of malaria.[15]

International interest in TCM has also facilitated research on TCM. In 1998, for example, the US National Institutes of Health established the National Centre for Complementary and Alternative Medicine (NCCAM), dedicated to funding research on complementary and alternative medicines, including TCM.[16]

In general, the government has increased drug innovation funding in pharmaceutical sector by launching, for instance, the '*Key Drug Innovation project'* in 2007 which was supported with about D16 billion USD from the central government and more than D49 million USD from local governments.[17]

Data generation related innovation is particularly important. The quality data platform of TCM includes the quality standards of Chinese medicinal materials, decoction pieces, and Chinese Patent medicine, so as to enhance the research on the technical standards and specifications of varieties, quality, planting, collecting, processing, preparing of decoction pieces and extraction of TCM. Here, for example, the DNA barcode for species identification system that was jointly established by the National Key Laboratory of TCM quality in Macao University and Beijing Union Medical College won the second place of the 2016 National Science and Technology Progress Award.[18] This barcode species identification system has established a "genetic identity card" for TCM. The achievement also established the world's largest TCM DNA barcode identification database, which contains more than 1.70 million DNA sequences, and may achieve rapid identification to almost all herbal species included in CP, USP, JP, EP, South Korea Pharmacopoeia and India Pharmacopoeia, etc., and promote TCM identification study to enter into the standardised gene identification era.[19] With regard to quality control, various chromatographic, spectrum, and computer coupling techniques such as[20] HPLC (high performance liquid chromatography), HPCE (high performance capillary electrophoresis) have been widely applied in TCM quality research and assessment.

7.4 Challenges

One of the major objectives of the innovation and R&D in TCM has been to establish TCM as evidence based medicine by making available clinical evidence from systematic research. Quantitatively, there is no shortage of clinical studies in TCM conducted worldwide. A search on the Clinicaltrials.gov found 436 trials on TCM and 607 acupuncture trials globally (as of November 2014), while a search on online scientific journal portals, for example, Pubmed, Chinese National Knowledge Infrastructure (CNKI), yielded more than ten thousand research papers covering a wide spectrum of research topics studying TCM from various approaches.[21] The critical problem lies in the dearth of good quality evidence and lack of strong research rigor in the studies published,

which undermine the credibility of the evidences.[22]

Another challenge that hinders innovation is the slow drug registration and approval for new drugs brought upon by a small number of reviewers at CFDA. While the US FDA employs 2000 individuals to review drug registration applications, CFDA employs 120 (although that number is increasing).[23] The drug registration process is lengthy with approval usually taking upto 8 years. With only 120 employees responsible for technical review of the CDE, staff shortages have contributed to delays in processing registration. In addition, new drugs approved in China by the CFDA must also find acceptance in the provincial markets, which may add substantial delay to distribution. Several policy documents in the last few years have focussed on the need for faster approval for drug registration. The CFDA has been attempting to delegate activities such as drug registration renewal, GMP certification, and approval of applications for contract drug manufacturing to provincial bureaus.

China is still weak in developing real innovative medicines. Considerable pharmaceutical R&D input, scientific publications and patents in China have not yet translated into major drug innovation based on analysis of worldwide recognized innovative drugs.[24]The policy focus has been drawn towards addressing factors that inhibit innovation in TCM.

7.5 Conclusion

China's support for innovation and R&D in TCM has been substantial. While the results have been limited in proportion to the policy support, it is preparing the sector towards modernisation for the long term. Hence, for example, laws and regulations to strengthen protection of TCM wild medicinal resources ensure long-term availability of the raw materials. Focus on active ingredients in TCM and innovation in drug administration through, for example, injectables are some ways to bring TCM at par with modern drugs. However, there are challenges with regard to approval processes.

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VIII

Internationalisation

8.1 Introduction

One of the recent policy initiatives for internationalisation of TCM, the *Strategic Plan for Development of Traditional Chinese Medicine 2016-2030* underlines the priorities of TCM development which includes participation in international cooperation and competition, promotion of localisation of TCM services and international education of TCM.[1]Trade has been discussed in previous chapters. This chapter focuses on TCM at international health platforms and expansion of TCM education and services through bilateral and multilateral engagements, and geostrategic engagements like Belt and Road Initiative. This chapter also studies international market entry strategies for TCM in important export destinations like US and EU.

8.2 International Organisations

The World Health Organisation: The intergovernmental organisations under the umbrella of UN like the World Health Organization (WHO) have played an important role in pushing member countries' agenda. In the last few decades globalisation of health issues has enhanced the role of WHO. It is a critical organisation in the global governance of health due to its essential role of establishing, monitoring and enforcing international norms and standards, and coordinating multiple actors towards common goals. In the context of regulatory cooperation, WHO has undertaken several reforms in programmes and priority setting, governance and management. China has effectively used the WHO platform for global outreach of TCM. Since the appointment Dr Margaret Chan as the DG of WHO in 2006 several initiatives in cooperation with China were undertaken. Organising the first WHO Congress on TM in Beijing in 2008, leading to the Beijing Declaration, facilitated China's initiatives for TCM's recognition through the WHO. The former Vice President of the Academy of Chinese Medical Sciences, responsible for leading the integration of TCM into the National Health Services of China, was given the responsibility of coordinating with WHO on traditional medicine in 2009.[2]China's close engagement with the framing of WHO TM strategies and at the 62nd and 67th WHO Assemblies resolution on stressing member states to implement the TM strategy 2014-2023 has added to expansion of knowledge on TCM in member countries. The recent inclusion of TCM in WHO's International Classification of Diseases (ICD) (11th revision) is a major step towards facilitating global acceptance of TCM therapies. The WHO describes ICD as a standardised system of alphanumeric

codes for diagnoses used in medical billing and coding throughout the world, as well as for epidemiology, research, and cataloguing causes of death. China's traction with WHO on TCM is also the result of several institutional cooperation arrangements. One of the several forms of regulatory cooperation provided by WHO to its members is the data collection and research which includes network of WHO Collaborating Centres for Traditional Medicine. While countries like India have two collaborating centres at the WHO, China has as many as nine collaborating centres. Non-profit TCM organisations like the World Federation of Chinese Medicine Societies (WFCMS) and World Federation of Acupuncture-Moxibustion Societies (WFAS) have established official relations with WHO.[3] This provides TCM NGOs with participation rights in international health affairs. The role of such organisations is important in policy development and setting the health agenda in WHO and in turn across the world.

International TCM NGOs

Non-State actors like NGOs associated with TCM standards and accreditations have played the role of quality control and assurance in international markets. The WFCMS mentioned above is one such international non-profit academic organisation for international exchange with headquarters in Beijing. It has 239 society members from 65 countries with 300,000 TCM practitioners as members[4]. Similarly the WFAS (mentioned above) established in 1987 with 194 participating countries in 53 nations is another influential organisation for standardisation of TCM. It has officially published four industrial standards. International TCM organisations have a strong support from Chinese TCM institutions. The European Foundation of Traditional Chinese Medicine (FEMTC) has among its members, the Presidents of Beijing and Yunnan Universities of Chinese Medicine, and the President of the China Academy of Chinese Medical Sciences.[5] Besides, it is supported by collaboration with the Guang An Men and Dong Zhi Men hospitals in Beijing and the Hospital of Chinese Medicine in Kunming, Yunnan. The FEMTC has affiliations with WFCMS, Pan European Federation of TCM Societies (PEFOTS), WFAS, and the European Federation of Biotechnology (EFB).[6] European Traditional Chinese Medicine Association (ETCMA) is another umbrella organisation representing over 12,000 practitioners in 14 different countries and founded by Arbeitsgemeinschaft für Klassische Akupunktur und Traditionelle Chinesische Medizin e.V (AGTCM) (Germany), British Acupuncture Council (BAcC) (United Kingdom), EUFOM (Belgium) and *Nederlandse Vereniging voor Acupunctuur* (NVA) (Netherlands).[7] International organisations mentioned above have been connecting national TCM institutions (including universities, academies, etc) with TCM related bodies. These have facilitated standard setting, expansion and popularisation of TCM internationally. Other international organisations, such as ISO, have already been discussed in Chapter 6.

8.3 The Belt and Road Initiative

The Belt and Road Initiative (BRI) has provided significant commercial, trading, and health potential for China. It has already injected 40 billion USD worth of initial funds, with private investors setting up funds with an initial capital sum of 30 billion CNY in March 2017 to support the group of projects under this initiative.[8] Along the Belt and Road route China has established overseas TCM centres and 43 bases for international cooperation on TCM in 35 countries.[9] Further, a development plan for TCM traditional Chinese medicine has been announced, with 30 Chinese medicine overseas R&D centres and 50 Chinese medicine foreign communication and cooperation bases scheduled to be constructed by 2020.[10] This plan is anticipated to strongly support industry growth with visiting patients especially from bordering countries like Tajikistan, Kyrgyzstan

and Kazakhstan. The 'Belt and Road Initiative' is expected to increase exports of TCM in the future. This is particularly likely to increase trade with Central Asia and Russia.

Within BRI China's engagement in Africa is specially growing on multiple agendas. It includes both trade and development assistance. Within development assistance programmes, health forms a major component. China's Medical Team programme cumulatively dispatched more than 25,000 medical professionals to 51 African counties and provided health care for more than 280 million patients.[11] As the bilateral relations between China and Africa have grown, many Chinese have rehabilitated or moved their businesses to Africa. At present, around 10 million Chinese expatriates work in Africa.[12] This Chinese Diaspora creates an assured demand for TCM medicines in Africa. Efforts to popularise TCM in Africa is also speculated to increase exports of TCM even though in value terms, it is still not a major contributor to TCM exports from China.

8.4 Market entry of TCM Products and Services

One of the strategies for internationalisation of TCM drugs has been to enter pharmaceutical markets known for high standards. Export of TCM has already been covered in Chapter 4. In this chapter, we explore China's market entry strategies for US and EU whose endorsement provides market entry into other regions.

United States

The US FDA standards on drugs are one of the more stringent standards internationally. The US FDA regulates cosmetics, dietary supplements, drugs (including new drugs), food and food additives under the Federal Food, Drugs and Cosmetics Act. A botanical product may be subject to regulation as a biological product, cosmetic, drug or dietary supplement. Many TCM products are permitted to be marketed as dietary supplements. As per the FDA publication on Guidance for Industry-Botanical Drug Products (revised in 2016), a botanical product (including those used in TCM) can be further developed through clinical trials and non-clinical studies to become an FDA approved drug through investigational new drug application (IND) and new drug application (NDA) process. China has attempted to introduce new drugs derived from TCM into the US market (Table 8.1).

