Development and Trade of Medicinal and Aromatic Plants (MAPs): Learnings from Comparative Analysis of China and India

Study Report

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Table of Contents

List of Tables

List of Boxes

Abbreviations

ABS	-	Access and Benefit Sharing
ADB	-	Asian Development Bank
ASEAN	-	The Association of Southeast Asian Nations
ASU	-	Ayurveda, Siddha, Unani
AYUSH	-	Ayurveda, Yoga & Naturopathy, Unani, Siddha, Sowa Rigpa and Homoeopathy
BRI	-	Belt and Road Initiative
CFDA	-	China Food and Drug Administration
CHAMF	-	Central Herbal Agro Marketing Federation of India
CHM	-	Chinese Herbal Medicine
CIMAP	-	Central Institute of Medicinal and Aromatic Plants
C&ISM	-	Criteria and Indicators for Sustainable Management
CITIES	-	Convention of International Trade in Endangered Species of Wild Fauna and Flora
CBD	-	Convention on Biological Diversity
CPC	-	Communist Party of China
CRISM	-	Centre for Research on Indian Systems of Medicine
CSIR	-	Council of Scientific & Industrial Research
CSPC	-	China's Strategy for Plant Conservation
DARE	-	Department of Agricultural Research and Education
DCA	-	Drugs and Cosmetics Act
DFO	-	Divisional Forest Officer
EPA	-	Environment Protection Act
EPC	-	Export Promotion Council
EXIM	-	Export Import Policy
FAO	-	Food and Agriculture Organization
FDI	-	Foreign Direct Investment
FCA	-	Forest Conservation Act
FRLHT	-	Foundation for Revitalization of Local Health Traditions
FTDRA	-	The Foreign Trade (Development and Regulations) Act,
GACP	-	Good Agriculture and Collection Practice
GAP	-	Good Agricultural Practices
GCP	-	Good Collection Practices
GDP	-	Gross Domestic Product
GEF	-	Global Environment Facility
GFCP	-	Good Field Collection Practices

GKS	-	Global Knowledge Scheme
GMP	-	Good Manufacturing Practices
GoI	-	Government of India
GRAS	-	Generally Recognized as Safe
GSP	-	Good Storage Practices
GTP	-	Global Triangle Partnership Scheme
HGT	-	Home Grown Technology
ICAR	-	The Indian Council of Agricultural Research
ICD	-	International Classification of Diseases
ICFRE	-	The Indian Council of Forestry Research and Education
ICMR	-	The Indian Council of Medical Research
IFA	-	Indian Forest Act
IIFM	-	Indian Institute of Forest Management
ILRT	-	Institute of Livelihood Research and Training
IND	-	Investigational New Drug
ISM & H	-	The National Policy on Indian Systems of Medicine & Homeopathy
IUCN	-	International Union for Conservation of Nature
JFMC	-	Joint Forest Management Committees
MAFW	-	Ministry of Agriculture and Farmers Welfare
MAP	-	Medicinal and Aromatic Plants
MEIS	-	Merchandise Exports from India Scheme
MFPF	-	Minor Forest Produce Federations
MoEF	-	Ministry of Environment and Forest
MOUs	-	Memorandum of Understanding
MPCA	-	Medicinal Plant Conservation Area
MPCDA	-	Medicinal Plants Conservation and Development Area's
MT	-	Metric Ton
NBA	-	National Biodiversity Authority
NBSAP	-	The National Biodiversity Strategy and Action Plan
NFP	-	National Forest Policy
NHFPC	-	National Health and Family Planning Commission
NMITLI	-	New Millennium Indian Technology Leadership Initiative
NMPB	-	National Medicinal Plant Board
NSAID	-	Non-Steroidal Anti-Inflammatory Drug
NTFP	-	Non- Timber Forest Produce
OTC	-	Over the Counter
PESA	-	The *Panchayats* Extension to the Scheduled Areas Act
PHARMEXCIL	-	Pharmaceuticals Export Promotion Council