Case Study: Salvia Droplet Pills

In the 1990s, the Ministry of Science and Technology chose a few patented TCM drugs to submit to the FDA for clinical testing.[13] Only one TCM drug had passed the second of the three clinical trials phases to qualify for the US drug market- Salvia Droplet Pills (CDSP) (product name T89) a combination of salvia and *notoginseng* extracts with synthetic borneol, for the treatment of chronic stable angina pectoris, also referred as *Danshen Plus Capsule*, made by the Tasly Group of Tianjin. In line with demands of US Standards Tasly has established international GAP standards for medicinal plant cultivation and collection; quality controls standards more rigorous than those of the Pharmacopoeia of China and as applied to US. In addition it has invested in R&D with a focus on clinical pharmacological research. The product is currently in phase three of clinical trials. In 2011, Tasly invested USD 40 million to build a manufacturing plant and training facility in Maryland.[14]Tasly has utilised its US approval for expansion of the product into other markets. Registration for clinical trials in US opened a window for exporting Danshen Plus capsule to US as food supplement. Thereafter it was registered as a drug in the Vietnam, Russia, Cuba, South Korea and UAE. In 2002, the product was registered as a drug in Mongolia, Hong Kong and Singapore. Tasly has also established offices in France, South Africa, and South Korea. Following the spread in international markets, Tasly further invested € 1,815,000 in

Table 8.1: Summary of the Nine TCM Products Filed for Application in FDA from China

Name	Indication	Clinical Phase in USA	Manufacturer
Dantonic	Angina pectoris	Phase III	Tasly Pharmaceuticals, Inc
Ginkgonin	Coronary heart disease; Angina pectoris	Phase III	ShanhaiXingling Sci & Tech Pharmaceutical Co., Ltd
KYG0395	Primary Dysmenorrhea	Phase II	Jiangsu Kanion Pharmaceutical Co., Ltd
Fuzheng Huayu Tablet	Chronic Hepatitis Infection	Phase II	Shanghai University of TCM & Shanghai Sundise Traditional Chinese Medicine Co., Ltd.
Xue Zhi Kang Capsule	Hyperlipidemia	Phase II	Beijing Peking University WBL Biotech Co., Ltd
WeiMaiNing	Lung cancer	Phase II	Huayi Pharmaceutical Co., Ltd
Kanglaite Injection	Stage IV NSCLC	Phase II	Kang Lai Te USA
Kanglaite	Gelcap Prostate Cancer	Phase II	Kang Lai Te USA
HMPL-004	Ulcerative Colitis	Phase III	Hutchison Whampoa Limited

Source: Wu, Yang, Hou, and Guo, 2015

50 per cent stake in Netherlands. Its products have been trademarked in 34 countries. Tasly's internationalisation strategy has been to push into a strategic market, a leading product, before expansion into other international markets. It has a marketed its product based on adaptation of TCM to Standards of leading markets.

This strategy has since been replicated by other firms seeking entry in US. Companies like Shanghai Sundise Traditional Chinese Medicine Co. Ltd, which submitted applications to the FDA in 2006 for *Huazheng Fuyu*, a drug that treats liver fibrosis. The drug was expected to complete phase three of the trial by 2019. Since the FDA attaches great value to data, production management, quality control, and information systems the company has invested in software frequently used in FDA clinical testing and overhauled its electronic data management system, making it the first company in Asia to use that system.

Another well-known Chinese start up, Hutchison MediPharma, has programmes in IBD (Phase 3) and oncology (Phase 2) ongoing in the U.S.[15] A global consulting firm, L.E.K., has identified over 30 other Chinese medicine sponsors in the U.S. and European regulatory registration processes.

However, the cost for entry into the US market is high and is feasible only for large TCM companies. Need for greater support from the government on research related to toxicity, pharmacology, and safety of drugs has therefore been highlighted by the industry. ***European Union***The main regulatory body for drug approval in EU is the European Medicines Agency (EMA) but each member state has its own regulatory agency. There are two systems in EU for registration of TM products. One is the centralised registration system via the EMA, and the other is the decentralised system. The working tasks of EMA include all administrative and executive aspects of pharmaceutical law.

In 2004, the EU amended its drug law so that clinical trials were not required for any traditional herbal medicine that has been used for at least 30 years preceding the date of application, including at least 15 years within the EU. Since the implementation of 2004/24/EC, in March 2012, Diao Xin Xue Kang Capsule was successfully approved by the Dutch Medicines Evaluation Board (MEB)[16].

International Pharamcopoeias

An important TCM internationalisation strategy has been to optimize TCM standards for the international market. Towards this aim, acceptability of TCM in the national pharmacopoeias of US Pharmacopoeia or the European Pharmacopoeia is imperative. Since more than 140 countries in the world have adopted the US pharmacopoeia, and the European Pharmacopoeia standard is widely used among all the European Union country members, China has recognised the importance of TCM pharmacopoeia accepted by the two mentioned pharmacpoeias. In recent years, 27 standards of "9 varieties" such as salvia miltiorrhiza, pseudo-ginseng and ganoderma have been included in the US Pharmacopoeia, and a number of standards have entered the US Pharmacopoeia audit procedure.[17]

In EU, since 2011 the SATCM has established a formal cooperation between the European Directorate for the Quality of Medicines (EDQM).An agreement between both parties was signed in June 2011 to prepare quality standards on a series of TCM herbal drugs and drug extracts. A National Key Laboratory for TCM (NKL-TCM) was established from China side. Scientists in China have joined the preparation of TCM drug monographs in the TCM Working Party (TCM WP) of EDQM by providing scientific literatures originating from ancient and modern Chinese documents (translating from Chinese language to English language), answering questions related to TCM drug processing, providing TCM drugs samples, participating in the preparation of TCM monographs by conducting scientific experimental works such as TLC and HPLC studies and developing new quality markers for TCM herbal drugs. From China side, a leading scientist in the field has been visiting TCM WP meeting on a regular basis, so that the interactions between scientists from China and Europe are strengthened considerably. Recently, SATCM also suggested 15 new herbal drugs to be added to the European Pharmacopoeia on TCM.[18] Hence a close engagement has been has been maintained by the SATCM to facilitate TCM in EU Pharmacopoeia. More than 10 TCM standards including Uncaria and Platycodon have entered the European pharmacopoeia or forum.[19]

8.5 TCM education in UK, US, Australia and Canada[20]

Chinese government and Chinese TCM Universities have been deeply engaged with expansion of TCM education in universities and other non-university education systems abroad. Most readily accepted TCM in the educational institutions have been acupuncture. Non-profit organisations like the British Acupuncture Accreditation Board (BAAB) have facilitated accreditations for educational institutions. The Chinese Diaspora has greatly facilitated popularisation of TCM education.

Countries like UK, US, Australia provide TCM education in universities and private schools, and through TCM training programmes and joint programmes. Canada offers TCM education in institutes outside the university education system. While UK has institutional collaboration between universities of UK and China, US only offer TCM education through private universities. In countries like Australia, TCM is a nationally regulated profession and courses are offered by private universities and schools. Institutional collaborations have been used to establish pedagogy, and establishment of local non-profit accreditation bodies has served to establish quality standards in education and practice.

United Kingdom

Institutional collaboration and non-profit standards organisations has been playing an important role in TCM education in UK.TCM education in UK includes private acupuncture schools and public universities with acupuncture and Chinese medicine programmes. Many programmes have been jointly developed through collaborations between TCM Universities in China and universities in UK. The first 5-year programme of Chinese medicine in Europe is jointly run by the Middlesex University and Beijing University if Chinese medicine.[21] University programmes are also offered by London South Bank University in cooperation with a Confucius Institute. Besides, some programmes are also offered by private colleges not validated by a university.

The role of non-profit organisations like the British Acupuncture Accreditation Board (BAAB) has been significant. The BAAB accredited curriculum for TCM in the UK generally consists of courses in TCM and western medicine. BAAB has approved 12 acupuncture colleges/schools or university Chinese or acupuncture programmes by 2015. Students obtain licenses as TCM practitioners after their courses and become members of the British Acupuncture Council (BAcC) or the Association of Traditional Chinese Medicine Practitioners. There are an estimated 3000 BAcC members providing over 2.3 million treatments a year in the UK.[22]

Australia

Compared to UK, TCM is a nationally regulated profession in Australia. Currently, 10 TCM programs, including eight bachelors and two masters programs have been approved by the Australian Health Practitioner Regulation Agency (AHPRA). These 10 TCM programmes are offered by six institutions, including three universities (RMIT University, the University of Technology Sydney [UTS], and the University of Western Sydney [UWS]), and three private schools (Endeavour College of Natural Health, the Southern School of Natural Therapies, and Sydney Institute of Traditional Chinese Medicine). Entry requirements into these courses include an Australian Tertiary Admission Rank (ATAR) in the 70s-80s (out of 100), which is higher than the average ATAR of around 70 and means TCM university programs are more competitive to gain entrance to than nursing degrees, but less so than modern medicine.

TCM research is not necessarily recognised as such in the national research assessment exercise, the "Excellence in Research for Australia" (ERA). Within the ERA, there is a single category for "complementary and alternative medicine" as a research field, and many of the TCM studies conducted are counted within the "clinical sciences" or "pharmacology and pharmaceutical sciences" categories, thereby masking the actual research strength of TCM in Australia.

Funds from the Chinese Government and Chinese pharmaceutical companies have provided important resources for CM research in Australia, and many universities and private colleges are affiliated with Chinese institutions. Recent years have seen substantial research funding for complementary medicine directed towards universities or university centres that do not necessarily teach it, for example, the establishment of the Zhendong Australia-China Centre for Molecular Traditional Chinese Medicine, University of Adelaide, and the Australian Research Centre in Complementary and Integrative Medicine (ARCCIM), University of Technology Sydney.

United States of America

US education programmes focus mainly on acupuncture. All educational institutions of acupuncture in the USA are private schools. In US the first acupuncture school (the New England School of Acupuncture) was established in 1975;

as of July 2015, the Accreditation Commission for Acupuncture and Oriental Medicine (ACAOM) has approved 84 private schools of Chinese medicine and acupuncture. After China, US has the highest number of educational institutions offering TCM education. Many non-profit organisations have been engaged in education and accreditation of acupuncture TCM practice. The admission requirements of Chinese medicine schools include completion of 2 years of university study or a certain number of credit hours of Western medicine courses after graduation from high school. The master's programs are generally 3-4 years, among which acupuncture programs require at least three years and oriental medicine programs require at least 4 years of study.

Canada

Canada offers TCM education outside the university education system. Currently, Chinese medicine and acupuncture education in Canada is generally provided by private acupuncture schools outside the university education system. Programmes are based on private clinical practice and university Chinese medicine and acupuncture training programmes.

8.6 Conclusion

Overall, global subscription to TCM education and practice has been initiated with acupuncture followed by TCM drugs. In major markets of US and EU, the effort has been to gain entry as drugs, though supplements are marketed too. Market entry as supplements has been facilitated through quality control and subscription to standards of importing destinations. Strong support for inclusion of TCM in US and EU Pharmacopoeias has also made a difference is greater acceptability of TCM. This is reflected in the fact that by 2010, Austria, Belgium, Bulgaria, Czech Republic, Denmark, Germany, Greece, Hungary, Latvia, Portugal, Slovenia, and Spain have recognised TCM.[23]

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IX

TCM and ISMs: A Comparative Analysis

As described in previous chapters, China has designed specific policy goals towards promotion of TCM since 1949. While India's TM history and use is comparable to China, ISM related policy supports have been largely subsumed within the broader healthcare paradigm for long. A focussed domestic and global AYUSH promotion has been a recent initiative. Hence, with 'early mover advantage' and structured, planned policy promotion, TCM has witnessed greater traction and penetration domestically and globally. Governance and sector promotion strategies in China and India have been varied to some extent though the challenges faced by the sector in the two countries have been similar. The following sections provide brief comparative observations on policy initiatives to promote systems of medicines in each country. It may be noted that currently there is no official data on the size of the manufacturing sector, on employment generated or on raw material availability. Hence comparative assessment on these parameters has been a challenge. Similarly, there is lack of clarity on whether the herbal sector is included within the definition of AYUSH.

9.1 Epistemological Similarities in Theory and Medicinal Plant Usage

Theory: TCM and ISM as systems of medicine have several similarities. Both are patient centric and not disease centric unlike the case of modern medicine. Both engage in therapeutic strategies for treatment of specific diseases or symptoms in a holistic fashion.

Overwhelming role of medicinal plants: The Chinese Pharmacopoeia (2015 edition) records a total of 644 species of medicinal plants. In the Ayurvedic pharmacopoeia of India, 540 species of medicinal plants are recorded, of which 364 species can be found in China. About 253 common species are recorded in both the Chinese and Indian pharmacopoeias as per literature survey of the pharmacopoeial volumes and published papers regarding common species in Ayurveda and TCM.[1] Some traditional medicine practices in India and China such as Tibetan medicine in China and *Sowa Rigpa* in India draw influences from both TCM and Ayurveda.

9.2 Governance

The governance of TCM is under the National Health and Family Planning Commission that oversees the health sector in general. Pharmaceutical products and TCM products share same regulations designed under the Drug Administration Law 2001. Like modern drugs, TCM administration is governed through institutions like the National Medical Products Administration (NMPA) (formerly the China Food and Drugs Administration [CFDA])

and the National Health and Family Planning Commission. The SATCM coordinates national and international TCM related matters.

For AYUSH sector, governance has shifted to a new Ministry that is almost entirely responsible for it. However, quality and safety subscription standards are designed by the CDSCO like that of modern drugs. Similarly, AYUSH is regulated under the Drugs and Cosmetics Act, 1940 just like the Drug Administration law 2001 of China.

9.3 Healthcare: Hospitals, Clinics and Pharmacies

As of August 2019, there were 3,896 AYUSH hospitals.[2] The total number of hospital beds recorded was 55,242 in 2017.[3] Besides, there are 8,954 licensed AYUSH manufacturing units. There are 11 premier AYUSH institutes including All India Institute of Ayurveda, Institute of Post-Graduate Teaching & Research in Ayurveda, Jamnagar (Gujarat), Morarji Desai National Institute of Yoga, National Institute of Ayurveda (NIA), Jaipur, National Institute of Siddha (NIS), Chennai, National Institute of Unani Medicine, Bangalore and Rashtriya Ayurved Vidyapeeth, New Delhi. On the other hand, China had recorded 3,695 hospitals in 2017 and 818,216 hospital beds in 2018.[4,5]

As compared to India, China has focussed on increasing the scale of each hospital by increasing the number of beds per hospital. India on the other hand has focussed on increasing the number of hospitals. Insurance for TCM treatments is available. India too is moving towards health insurance for ISMs. This is expected to increase the usage of ISM therapies to a great extent. China has also integrated TCM clinics at the village level. India too is progressing towards setting up ISM related healthcare units at the primary level. However, like China, the first point of preference for patients in India is the modern healthcare systems.

India may consider focusing on improving the infrastructure and quality of existing AYUSH hospitals rather than increasing the number of institutions. Grading of AYUSH hospitals as per the existing quality and infrastructure such as number of beds and qualified doctors, size of medical facilities and R&D investments will serve as a reference point not only for patients, but also for administrators, researchers and policy makers for further improving quality of the establishments. A grading system for AYUSH hospitals is also likely to increase competition in the market leading to increase in innovation and quality of services. Like China, investment in digital technology for efficient service delivery and investment in modern diagnostics for efficient AYUSH treatments using modern diagnostic tools is also essential. AYUSH pharmacies and general pharmacies that sell AYUSH products also require strict monitoring. Regulating pharmacies with only licensed pharmacists to be allowed to dispense AYUSH drugs is imperative. Even in general pharmacy, requirement of AYUSH pharmacist should be made mandatory, if AYUSH products are to be sold.

9.4 Education

There are more than 468 AYUSH colleges offering UG and PG degrees. The graduate level courses are ordinarily for five and a half years and post graduate degree course is of three years duration leading to specialty in the selected subject with the degree of MD (Ayurveda Vachaspati) /MS (Ayurveda Dhanwantari) after successfully completion of the course. Thereafter, PhD, generally for three year duration, is offered.

According to 2013 data from the SATCM, 45 TCM tertiary institutions and another 215 tertiary institutions provide TCM programmes/ majors in mainland China. These tertiary institutions include modern medical education institutions that offer TCM majors as well. While China offers similar duration for UG,

PG and PhD programmes, its education programmes are also evolving with several new models being adopted. For example:

- In 2007, Beijing University of Chinese Medicine adopted a "TCM education reform experimental programme." Students were admitted to this programme by an independent student recruitment process that selected applicants from families of TCM practitioners instead of through a college entrance examination.[6] Once enrolled, students were assigned to different supervisors. This programme is a combination of institutional education, master–apprentice education, and father-son education models.[7]
- In 2011, Beijing University of Chinese Medicine started a 9-year Chinese medicine programme called the "*Qihuang* Programme." This is a combined undergraduate and doctoral programme. During the first five years, students are trained according to an undergraduate teaching plan. In the fourth year, an entrance examination is held to enrol eligible students directly into the subsequent doctoral programme.
- In 2015, Beijing University of Chinese Medicine implemented new innovative models of programmes towards non-Chinese Medicine majors. For instance, the new Chinese Materia Medica programme, called the "*Shizhen Guoyao* Programme", is an 8-year integral programme comprising both domestic and international training and combining bachelor's and doctoral degrees.
- Other new programmes include the 'Excellent Pharmacist of Chinese Medicine Programme" which is a 6-year combined bachelor and master degree and aims to produce highly qualified professionals who have specialised skills in Chinese *materia-medica* integrated pharmaceutical care.

As compared to ISM education, TCM education has several distinctive features:

- TCM education is included as a part of modern medical education.
- Top TCM universities like the Chengdu University of TCM offer non-medical disciplines apart from TCM medical education. These include disciplines such as business management, economics, trade, language, engineering, etc. The uniqueness of this approach is the inclusion of TCM education as compulsory subject in selected semesters. The benefit of this model is that it prepares a workforce in management of TCM sector that could include business, trade, marketing, production, hospitality, etc.
- Similar to China, India could consider nurturing select premier AYUSH Universities/educational institutions offering educational training beyond AYUSH sciences. This could include education in all major disciplines (medical and non-medical) such as business management, accounting, languages, economics, environmental studies, agricultural sciences, etc. These institutions may make it mandatory for all students enrolled at the institution to undergo two compulsory semesters on AYUSH sciences. Further, AYUSH medical education itself requires multidisciplinary programmes, integrating humanities, social sciences and natural sciences to encourage quality research on the entire spectrum of AYUSH sector as compared to limited research on clinical studies. Disciplines like engineering, physics, chemistry, zoology, medical sciences, dental sciences, molecular biology, etc. in AYUSH institutions will foster deeper scientific research in AYUSH. There is also a need to prescribe curriculum and planning for international students to encourage greater intake of international students, keeping in view the TM systems in other countries.

9.5 Manufacturing

While India has recorded existence of 8,954 licensed big and small manufacturing units in 2019, China has recorded 1640 TCM manufacturing units in 2016.[8] However, despite low industry concentration TCM manufacturing companies enjoy high revenue earnings. Revenue of prominent TCM manufacturing companies have been as high as USD 912.4 million (2017) for Kangmei Pharmaceutical, USD 1981.6 million (2017) for Beijing Tong Ren Tan Company Ltd, USD 2,384.3 million Tasly Pharmaceutical Group, USD 19,384.7 million (2017) for Shanghai Pharmaceutical Co. Ltd and USD 1.29 billion (2017) for Chongqing Taiji Industry (Group) Co. Ltd.[9] AYUSH manufacturing companies that have generated revenue on a comparative scale include companies like Dabur India Limited with USD 1087.996 Million revenue generated in 2017.[10] Further, several TCM manufacturing companies are listed in Shanghai and Hong Kong Stock exchanges. In India, Dabur India Limited is listed in the national stock exchange. The difference between the size of operations and the revenue generation of the TCM and AYUSH manufacturing sector is substantial as is evident with the number of large players in traditional medicine sector in China.

AYUSH manufacturing is spread over small, medium and very few large enterprises with only about 50 companies having revenue above INR 100 crore in 2016-17. The TCM manufacturing industry is spread over 1,640 units, though 5-6 companies control almost 10 per cent of market share and revenue ranging between USD 912 million and USD 1.29 billion as outlined above. China's policy focus increases compliance requirements for TCM manufacturers to acquire Good Manufacturing Practices (GMP) certification. It also encourages mergers and acquisitions. These strategies are expected to eliminate small and uncompetitive enterprises while at the same time improve product standards.

High product standards are imperative for all traditional medicines. Though AYUSH product standards have been increasing in recent years as competition increases, the industry can be facilitated towards higher standards with greater regulatory supervision over standards subscriptions and strong enforcement of laws regulating distribution and supply channels, fake AYUSH drugs and false advertisements of AYUSH drugs. Compared to modern medicine products ISM drugs are in greater need to establish their scientific credentials, quality and safety standards in view of prevailing misconceptions among many.

9.6 Trade

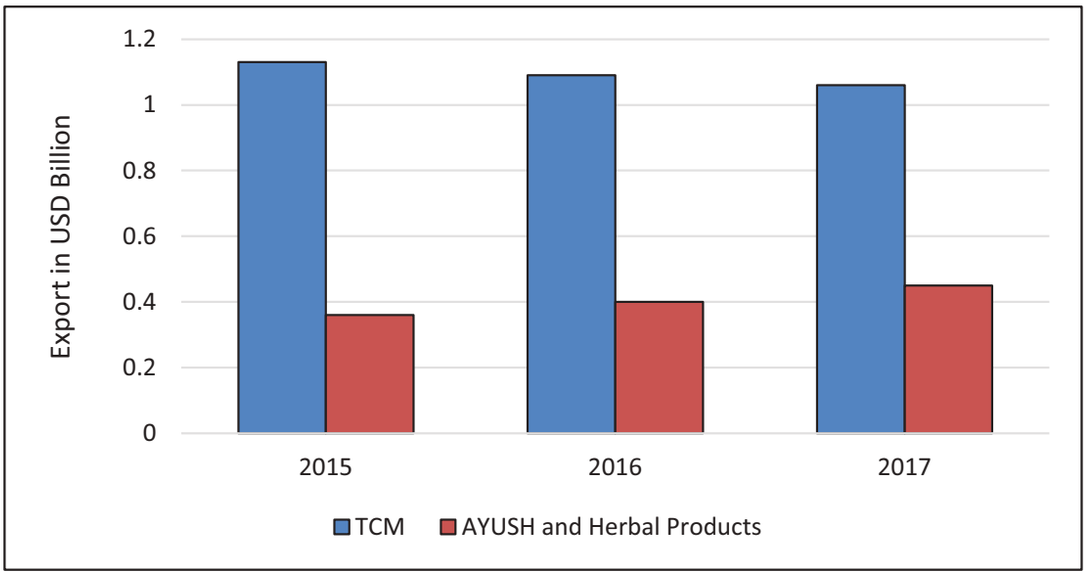
China's value of export as compared to India is higher (Figure 9.1).