PIC	-	Prior Informed Consent
R&D	-	Research and Development
RGICS	-	Rajiv Gandhi Institute for Contemporary Studies
SATCM	-	State Administration of Traditional Chinese Medicine
SDA	-	State Drug Administration
SFDA	-	State Food and Drug Administration of China
SHEFEXIL	-	Shellac & Forest Products Export Promotion Council
SIHR	-	Scheme for Integrated Health Research
SOP	-	Standard Operating Procedures
T and CM	-	Traditional and Complementary Medicine (T and CM)
TCM	-	Traditional Chinese Medicine
TIFAC	-	Technology Information Forecast and Assessment Council
TIM	-	Traditional Indian Medicine
TISM	-	Traditional Indian System of Medicine
TK & GRs	-	Traditional Knowledge and Genetic Resources
TKDL	-	Traditional knowledge digital library
TRAFFIC	-	Trade Record Analysis of Flora and Fauna in Commerce
UN	-	United Nations
UNDP	-	United Nations Development Programme
US	-	United States
USD	-	United States Dollar
VCSMPP	-	Voluntary Certification Scheme for Medicinal Plants Produce
WHO	-	World Health Organisation
WLPA	-	Wildlife Protection Act
WPA	-	Wildlife Protection Act
WTO	-	World Trade Organization
WWF	-	World Wildlife Fund

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Executive Summary

Alternative medicines are slowly taking up important space in world health market. The market growth is being stimulated by nature-based products, based on the presumption that these products cause lesser side effects than modern medicines and its comparatively lower costs.

The Global Herbal Medicine Market is expected to register a Compound annual growth rate (CAGR) of 5.88% to reach USD 1, 29,689.3 million by 2023. Today about 80% of the world's population rely primarily on plants and plant extracts for healthcare.[1] The projection made by World Health Organization (WHO) states that the global herbal market would grow to $5 trillion by 2050.[2]

Assessing the need to ensure universal healthcare including for the poor, WHO has taken the lead, indicating the need for collaborations between traditional systems such as the Indian and the Chinese, with contemporary western biomedicine. In India and China, the WHO has taken systematic steps to bring the respective Traditional and Complementary Medicine (T and CM) of each country to the forefront in the world market so that a large section of world population can access healthcare services which have been cost effective healthcare options without any side-effect on health.

Both India and China have very long history of use of plants and their extracts for treatment human and veterinary ailments. Ayurveda in India boasts of known herbal medicines. Its pioneer was Shushrut and Charak. The formulations are very relevant and in common use even today. In China also the old anecdotal accounts of use of herbal products for treatment of terminally ill patients through Traditional Chinese Medicine (TCM) is getting popular faster than any other country in the world. Both the countries are also rich in terms of bio-diversity and contribute about 70% of total supply of raw material for traditional medicines used worldwide.

India and China are both making efforts to develop their respective traditional system of medicines to provide healthcare services to their citizens but also overseas markets so that these system not only find place in providing cost-effective healthcare option to the world population but also contribute towards the livelihood promotion of the communities – forest produce gatherers and cultivators.

[1] https://www.medgadget.com/2019/08/herbal-medicine-market-global-industry-outlook-2019-size-estimation-share-business-growth-competitive-landscape-to-reach-usd-1-29-billion-till-2023-arkopharma-bayer-ag-beovita-hishimo-pharma.html
[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3887317/

As per data of China Chamber of Commerce for Import & Export of Medicine & Health Products, China exported 358,000 tons of traditional Chinese medicine, up 0.7 percent year-on-year. Export value was $3.6 billion, up 2.1 percent in 2017. TCM market is rapidly developing since later 1990s in China. It has successfully established its hold over the TCM market, and is progressively being recognized for its efforts put in so far in the sector. In the modern world market, TCM encompasses a wide range of items: traditional Chinese medicinal materials, decoction pieces, Chinese patented medicines, herbal extracts, and health care products which are used locally as well as exported outside China.