Key distinction is that while export in AYUSH and herbal products has been slowly increasing, export of TCM has declined over the last few years.

9.7 Quality, Safety and Standards

Quality Assurance and Standards: Quality assurance and standards development have been equally challenging in both countries. Quality issues of herbal medicines can be classified into two categories: external and internal. External issues are contamination (e.g. toxic metals, pesticide residues and microbes), adulteration and misidentification, and internal factors are complexity and non-uniformity of the ingredients in herbal medicines.[11] Natural products are rarely evaluated in the well-controlled clinical trials that are required to receive approval by regulatory bodies; therefore, they tend to have less modern scientific evidence to support their efficacy. Despite long term usage there is little systematic evidence of safety and efficacy in traditional medicine sector. However, all medicinal compounds are chemicals, whether synthesised in plants, animals, or in manufacturing laboratories. Therefore, all medicinal chemical compounds

Figure 9.1: Export of TCMs and AYUSH Products from India and China



Source: IBIS World Industry Report 2019 and Press Information Bureau, Government of India, 2019.

should be held accountable to similar standards of quality (identity, purity, and stability), clinical effectiveness and safety; irrespective of their source.

China's ambitious global TCM promotion plans have laid strong emphasis on quality control and standards subscription and regulation in TCM. Development of a single pharmacopoeia (that includes TCM and western medicines), pharmaco-vigilance, market surveillance and launch of relevant standards in products and services are important TCM policy initiatives towards quality assurance. Single pharmacopoeia has reduced confusion and has provided ease of reference for enforcement agencies. Further, China's efforts at post market surveillance with tougher laws and enforcement include the latest proposed amendment in the Drug Administration Law 2001. It proposes to introduce 'full traceability' mechanism and a drug recall system.[12] Manufacturers who fail to discover or remove drug safety risks will be subjected to suspension of production and sales. The draft also proposes drug safety credit system for timely updation and publication of drug safety information, including manufacturing permits, results of daily inspections and violations. Tougher punishments are proposed with increase in upper and lower limits of penalties.[13] For example, manufacturing and selling fake drugs and also selling without a licence is liable to be fined up to 30 times their earnings as compared to two to five times currently. The draft also seeks to amplify personal risks of perpetrators where for example anyone involved in counterfeit drugs including legal representatives of pharmaceutical companies or those in charge of manufacturing to be fined or barred from industry as the case may be.

As discussed in Chapter 6, there are several standards at enterprise, provincial, ministry to national levels on TCM and allied sectors. There are more than 480 standards at enterprise level alone. Several national standards are 'compulsory standards' similar to a regulation. These include Good Laboratory Practice (GLP), Good Clinical Practice (GCP) Good Supply Practice (GCP) all regulated by the Drug Administration law 2001.

In India the Drugs and Cosmetics Act 1940, Chapter IV specifically outlines safety provisions, penalty and cognisance for offenses related to ASU drugs manufacture and sale. Penalty ranges from imprisonment for three years or fine of Fifty Thousand Rupees as outlined under Section 27 A of the Act. At present, law enforcement on quality and safety of pharmaceuticals in general has been perceived by many, especially in the West, as insufficient in both China and India. Voluntary standards on AYUSH primarily include GMP, GAP, and GCP standards issued by the Ministry of AYUSH. Recently, the CDSCO has issued draft Guidelines on Good Distribution Practices for pharmaceutical products[14] and these would apply to AYUSH products too.

9.8 Sustained Supply of Medicinal Plants

Supply of medicinal plants has been equally challenging for both countries. In view of heavy dependence of the sector on biological resources and depleting resources leading to threats to sustainability, policy makers in both countries have been focussing on encouraging medicinal plants cultivation programmes in both countries. Several large industry players in both countries opt for contract farming to ensure uniform supply of raw materials.

India's National AYUSH Mission's Medicinal Plant Cultivation Programme is a focussed programme aimed at supporting increase in medicinal plant cultivation. China, in comparison, has linked its medicinal plant cultivation to poverty alleviation programmes, thereby encouraging the promotion of the sector as a poverty alleviation tool. The government supports the development of the medicinal plant cultivation industry by issuing preferential policies and giving subsidies to farmers though the *China Herbal Industry Poverty Alleviation Action Plan (2017-2020)*. It also provides technical support and marketing information for farmers. Towards this end, as described in Chapter 5, cooperatives have been established as a part of the holistic approach to promoting cultivation along with R&D on medicinal plant species. The high demand medicinal plants receive special R&D attention and research base as well as planting base has been created for these plants with the help of provincial and central governments. There are more than 200 such planting bases.

Dedicated marketplaces for trading of medicinal plants and associated products in China is another distinctive feature. Such marketplaces include infrastructural support like zero value added tax for export (where exporters collaborate to make the value of the package towards a certain monetary denomination determined by the administration), currency exchange facilities and certification of products.

India's recent stimulus for overhauling of the medicinal plant sector to cover 10 lakh hectares under herbal cultivation in 2 years[15] is a welcome measure. NMPB has already supported 2.5 lakh hectares of medicinal plant cultivation. This new stimulus along with establishment of network of regional *mandi*s of medicinal plants is expected to support the AYUSH industry and provide employment and income generation to a large section of the farming community. The medicinal plant cultivation has to develop along with growth in the AYUSH and herbal products sector.

9.9 Innovation and R&D

R&D is considered as one of the key factors contributing to the growth of a sector. In TM it becomes particularly relevant as innovation in drug discovery, product development and services creates scope for greater market penetration of the system.

Drug discovery: As compared to India, China has managed to secure through its R&D support policies some relevant drug discoveries based on TCM. These include the Nobel prize awarded medicine innovation of anti-malaria

drug artemisinin from *Artemisia annua L.* by Youyou Tu. In India several new drugs are being developed by Research Councils under Ministry of AYUSH.

IPRs: Intellectual Property Rights (IPRs) are an important indication of innovation related developments in a sector. In China, IP protection for TCM is available through laws that cover traditional modes of IP protection (Trademark Law 1982, Patent Law 1984) as well as through legislations that are meant specifically for TCM such as the 'Regulations on Protection of TCM, 1993.[16] Further, the Regulations on New Plant Variety Protection brought out in 1997 allows protection of new plant varieties including ones developed from wild , such as medicinal plants.

There is high asymmetry between the number of patents for TCM and AYUSH systems in the countries of origin. While there were 6,839 TCM patents in force in 2016 in China, the number of AYUSH patents that were in force in India was only 38 patents.

Public and private investment in R&D in TCM is very high. Focus on single molecule new drug discovery derived from TCM has been there as far back as 1959. A dedicated R&D programme for sustained supply of medicinal plants through cultivation is being undertaken. Research programme on more than 200 highly used medicinal plants is being undertaken to reduce dependence on collection from wild.

9.10 Internationalisation

Both India and China have policy directives towards global promotion of respective TM systems. Towards this end, China has included TCM promotion in most of its geostrategic programmes, and multilateral and bilateral engagements. The most prominent geostrategic platform is the Belt and Road initiative. India's strategic use of ISMs as a soft power tool has been limited.

Both India and China have encouraged research collaborations by its institutions with universities abroad and also supported establishing academic chairs on TM in foreign countries. Further, both countries have signed MoUs with many countries on collaboration in TM sector in general.

In addition, deeper cooperation with international agencies like WHO and ISO has been undertaken by both India and China, though China has been an early starter. ICD 11 revision of Codes (launched in May 2019) that includes TCM began as far back as 2004.[17] Similarly, in ISO, the Technical Committee for Traditional Chinese Medicine (TC249) was formed in 2009 and the 22 international ISO standards on TCM were published in 2017.[18] ICD's inclusion of ISMs and ISO's standards development for ISMs is under process.

China has leveraged institutions in China and abroad more effectively. For example, for ICD-11 American Association of Acupuncture and Oriental Medicine was approached in 2005, and since then, the United States has participated through the auspices of private donors and collective efforts within the acupuncture and oriental medical field with support from colleges, vendors, and professionals.[19]

The existence of international NGOs on TCM is another distinctive feature *vis a vis* ISM. Non- State actors like NGOs associated with TCM standards and accreditations have played the role of quality control and assurance in international markets. The World Federation of Chinese Medicine Societies (WFCMS) and World Federation of Acupuncture-Moxibustion Societies (WFAS) have established official relations with WHO.[20] This provides TCM NGOs with participation rights in international health affairs. The role of such organisations is important in policy development and setting the health agenda in WHO and in turn across the world. The WFCMS mentioned above is one such international non-profit academic organisation for international exchange with headquarters in Beijing. It has 239 society members from 65 countries with 300,000 TCM

practitioners as members.[21] Similarly, the WFAS (mentioned above) established in 1987 with 194 participating countries in 53 nations is another influential organisation for standardisation of TCM. It has officially published four industrial standards. International TCM organisations have a strong support from Chinese TCM institutions. The European Foundation of Traditional Chinese Medicine (FEMTC) has among its members, the Presidents of Beijing and Yunnan Universities of Chinese Medicine, and the President of the China Academy of Chinese Medical Sciences.[22] Besides, it is supported by collaboration with the Guang An Men and Dong Zhi Men hospitals in Beijing and the Hospital of Chinese Medicine in Kunming, Yunnan. The FEMTC has affiliations with WFCMS, Pan European Federation of TCM Societies (PEFOTS), WFAS, and the European Federation of Biotechnology (EFB).[23] European Traditional Chinese Medicine Association (ETCMA) is another umbrella organisation representing over 12,000 practitioners in 14 different countries and founded by Arbeitsgemeinschaft für Klassische Akupunktur und Traditionelle Chinesische Medizin e.V . (AGTCM) (Germany), British Acupuncture Council (BAcC) (United Kingdom), EUFOM (Belgium) and Nederlandse Verenigingvoor Acupunctuur (NVA) (Netherlands).[24]

TCM industry has therefore distinguished itself with:

- Building of dedicated international TCM NGOs that act pressure groups for acceptance of TCM in international destinations; and
- Market entry of strategic markets like US and EU with higher entry thresholds that will in turn facilitate easier access to other markets. Heavy investment in R&D and clinical trials for TCM drugs to ensure entry as drugs is being undertaken by large TCM companies.

India's engagement with WHO on AYUSH has increased significantly over the last few years. Establishment of credible international non-profit organisations catering to ISMs would also be a crucial step towards internationalisation of AYUSH though systems such as Yoga already enjoy a wide global popularity. Creation and capacity building of international ISM NGOs in popularising and regulating ISM products and services at international destinations is imperative for further international acceptance of these systems.

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Appendix 1: Supplementary Tables and Figures[1]

Table A1: R&D Personnel in Pharmaceutical Industry by Industrial Sector in China (2016)

Industry	Number of Enterprises Having R&D Activities	R&D Personnel	Full time Personnel	Researchers	Full Time Equivalent
Manufacture of Medicine	3607	187542	134885	71909	130570
Manufacture of Chemical Medicine	1389	93043	67374	36768	66477
Production of Finished TCM Medicine	803	42526	29162	15307	27624
Manufacture of Biologic Medicine	601	27490	20524	11193	20107

Table A2: R&D Personnel in Pharmaceutical Industry by Industrial Sector In Large Size Enterprise in China (2016)

Industry	Number of Enterprises Having R&D Activities	R&D Personnel	Full time Personnel	Researchers	Full Time Equivalent
Manufacture of Medicine	266	65867	47740	27874	48318
Manufacture of Chemical Medicine	142	39984	28913	17587	29947
Production of Finished TCM Medicine	76	16865	11680	6396	11687
Manufacture of Biologic Medicine	26	3978	2942	1859	3029

Table A3: R&D Personnel in High-tech Industry by Industrial Sector in Medium Size Enterprise in China (2016)

Industry	Number of Enterprises Having R&D Activities	R&D Personnel	Full time Personnel	Researchers	Full Time Equivalent
Manufacture of Medicine	993	64234	46407	23921	43885
Manufacture of Chemical Medicine	453	32266	23386	11990	222528
Production of Finished TCM Medicine	247	13188	8916	4730	8222
Manufacture of Biologic Medicine	134	11589	8903	4673	8345

Table A4: R&D Personnel in High-tech Industry of State-owned and State-controlled Enterprises by Industrial Sector in China (2016)

Industry	Number of Enterprises Having R&D Activities	R&D Personnel	Full time Personnel	Researchers	Full Time Equivalent
Manufacture of Medicine	294	28604	19482	11809	21451
Manufacture of Chemical Medicine	139	17110	11866	6993	13043
Production of Finished TCM Medicine	91	6755	4428	2845	5034
Manufacture of Biologic Medicine	40	3057	1963	1363	2185

Table A5: R&D Personnel in High-tech Industry by Industrial Sector and Registration Status in China (2016)

Registration Status	Industry	Manufacture of Medicine	Manufacture of Chemical Medicine	Production of Finished Traditional Chinese Herbal Medicine	Manufacture of Biologic Medicine
Domestic Funded	Number of Enterprises Having R&D Activities	3113	1155	723	501
	R&D Personnel	152494	72169	36877	21190
	Full time Personnel	107283	51090	24728	15461
	Researchers	57145	27618	13004	8658
	Full Time Equivalent	104069	50901	23228	15181
State Owned	Number of Enterprises Having R&D Activities	18	3	8	3
	R&D Personnel	960	59	194	448
	Full time Personnel	707	54	130	324
	Researchers	397	29	83	210
	Full Time Equivalent	755	56	104	399
Enterprise With Funds from Hong Kong, Macau, Taiwan	Number of Enterprises Having R&D Activities	231	101	53	45
	R&D Personnel	18158	10209	3291	3696
	Full time Personnel	14438	8133	2588	2908
	Researchers	7442	4436	1232	1441
	Full Time Equivalent	13666	7548	2548	2894
Foreign Funded Enterprise	Number of Enterprises Having R&D Activities	263	133	27	55
	R&D Personnel	16890	10665	2358	2604
	Full time Personnel	13164	8151	1846	2155
	Researchers	7322	4714	1071	1094
	Full Time Equivalent	12835	8027	1847	2032

Table A6: Statistics on R&D and Related Activities in Large and Medium-sized Enterprises by Industrial Sector in China

Intra Mural Expenditure on R&D (10000 Yuan)

Industry	Intra Mural Expenditure on R&D (10000 Yuan)					
	2000	2005	2013	2014	2015	2016
Manufacture of Medicines	135888	399510	2588803	2897090	3262105	3598556
Manufacture of Chemical Medicine	88357	273832	1532980	1693918	1917865	2078484
Production of Finished Traditional Chinese Herbal Medicine	29227	91512	518065	550035	573991	678393
Manufacture of Biological Medicine	16571	22955	329758	402687	458219	510471

Expenditure on New Products Development (10000 Yuan)

Industry	Expenditure on New Products Development (10000 Yuan)					
	2000	2005	2013	2014	2015	2016
Manufacture of Medicines	149276	447725	2669404	3033372	3149432	3682217
Manufacture of Chemical Medicine	91707	300482	1536796	1737541	1796571	2099441
Production of Finished Traditional Chinese Herbal Medicine	38556	97048	523000	571590	573748	718069
Manufacture of Biological Medicine	15925	28373	363044	466113	467876	512619

Sales Revenue of New Products (10000 Yuan)

Industry	Sales Revenue of New Products (10000 Yuan)					
	2000	2005	2013	2014	2015	2016
Manufacture of Medicines	1720272	4693608	29908269	36253991	39407601	44311703
Manufacture of Chemical Medicine	1348607	3327695	17841904	20841163	22296183	25200221
Production of Finished Traditional Chinese Herbal Medicine	251856	1045794	6469151	8540698	9196399	10606575
Manufacture of Biological Medicine	95979	171308	2324121	3085270	3672188	3935299

Patent Applications (piece)

Industry	Patent Applications (piece)					
	2000	2005	2013	2014	2015	2016
Manufacture of Medicines	579	2708	10043	11514	9260	9633
Manufacture of Chemical Medicine	215	1133	4501	4689	4707	4475
Production of Finished Traditional Chinese Herbal Medicine	286	1288	3114	3655	1892	2193
Manufacture of Biological Medicine	43	242	1062	1546	1338	1348

Number of Patents (in Force)

Industry	Number of Patents (in Force)					
	2000	2005	2013	2014	2015	2016
Manufacture of Medicines	460	1134	12795	16161	21563	24640
Manufacture of Chemical Medicine	165	495	6302	7973	11448	12828
Production of Finished Traditional Chinese Herbal Medicine	211	497	4661	5513	6114	6839
Manufacture of Biological Medicine	37	49	1197	1746	2342	3265

Expenditure on Technical Renovation (10000 Yuan)

Industry	Expenditure on Technical Renovation (10000 Yuan)					
	2000	2005	2013	2014	2015	2016
Manufacture of Medicines	288150	441007	1007416	1013484	943098	752829
Manufacture of Chemical Medicine	240426	299639	632456	616380	561554	494616
Production of Finished Traditional Chinese Herbal Medicine	41244	115426	202612	250418	255940	184570
Manufacture of Biological Medicine	4751	14754	66729	57327	58877	31184

Expenditure for Acquisition of Foreign Technology (10000 Yuan)

Industry	Expenditure for Acquisition of Foreign Technology (10000 Yuan)					
	2000	2005	2013	2014	2015	2016
Manufacture of Medicines	45441	35815	50838	40210	55800	41232
Manufacture of Chemical Medicine	28040	28159	29884	26022	47092	30247
Production of Finished Traditional Chinese Herbal Medicine	9602	4874	5240	1354		1290
Manufacture of Biological Medicine	7353	151	3312	3422	1252	3887

Expenditure for Assimilation of Technology (10000 Yuan)

Industry	Expenditure for Assimilation of Technology (10000 Yuan)					
	2000	2005	2013	2014	2015	2016
Manufacture of Medicines	12121	34971	58841	67368	32034	27492
Manufacture of Chemical Medicine	11034	31449	40469	49824	20800	23828
Production of Finished Traditional Chinese Herbal Medicine	226	3417	5721	5007	5544	1643
Manufacture of Biological Medicine	771	55	2851	4386	3842	443

Expenditure on Purchase of Domestic Technology (10000 Yuan)

Industry	Expenditure on Purchase of Domestic Technology (10000 Yuan)					
	2000	2005	2013	2014	2015	2016
Manufacture of Medicines	61208	56041	184830	162309	156549	155415
Manufacture of Chemical Medicine	19286	46206	142386	115038	113443	119207
Production of Finished Traditional Chinese Herbal Medicine	37713	8399	27832	28733	25166	23281
Manufacture of Biological Medicine	3691	897	3834	6884	8441	9289

Number of R&D institutions

Industry	Number of R&D institutions					
	2000	2005	2013	2014	2015	2016
Manufacture of Medicines	512	581	1217	1217	1326	1418
Manufacture of Chemical Medicine	308	339	639	630	665	733
Production of Finished Traditional Chinese Herbal Medicine	145	176	327	318	339	344
Manufacture of Biological Medicine	43	31	134	154	171	168

Personnel in R&D Institution

Industry	Personnel in R&D Institution					
	2000	2005	2013	2014	2015	2016
Manufacture of Medicines	16366	22081	86986	89156	92964	99002
Manufacture of Chemical Medicine	10749	13181	48302	49881	50167	54835
Production of Finished Traditional Chinese Herbal Medicine	3593	6340	21378	23023	24257	25100
Manufacture of Biological Medicine	1507	1577	9204	9337	10872	11494

Expenditure in the R&D institution

Industry	Expenditure in the R&D institution					
	2000	2005	2013	2014	2015	2016
Manufacture of Medicines	121593	337652	2034537	2120424	2326326	2610464
Manufacture of Chemical Medicine	76463	219877	1230922	1311379	1416064	1603059
Production of Finished Traditional Chinese Herbal Medicine	30744	90525	414568	428814	466991	519897
Manufacture of Biological Medicine	10305	16358	243229	265217	308588	315641

Full Time Equivalent of R&D Personnel (man-Year)

Industry	Full Time Equivalent of R&D Personnel (man-Year)					
	2000	2005	2013	2014	2015	2016
Manufacture of Medicines	12238	19584	94133	100381	92414	92173
Manufacture of Chemical Medicine	7794	12574	53702	57750	53487	52476
Production of Finished Traditional Chinese Herbal Medicine	2797	4976	22236	23041	19801	19908
Manufacture of Biological Medicine	1406	1534	9701	10723	11088	11374

Table A7: Statistics on R&D and Related Activities of State-owned and State-controlled Enterprises in Large and Medium-sized Enterprises by Industrial Sector in China

i. Full Time Equivalent of R&D Personnel (man-Year)