India stands as the 2nd largest exporter of herbal medicines only after China. Both the countries are producing over 70 percent of the herbal medicines demand across the globe. India exported raw herbs worth USD330.18 million during 2017–18 with a growth rate of 14.22% over the previous year (MoC&I, 2019). The export of value-added extracts of medicinal herbs/herbal products during 2017–18 stood at USD 456.12 million recording a growth rate of 12.23% over the year before (MoC&I, 2019). When these figures are compared with China's export of TCM in 2017 at $ 3.6 billion, India is much more behind China in terms of production and export of traditional medicines.

The present study attempts to understand and analyse the major initiatives in terms of i) legal and policy provisions made by both the countries for development of medicinal plant sector and promotion of herbal healthcare i) initiatives made for in-situ conservation and ex-situ cultivation of medicinal plants ii) development of processing facilities and manufacturing of traditional medicines and initiatives for promotion of trade and export of traditional medicines.

Legal and policy initiative

Both India and China have taken up various initiatives to develop legal and policy frameworks for development of MAP sector and promoting herbal based healthcare domestically and globally.

In India, the policies / legislations made whether at central or the state level have orientation to conservation, propagation, cultivation and institutionalization etc. The Central government has also come up with a new draft National Forest Policy in 2018 which plans to enhance forest-industry interface by supporting the strengthening of partnership that forest based industries have established with farmers. The Standard Operating Procedures, the quality standards and the policy framework is still in its evolving phase. Multiple Ministries and authorities of Government- both Central and State ranging from Ministry of Environment and Forest, Ministry of AYUSH, Ministry of Agriculture and Farmer's Welfare, Ministry of Commerce and Industry, Ministry of Tribal Affairs, Ministry of Panchayat and Rural Development, etc. regulate the MAPs sector in their respective jurisdiction. Lack of synergy in legal and policy framework of different legal authorities hinder the growth of MAP and traditional Indian system of medicines (TISM)

which largely depend on medicinal plants as raw materials. Also, the focus of legal and policy provisions are more on conservation of MAPs rather than cultivation, processing and export promotion. The field compliance of various legal and policy provisions are not adequate and needs strict regulation.

According to industry experts, insufficient regulatory guidelines for different aspects of production are an important reason for quality issues with herbals medicinal products. National Medicinal Plant Board (NMPB) developed India specific Good agricultural practices and good field collection practices in line GACP developed by World Health Organization (WHO). But main problem is poor implementation of guidelines in field and forest both. There is little awareness about these guidelines among manufacturer and traders in herbal medicines. Even companies who are following it find it difficult to implement it completely.

Western system of medicine dominated the healthcare system in India due to its promotion from the colonial era. After independence, the same trend continued. In 1970s, Government started focusing on promotion of traditional Indian system of medicines. Overtime, India has taken several steps to protect and promote the Indian System of Medicines. However the expansion of ISM domestically and in the international market is much short of expectation.

In contrast, China has made provisions for promotion of TCM in its Constitution. It talks about giving equal importance to TCM in comparison to western medicines. China has made various policy provision to integrate TCM into the education and healthcare sector. TCM was given priority in rural healthcare system through institutionalizing TCM under the grass-root healthcare. It made policy provision to treat TCM at par with western medicines and combined both the healthcare system at education, management and practice levels. The comparative advantage of policy support in China has benefitted the TCM industry to a large extent. Since 1978, the Government provided support in areas of human resources, finance, and supplies, rigorously promoting the development of TCM.

The Drug Administration Law of the People's Republic of China, 1984 is the main law which regulate manufacturing, distribution and preparation of all medicines. There Regulation on Protection of Wild Medicinal Resources, 1987 ensures sustainable collection of wild medicinal resources and encouraging cultivation of medicinal plants. National regulation of TCM accelerated in 1992 with the Regulations 122 on Protection of TCM which came into effect in 1993. This regulation aims to raise the quality of all varieties of traditional Chinese medicines, promote the development of TCM medicine and protect the legal rights and interests of enterprises engaging in the production of TCM. Regulation on Traditional Chinese Medicines, 2003 regulates establishment of medical institutions, research and practices related to TCM, and liabilities and penalties in case of failure to subscribe to prescribed rules for the same, taking care of the need for such regulations before it got out of hands.