Industry	Full Time Equivalent of R&D Personnel (man-Year)					
	2000	2005	2013	2014	2015	2016
Manufacture of Medicines	5875	8813	23745	23117	19922	19122
Manufacture of Chemical Medicine	4347	6234	15130	15086	12760	12052
Production of Finished Traditional Chinese Herbal Medicine	790	1712	4477	5174	4119	4649
Manufacture of Biological Medicine	722	668	2892	1894	1981	1401

ii. Intra Mural Expenditure on R&D

Industry	Intra Mural Expenditure on R&D					
	2000	2005	2013	2014	2015	2016
Manufacture of Medicines	42131	145225	512722	535036	542405	547940
Manufacture of Chemical Medicine	30935	103304	299149	302081	314813	322798
Production of Finished Traditional Chinese Herbal Medicine	6627	32040	113054	128806	115097	132703
Manufacture of Biological Medicine	4320	6280	71425	81584	88475	62660

iii. Expenditure on New Products Development (10000 Yuan)

Industry	Expenditure on New Products Development (10000 Yuan)					
	2000	2005	2013	2014	2015	2016
Manufacture of Medicines	48657	149858	476746	514206	500992	537032
Manufacture of Chemical Medicine	36158	106835	257925	287350	290836	308312
Production of Finished Traditional Chinese Herbal Medicine	6390	32650	117215	127519	99345	133021
Manufacture of Biological Medicine	5744	5844	77218	80907	91411	68384

iv. Sales Revenue of New Products

Industry	Sales Revenue of New Products					
	2000	2005	2013	2014	2015	2016
Manufacture of Medicines	660791	1495400	5069973	5655185	6099730	6884447
Manufacture of Chemical Medicine	598623	1016304	2881728	3040150	3258134	3739414
Production of Finished Traditional Chinese Herbal Medicine	49137	378861	1315105	1572865	1788373	2259312
Manufacture of Biological Medicine	12316	48681	325980	508217	467925	307176

v. Sales Revenue of New Products

Industry	Sales Revenue of New Products					
	2000	2005	2013	2014	2015	2016
Manufacture of Medicines	660791	1495400	5069973	5655185	6099730	6884447
Manufacture of Chemical Medicine	598623	1016304	2881728	3040150	3258134	3739414
Production of Finished Traditional Chinese Herbal Medicine	49137	378861	1315105	1572865	1788373	2259312
Manufacture of Biological Medicine	12316	48681	325980	508217	467925	307176

vi. Patent Applications (piece)

Industry	Patent Applications (piece)					
	2000	2005	2013	2014	2015	2016
Manufacture of Medicines	128	859	1479	1567	1179	1513
Manufacture of Chemical Medicine	68	467	686	683	597	621
Production of Finished Traditional Chinese Herbal Medicine	52	336	568	641	397	667
Manufacture of Biological Medicine	8	45	166	192	135	100

vii. Number of Patents (in Force)

Industry	Number of Patents (in Force)					
	2000	2005	2013	2014	2015	2016
Manufacture of Medicines	129	370	2923	3230	3955	3889
Manufacture of Chemical Medicine	101	206	1311	1712	1946	2183
Production of Finished Traditional Chinese Herbal Medicine	16	148	1235	1007	1428	1216
Manufacture of Biological Medicine	12	16	319	412	462	362

viii. Expenditure on Technical Renovation (10000 Yuan)

Industry	Expenditure on Technical Renovation (10000 Yuan)					
	2000	2005	2013	2014	2015	2016
Manufacture of Medicines	110643	151727	217482	237937	150752	121028
Manufacture of Chemical Medicine	104095	121544	167126	149496	108915	87472
Production of Finished Traditional Chinese Herbal Medicine	4988	28015	34509	70774	23988	13848
Manufacture of Biological Medicine	1483	1850	3276	4140	3776	4267

ix. Expenditure for Acquisition of Foreign Technology (10000 Yuan)

Industry	Expenditure for Acquisition of Foreign Technology (10000 Yuan)					
	2000	2005	2013	2014	2015	2016
Manufacture of Medicines	16437	12056	14161	13356	9621	15043
Manufacture of Chemical Medicine	14811	11320	8166	4571	2425	6272
Production of Finished Traditional Chinese Herbal Medicine	1220	584	206	178	181	1163
Manufacture of Biological Medicine	406	151	199	2176	68	2070

x. Expenditure for Assimilation of Technology (10000 Yuan)

Industry	Expenditure for Assimilation of Technology (10000 Yuan)					
	2000	2005	2013	2014	2015	2016
Manufacture of Medicines	8848	10721	12655	18636	8354	9647
Manufacture of Chemical Medicine	8609	10292	10538	16283	7022	7925
Production of Finished Traditional Chinese Herbal Medicine	45	377	629	872	48	565
Manufacture of Biological Medicine	194	52	229	200		

xi. Expenditure on Purchase of Domestic Technology (10000 Yuan)

Industry	Expenditure on Purchase of Domestic Technology (10000 Yuan)					
	2000	2005	2013	2014	2015	2016
Manufacture of Medicines	9273	20216	23689	27213	15799	17445
Manufacture of Chemical Medicine	7374	17437	19857	21894	13516	15828
Production of Finished Traditional Chinese Herbal Medicine	1390	2154	2590	3864	523	830
Manufacture of Biological Medicine	510	423	954	374	1442	8

xii. Number of R&D institutions

Industry	Number of R&D institutions					
	2000	2005	2013	2014	2015	2016
Manufacture of Medicines	209	216	225	202	233	239
Manufacture of Chemical Medicine	140	130	110	103	123	120
Production of Finished Traditional Chinese Herbal Medicine	48	63	84	75	82	86
Manufacture of Biological Medicine	17	15	22	16	19	20

xiii. Full Time Equivalent of R&D Personnel (man-Year)

Industry	Full Time Equivalent of R&D Personnel (man-Year)					
	2000	2005	2013	2014	2015	2016
Manufacture of Medicines	5875	8813	23745	23117	19922	19122
Manufacture of Chemical Medicine	4347	6234	15130	15086	12760	12052
Production of Finished Traditional Chinese Herbal Medicine	790	1712	4477	5174	4119	4649
Manufacture of Biological Medicine	722	668	2892	1894	1981	1401

xiv. Personnel in R&D Institution

Industry	Personnel in R&D Institution					
	2000	2005	2013	2014	2015	2016
Manufacture of Medicines	6359	8261	15574	15097	17477	17144
Manufacture of Chemical Medicine	4779	5476	8708	8090	9445	9328
Production of Finished Traditional Chinese Herbal Medicine	996	1989	4011	4703	5212	5549
Manufacture of Biological Medicine	544	522	1780	1147	1533	1001

xv. Expenditure in the R&D institution

Industry	Expenditure in the R&D institution					
	2000	2005	2013	2014	2015	2016
Manufacture of Medicines	41990	125836	373424	366802	442410	417018
Manufacture of Chemical Medicine	29328	85074	193413	184063	249155	237153
Production of Finished Traditional Chinese Herbal Medicine	7428	31355	111524	115477	122032	121122
Manufacture of Biological Medicine	3627	4935	45182	47431	48527	30385

Table A8: Statistics on R&D and Related Activities of Domestic Funded Enterprises in Large and Medium-sized Enterprises by Industrial Sector in China

i. Full Time Equivalent of R&D Personnel (man-Year)

Industry	Full Time Equivalent of R&D Personnel (man-Year)					
	2000	2005	2013	2014	2015	2016
Manufacture of Medicines	10677	16539	69892	74851	70388	70988
Manufacture of Chemical Medicine	6855	10352	38000	41109	39372	39436
Production of Finished Traditional Chinese Herbal Medicine	2376	4354	18756	19152	16257	16358
Manufacture of Biological Medicine	1222	1413	6727	7387	7777	7830

ii. Intra Mural Expenditure on R&D

Industry	Intra Mural Expenditure on R&D					
	2000	2005	2013	2014	2015	2016
Manufacture of Medicines	105252	306401	1865599	2095151	2406149	2611739
Manufacture of Chemical Medicine	64927	203950	1029722	1139337	1334066	1399592
Production of Finished Traditional Chinese Herbal Medicine	24645	76775	425519	447477	475659	569693
Manufacture of Biological Medicine	14090	19148	233892	288512	316983	356914

iii. Expenditure on New Products Development (10000 Yuan)

Industry	Expenditure on New Products Development (10000 Yuan)					
	2000	2005	2013	2014	2015	2016
Manufacture of Medicines	118340	335802	1951942	2222787	2357781	2676742
Manufacture of Chemical Medicine	71081	217035	1050724	1196405	1273062	1393590
Production of Finished Traditional Chinese Herbal Medicine	31824	77861	440609	475858	486258	611831
Manufacture of Biological Medicine	12492	24091	257535	324434	322971	370481

iv. Sales Revenue of New Products (10000 Yuan)

Industry	Sales Revenue of New Products(10000 Yuan)					
	2000	2005	2013	2014	2015	2016
Manufacture of Medicines	1382686	3827635	23092736	27103052	29213886	33965933
Manufacture of Chemical Medicine	1082852	2592266	12684404	13878247	14933248	17616413
Production of Finished Traditional Chinese Herbal Medicine	213073	926895	5676796	7136273	7873226	9226800
Manufacture of Biological Medicine	70466	164505	1884620	2571625	2754715	3206424

v. Patent Applications (piece)

Industry	Patent Applications (piece)					
	2000	2005	2013	2014	2015	2016
Manufacture of Medicines	492	2114	7939	9181	6985	7630
Manufacture of Chemical Medicine	200	870	3152	3531	3315	3327
Production of Finished Traditional Chinese Herbal Medicine	242	1033	2898	3401	1639	1946
Manufacture of Biological Medicine	15	171	778	950	825	925

vi. Number of Patents (in Force)

Industry	Number of Patents (in Force)					
	2000	2005	2013	2014	2015	2016
Manufacture of Medicines	292	861	10037	12294	17012	19131
Manufacture of Chemical Medicine	154	427	4458	5652	8490	9201
Production of Finished Traditional Chinese Herbal Medicine	77	366	4194	4658	5391	6043
Manufacture of Biological Medicine	14	40	872	1200	1618	2401

vii. Expenditure on Technical Renovation (10000 Yuan)

Industry	Expenditure on Technical Renovation (10000 Yuan)					
	2000	2005	2013	2014	2015	2016
Manufacture of Medicines	263464	363380	873390	862731	779219	638813
Manufacture of Chemical Medicine	223744	257301	522857	506005	451177	401306
Production of Finished Traditional Chinese Herbal Medicine	34240	81966	189416	229248	243210	173570
Manufacture of Biological Medicine	3751	13554	58944	40388	28960	22744

viii. Expenditure for Acquisition of Foreign Technology (10000 Yuan)

Industry	Expenditure for Acquisition of Foreign Technology (10000 Yuan)					
	2000	2005	2013	2014	2015	2016
Manufacture of Medicines	36257	22772	36042	24908	48821	35797
Manufacture of Chemical Medicine	25613	15551	18573	11636	40391	25350
Production of Finished Traditional Chinese Herbal Medicine	9202	4440	3436	1354	181	1251
Manufacture of Biological Medicine	1120	151	2261	2856	974	3441

ix. Expenditure for Assimilation of Technology (10000 Yuan)

Industry	Expenditure for Assimilation of Technology (10000 Yuan)					
	2000	2005	2013	2014	2015	2016
Manufacture of Medicines	11140	21741	45769	51977	27476	22805
Manufacture of Chemical Medicine	10054	18575	28314	35345	16308	19194
Production of Finished Traditional Chinese Herbal Medicine	225	3061	5073	4186	5544	1643
Manufacture of Biological Medicine	771	55	2851	4386	3821	443

x. Expenditure on Purchase of Domestic Technology (10000 Yuan)

Industry	Expenditure on Purchase of Domestic Technology (10000 Yuan)					
	2000	2005	2013	2014	2015	2016
Manufacture of Medicines	56493	45482	128658	124797	119897	118198
Manufacture of Chemical Medicine	15849	37349	94721	86992	79984	85232
Production of Finished Traditional Chinese Herbal Medicine	36570	7138	20633	21993	22507	20270
Manufacture of Biological Medicine	3556	605	2921	5878	8057	9289

xi. Number of R&D institutions

Industry	Number of R&D institutions					
	2000	2005	2013	2014	2015	2016
Manufacture of Medicines	452	483	959	973	1056	1132
Manufacture of Chemical Medicine	278	268	494	491	520	579
Production of Finished Traditional Chinese Herbal Medicine	124	153	279	275	279	291
Manufacture of Biological Medicine	35	29	98	113	126	119

xii. Personnel in R&D Institution

Industry	Personnel in R&D Institution					
	2000	2005	2013	2014	2015	2016
Manufacture of Medicines	14513	18434	64217	67605	71571	75130
Manufacture of Chemical Medicine	9796	10562	34365	36053	36398	39909
Production of Finished Traditional Chinese Herbal Medicine	3005	5623	17979	19761	20793	21224
Manufacture of Biological Medicine	1209	1358	5753	6127	7804	7674

xiii. Expenditure in the R&D institution

Industry	Expenditure in the R&D institution					
	2000	2005	2013	2014	2015	2016
Manufacture of Medicines	98836	275045	1415999	1520382	1655452	1791508
Manufacture of Chemical Medicine	60200	171180	793763	889149	934056	1036163
Production of Finished Traditional Chinese Herbal Medicine	26239	81481	340405	360199	401957	425581
Manufacture of Biological Medicine	8803	14143	168852	180176	207109	191143

Table A9: Statistics on R&D and Related Activities of foreign Funded Enterprises in Large and Medium-sized Enterprises by Industrial Sector in China

i. Full Time Equivalent of R&D Personnel (man-Year)

Industry	Full Time Equivalent of R&D Personnel (man-Year)					
	2000	2005	2013	2014	2015	2016
Manufacture of Medicines	1123	2424	13232	14102	11589	10128
Manufacture of Chemical Medicine	665	1894	10000	10223	8168	6590
Production of Finished Traditional Chinese Herbal Medicine	332	333	1575	1629	1616	1607
Manufacture of Biological Medicine	109	121	1239	1471	1176	1262

ii. Intra Mural Expenditure on R&D

Industry	Intra Mural Expenditure on R&D					
	2000	2005	2013	2014	2015	2016
Manufacture of Medicines	24491	74443	403182	433100	436863	478817
Manufacture of Chemical Medicine	18884	59703	297316	319096	336846	355440
Production of Finished Traditional Chinese Herbal Medicine	3549	6344	50091	52045	48723	54973
Manufacture of Biological Medicine	1915	3807	44000	45072	33583	42486

iii. Expenditure on New Products Development (10000 Yuan)

Industry	Expenditure on New Products Development (10000 Yuan)					
	2000	2005	2013	2014	2015	2016
Manufacture of Medicines	23945	90178	386912	405689	371664	515040
Manufacture of Chemical Medicine	15784	70318	272977	270497	272687	397441
Production of Finished Traditional Chinese Herbal Medicine	5701	10997	42142	47758	42655	49805
Manufacture of Biological Medicine	2315	4282	51507	68235	37506	39535

iv. Sales Revenue of New Products

Industry	Sales Revenue of New Products					
	2000	2005	2013	2014	2015	2016
Manufacture of Medicines	273340	741324	4001660	4702503	4876949	5065970
Manufacture of Chemical Medicine	214036	658184	3226567	3938720	4156155	4339994
Production of Finished Traditional Chinese Herbal Medicine	28409	73537	463989	508689	264792	200506
Manufacture of Biological Medicine	23358	6803	101438	157165	255264	314338

v. Patent Applications (piece)

Industry	Patent Applications (piece)					
	2000	2005	2013	2014	2015	2016
Manufacture of Medicines	48	459	1136	1444	1006	977
Manufacture of Chemical Medicine	13	188	684	607	573	609
Production of Finished Traditional Chinese Herbal Medicine	29	195	84	109	147	106
Manufacture of Biological Medicine	6	71	136	445	195	134

vi. Number of Patents (in Force)

Industry	Number of Patents (in Force)					
	2000	2005	2013	2014	2015	2016
Manufacture of Medicines	67	252	1345	2210	2077	2394
Manufacture of Chemical Medicine	5	56	929	1254	1329	1598
Production of Finished Traditional Chinese Herbal Medicine	61	122	190	491	385	387
Manufacture of Biological Medicine	1	9	160	374	266	259

vii. Expenditure on Technical Renovation (10000 Yuan)

Industry	Expenditure on Technical Renovation (10000 Yuan)					
	2000	2005	2013	2014	2015	2016
Manufacture of Medicines	15978	52192	77313	68248	95191	78143
Manufacture of Chemical Medicine	8480	29971	68070	60778	68035	70505
Production of Finished Traditional Chinese Herbal Medicine	6498	20560	7686	4795	3326	1524
Manufacture of Biological Medicine	1000	1200	211	527	17569	5030

viii. Expenditure for Acquisition of Foreign Technology (10000 Yuan)

Industry	Expenditure for Acquisition of Foreign Technology (10000 Yuan)					
	2000	2005	2013	2014	2015	2016
Manufacture of Medicines	8898	9383	10224	7259	3727	1992
Manufacture of Chemical Medicine	2140	9183	9166	6909	3492	1941
Production of Finished Traditional Chinese Herbal Medicine	400	200				
Manufacture of Biological Medicine	6233		428		235	

ix. Expenditure for Assimilation of Technology (10000 Yuan)

Industry	Expenditure for Assimilation of Technology (10000 Yuan)					
	2000	2005	2013	2014	2015	2016
Manufacture of Medicines	961	3405	5986	6727	788	919
Manufacture of Chemical Medicine	960	3049	5093	5954	721	866
Production of Finished Traditional Chinese Herbal Medicine	1	356	627	727		
Manufacture of Biological Medicine					22	

x. Expenditure on Purchase of Domestic Technology (10000 Yuan)

Industry	Expenditure on Purchase of Domestic Technology (10000 Yuan)					
	2000	2005	2013	2014	2015	2016
Manufacture of Medicines	1557	6808	20801	19433	24059	28382
Manufacture of Chemical Medicine	562	5598	18146	15420	22067	27831
Production of Finished Traditional Chinese Herbal Medicine	980	918	1844	3584	1537	490
Manufacture of Biological Medicine	15	292	470	373	384	

xi. Number of R&D institutions

Industry	Number of R&D institutions					
	2000	2005	2013	2014	2015	2016
Manufacture of Medicines	36	62	139	127	123	138
Manufacture of Chemical Medicine	16	46	78	73	73	76
Production of Finished Traditional Chinese Herbal Medicine	14	12	20	17	16	17
Manufacture of Biological Medicine	5	2	21	23	20	25

xii. Personnel in R&D Institution

Industry	Personnel in R&D Institution					
	2000	2005	2013	2014	2015	2016
Manufacture of Medicines	1081	2695	11755	11338	10065	10158
Manufacture of Chemical Medicine	487	1959	7478	7298	6774	6618
Production of Finished Traditional Chinese Herbal Medicine	459	425	1518	1542	1474	1589
Manufacture of Biological Medicine	121	219	1842	1921	1272	1270

xiii. Expenditure in the R&D institution

Industry	Expenditure in the R&D institution					
	2000	2005	2013	2014	2015	2016
Manufacture of Medicines	17518	42017	358668	317358	345722	393935
Manufacture of Chemical Medicine	12491	32989	270660	217920	264219	286320
Production of Finished Traditional Chinese Herbal Medicine	3856	4162	39842	34152	38842	51223
Manufacture of Biological Medicine	685	2216	34794	51616	32516	36799

Table A10: R&D Expenditure in High-tech Industry by Industrial Sector in China, 2016 (10000 Yuan)

R&D Expenditure in High-tech Industry by Industrial Sector, 2016 (10000 Yuan)						
Industry	Intramural Expenditure on R&D	Labour Cost	Equipment	Govt. Funds	Self Raised Funds by Enterprise	External Expenditure on R&D
Manufacture of Medicines	4884712	1413371	602626	223677	4621319	600518
Manufacture of Chemical Medicine	2522862	749864	302189	104572	2399303	354151
Production of Finished Traditional Chinese Herbal Medicine	927503	265387	120014	55301	866563	117401
Manufacture of Biological Medicine	831891	230477	100468	45004	778373	97569

Table A11: R&D Expenditure in High-tech Industry by Industrial Sector and Scale of Enterprise in China, 2016 (10000 Yuan)

R&D Expenditure in High-tech Industry by Industrial Sector and Scale of Enterprise, 2016 (10000 Yuan)						
	Large Sized Enterprise					
Industry	Intramural Expenditure on R&D	Labour Cost	Equipment	Govt. Funds	Self Raised Funds by Enterprise	External Expenditure on R&D
Manufacture of Medicines	1953878	596830	208171	94082	1850864	271793
Manufacture of Chemical Medicine	1283477	388174	135995	61210	1217008	193455
Production of Finished Traditional Chinese Herbal Medicine	377938	115836	43180	24768	352179	46553
Manufacture of Biological Medicine	131787	41256	14139	5964	123143	20849
	Medium Size Enterprise					
	Intramural Expenditure on R&D	Labour Cost	Equipment	Govt. Funds	Self Raised Funds by Enterprise	External Expenditure on R&D
Manufacture of Medicines	1644678	463660	196673	73121	1558298	212588
Manufacture of Chemical Medicine	795007	230132	106534	28578	760144	110919
Production of Finished Traditional Chinese Herbal Medicine	300455	82575	30902	19492	279627	36476
Manufacture of Biological Medicine	378683	103160	39486	19868	356843	55426

Table A12: R&D Expenditure in High-tech Industry in China, 2016 (10000 Yuan)

R&D Expenditure in High-tech Industry of State-owned and State-controlled Enterprises by Industrial Sector, 2016 (10000 Yuan)						
Industry	Intramural Expenditure on R&D	Labour Cost	Equipment	Govt. Funds	Self Raised Funds by Enterprise	External Expenditure on R&D
Manufacture of Medicines	618189	219020	70347	38695	577196	101980
Manufacture of Chemical Medicine	348731	120086	49716	17602	330548	67509
Production of Finished Traditional Chinese Herbal Medicine	141143	57368	11060	8210	132158	16548
Manufacture of Biological Medicine	92914	30715	8772	11619	80718	14747

TableA13: R&D Expenditure in High-tech Industry in China, 2016 (10000 Yuan)

R&D Expenditure in High-tech Industry of State-owned and State-controlled Enterprises by Industrial Sector, and Registration status, 2016 (10000 Yuan)						
	Domestic Funded					
Industry	Intramural Expenditure on R&D	Labour Cost	Equipment	Govt. Funds	Self Raised Funds by Enterprise	External Expenditure on R&D
Manufacture of Medicines	3745150	1053858	488718	175152	3535210	435577
Manufacture of Chemical Medicine	1773577	516251	224916	78259	1679333	242808
Production of Finished Traditional Chinese Herbal Medicine	800760	224797	109304	47440	747984	93932
Manufacture of Biological Medicine	630812	165192	80101	32023	591620	68795
	State-Owned Enterprise					
Manufacture of Medicines	28157	10281	4160	5722	22070	3186
Manufacture of Chemical Medicine	2097	864	187		2097	868
Production of Finished Traditional Chinese Herbal Medicine	2092	1100	161	256	1836	320
Manufacture of Biological Medicine	18867	7201	3760	5051	13816	1999
	Enterprise with Funds from Hong Kong, Macau, Taiwan					
Manufacture of Medicines	583373	165962	54551	28103	552979	84624
Manufacture of Chemical Medicine	360582	97885	33289	14720	345053	46572
Production of Finished Traditional Chinese Herbal Medicine	64825	20900	4692	2907	61777	10109
Manufacture of Biological Medicine	132185	39393	15319	9759	121361	27121
	Foreign Funded Enterprise					
Manufacture of Medicines	556189	193550	59358	20423	533131	80317
Manufacture of Chemical Medicine	388703	135728	43985	11594	374917	64772
Production of Finished Traditional Chinese Herbal Medicine	61918	19690	6018	4954	56802	13361
Manufacture of Biological Medicine	68894	25893	5047	3223	65392	1653

Table A14: New Products Development and Sale in High-tech in China, 2016 (10000 Yuan)

Industry	New Products	Expenditure on New Products Development	Sales Revenue on New Products	Exports
Manufacture of Medicines	25320	4978806	54227527	4896556
Manufacture of Chemical Medicine	12642	2532006	28629123	3034577
Production of Finished Traditional Chinese Herbal Medicine	5431	966074	13037869	352638
Manufacture of Biological Medicine	3720	827243	5807141	921789

Table A15: New Products Development and Sale in High-tech Industry by Industrial Sector and Scale of Enterprise in China, 2016 (10000 Yuan)

	Large Sized Enterprise			
Industry	New Products	Expenditure on New Products Development	Sales Revenue on New Products	Exports
Manufacture of Medicines	6548	1957350	26650602	2433600
Manufacture of Chemical Medicine	4175	1284322	16000686	1740302
Production of Finished Traditional Chinese Herbal Medicine	1633	391603	7088236	271142
Manufacture of Biological Medicine	314	124368	905672	225868
	Medium Sized Enterprise			
Manufacture of Medicines	8643	1724867	17661101	1755997
Manufacture of Chemical Medicine	4625	815119	9199535	963959
Production of Finished Traditional Chinese Herbal Medicine	1812	326466	3518338	43646
Manufacture of Biological Medicine	1298	388251	3029627	505395

Table A16: New Products Development and Sale in High-tech Industry of state owned and state controlled Enterprise by Industrial Sector in China, 2016 (10000 Yuan)

Industry	New Products	Expenditure on New Products Development	Sales Revenue on New Products	Exports
Manufacture of Medicines	3476	601361	7495639	806322
Manufacture of Chemical Medicine	1982	331792	3941798	667268
Production of Finished Traditional Chinese Herbal Medicine	909	143360	2379816	12567
Manufacture of Biological Medicine	392	90786	549665	46949

Table A17: New Products Development and Sale in High-tech Industry by Industrial Sector and Registration status in China, 2016 (10000 Yuan)

	Domestic Funded			
Industry	New Products	Expenditure on New Products Development	Sales Revenue on New Products	Exports
Manufacture of Medicines	20518	3803932	42782114	3590451
Manufacture of Chemical Medicine	9923	1753405	20592354	2280836
Production of Finished Traditional Chinese Herbal Medicine	4600	838123	11423501	170542
Manufacture of Biological Medicine	2880	633908	4898484	774846
	State-Owned Enterprises			
Manufacture of Medicines	151	22777	246304	15287
Manufacture of Chemical Medicine	16	1832	54612	222
Production of Finished Traditional Chinese Herbal Medicine	32	3017	3134	
Manufacture of Biological Medicine	55	11471	131155	15065
	Enterprise with Funds from Hong Kong, Macau, Taiwan			
Manufacture of Medicines	2600	570553	5714599	499440
Manufacture of Chemical Medicine	1429	342542	3375492	205626
Production of Finished Traditional Chinese Herbal Medicine	540	70505	1377077	179669
Manufacture of Biological Medicine	465	126462	468572	62159
	Foreign Funded Enterprises			
Manufacture of Medicines	2202	604321	5730814	806665
Manufacture of Chemical Medicine	1290	436059	4661277	548115
Production of Finished Traditional Chinese Herbal Medicine	291	57447	237291	2428
Manufacture of Biological Medicine	375	66872	440085	84784

Table A18: Technology Acquisition and Renovation in High-tech Industry in China, 2016 (10000 Yuan)

Technology Acquisition and Renovation in High-tech Industry by Industrial Sector and Registration Status, 2016 (10000 Yuan)				
	Domestic Funded			
Industry	Expenditure for Acquisition of Foreign Technology	Expenditure for Assimilation of Technology	Expenditure on Purchase of Domestic Technology	Expenditure for Technical Renovation
Manufacture of Medicines	38503	27627	141301	810491
Manufacture of Chemical Medicine	25959	19952	93002	466751
Production of Finished Traditional Chinese Herbal Medicine	1451	1709	22907	210927
Manufacture of Biological Medicine	5021	1245	11893	66224
	State-Owned Enterprises			
Manufacture of Medicines	13	15	12	5497
Manufacture of Chemical Medicine				1353
Production of Finished Traditional Chinese Herbal Medicine				2450
Manufacture of Biological Medicine	13	15	12	1694
	Enterprise with Funds from Hong Kong, Macau, Taiwan			
Manufacture of Medicines	4767	3769	9825	43304
Manufacture of Chemical Medicine	2957	3769	7094	27656
Production of Finished Traditional Chinese Herbal Medicine	1364		2521	11990
Manufacture of Biological Medicine	446		40	3476
	Foreign Funded Enterprises			
Manufacture of Medicines	3338	1187	30002	80454
Manufacture of Chemical Medicine	3270	866	28001	71422
Production of Finished Traditional Chinese Herbal Medicine			490	1826
Manufacture of Biological Medicine	17	268	1400	5464

Table A19: R&D Institutions in High-tech Industry by Industrial Sector in China (2016)

Industry	Number of Enterprises with R&D institutions	R&D Institutions	Personnel in R&D Institutions	Expenditure in R&D Institutions (10000 Yuan)	Equipment (10000 Yuan)
Manufacture of Medicines	2310	3043	133133	3294409	3230752
Manufacture of Chemical Medicine	933	1299	66967	1841436	1747400
Production of Finished Traditional Chinese Herbal Medicine	479	623	32142	650422	565828
Manufacture of Biological Medicine	380	504	19182	495203	539705

Table A20: R&D Institutions in High-tech Industry by Industrial Sector and Scale of Enterprise in China (2016)

	Large Sized Enterprise				
Industry	Number of Enterprises with R&D institutions	R&D Institutions	Personnel in R&D Institutions	Expenditure in R&D Institutions (10000 Yuan)	Equipment (10000 Yuan)
Manufacture of Medicines	211	437	51436	1479779	1398788
Manufacture of Chemical Medicine	119	277	30777	1012513	947151
Production of Finished Traditional Chinese Herbal Medicine	62	107	15407	337509	236690
Manufacture of Biological Medicine	17	31	2936	73075	123843
	Medium Sized Enterprise				
Manufacture of Medicines	706	981	47566	1130685	1129886
Manufacture of Chemical Medicine	330	456	24058	590546	547219
Production of Finished Traditional Chinese Herbal Medicine	166	237	9693	182388	207423
Manufacture of Biological Medicine	91	137	8558	242566	208870

Table A21: R&D Institutions in High-tech Industry of State Owned and State Controlled Enterprises by Industrial Sector in China (2016)

Industry	Number of Enterprises with R&D institutions	R&D Institutions	Personnel in R&D Institutions	Expenditure in R&D Institutions (10000 Yuan)	Equipment (10000 Yuan)
Manufacture of Medicines	206	323	19339	448114	433859
Manufacture of Chemical Medicine	96	152	10129	251220	222509
Production of Finished Traditional Chinese Herbal Medicine	70	107	6100	125649	88896
Manufacture of Biological Medicine	23	40	1647	37669	74060

Table A22: R&D Institutions in High-tech Industry by Industrial Sector and Registration Status of the Enterprise in China (2016)

	Domestic Funded				
Industry	Number of Enterprises with R&D institutions	R&D Institutions	Personnel in R&D Institutions	Expenditure in R&D Institutions (10000 Yuan)	Equipment (10000 Yuan)
Manufacture of Medicines	1968	2567	104574	2376792	2428439
Manufacture of Chemical Medicine	774	1066	49926	1230365	1298758
Production of Finished Traditional Chinese Herbal Medicine	427	546	27600	544281	434583
Manufacture of Biological Medicine	307	400	14059	339038	364299
	State-Owned Enterprises				
Manufacture of Medicines	14	21	671	8746	17536
Manufacture of Chemical Medicine	3	3	65	2123	1824
Production of Finished Traditional Chinese Herbal Medicine	6	6	145	1715	1439
Manufacture of Biological Medicine	3	9	390	4388	13803
	Enterprise with Funds from Hong Kong, Macau, Taiwan				
Manufacture of Medicines	168	242	16064	472930	358087
Manufacture of Chemical Medicine	74	112	9066	299877	173444
Production of Finished Traditional Chinese Herbal Medicine	37	54	2758	49417	38786
Manufacture of Biological Medicine	35	54	3333	105250	124269
	Foreign Funded Enterprises				
Manufacture of Medicines	174	234	12495	444687	444225
Manufacture of Chemical Medicine	85	121	7975	311194	275197
Production of Finished Traditional Chinese Herbal Medicine	15	23	1784	56724	92459
Manufacture of Biological Medicine	38	50	1790	50915	51138

Endnote

1. The figures are taken from China Hi-Technology Industry Yearbook, 2017.

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