China has strived to put in place all standards and regulations, early, so it does not have to work for taking care of the negative repercussions later as an outcome of wrong policies and programmes. TCM was prioritized again in 2012, the government reinstated the necessity to pay equal attention to the development of TCM and Western medicine. It also supported the development of TCM and ethnic minority medicine.

The National Medium-and Long-Term Programme for Science and Technology Development (2006-2020) sets out inheritance, innovation, modernization, and internationalization of TCM as the four basic tasks for Ministries involved in policy- making. It has further established therapy, evaluation technologies and standards of researching TCM with research development and manufacturing technologies of modern TCM as goal. It calls for a combination of classic heritage of TCM with innovations of life-science to develop TCM, therefore inculcating the best of the old and new sciences. The focus is on translating TCM into clinical effectiveness.

The Development Plan for Traditional Chinese Medicine-Related Health Services (2015-2020) focuses on vigorous development of TCM related health boosting and healthcare services, the acceleration of the development of TCM-related medical services including promoting insurance under TCM sector. The 12th Five-Year Plan (2011-2015) explicitly states 'supporting the development of TCM and emphasizes also on paying equal attention to TCM at par with modern medicine, developing TCM medical treatment and preventive healthcare services, promoting inheritance and innovation of TCM, and developing TM education and medical institutions among others. Law on Traditional Chinese Medicine, 2017-20: This law is intended to provide a sound policy environment and legal basis for TCM development.

The TCM law describes establishment and improvement of regulatory system, governing TCM; and IPR protection and full supply chain quality control of medical materials. The Strategic Plan on the Development of Traditional Chinese Medicine (2016-2030) makes TCM development a national strategy with systemic plans for TCM development in future. These decisions and plans have mapped out a grand blueprint that focuses on the full revitalization of TCM, accelerated reform of the medical and healthcare system, the building of a medical and healthcare system with Chinese characteristics, and the advancement of the healthy China plan, thus bringing in a new era of TCM in the country.[3] The Healthy China 2030 Plan is an important national medium- and long-term strategic plan in the health sector. It is an important medium for implementing the country's commitment to the UN 2030 Agenda for Sustainable Development. It is important to integrate healthcare delivery system moving from an extensive development mode based on scale to an intensive one focusing on quality and efficiency.

[3] http://www.chinadaily.com.cn/china/2016-12/06/content_27584111_5.htm

Innovation and Development Planning Outline for Traditional Chinese Medicine (2006-2020) called for a diversified and multichannel investment system in support of progress of the TCM, which can be formed, among others, by means of international cooperation assets. The 13th Five-Year Plan (2016-2020) sets target to improve the medicine quality of a large number of bio-pharmaceutical enterprises to get in line with international standard and at least 100 pharmaceutical preparation enterprises obtain the authentication of American, European, Japanese countries and also the WHO. China plans to provide every Chinese citizen access to basic TCM services by 2020, and by 2030 TCM services will cover all areas of medical care.

China also collaborated with WHO which is supporting China Food and Drug Administration (CFDA), National Health and Family Planning Commission (NHFPC) and other ministries as required to strengthen the national regulatory system to achieve an advanced international level of regulatory capacity and leadership in the regulation of health services, food safety, and health products and technologies, including TCM products, to better protect population health.

In India, although the sector has a number of legislations and policies, but the practice is alarmingly disorganized; thereby raising serious concerns regarding the quality of practice, provision of medicines and the standard of education imparted in the institutions. There have been various cases reported of fake medicines being sold and fake claims made, which have an adverse image on the status of the medicine system.

Initiative for promotion of Medicinal and Aromatic Plants

India and China both are rich is bio-diversity and contribute highest number of medicinal plants (about 70%) used for making herbal medicines under TISM and TCM. The demand for traditional medicines are growing domestically and globally. To conserve the valuable herbal wealth and augment production of medicinal plants both countries have undertaken several measures.

The source of 80% of raw material for TISM and TCM is forest. Unsustainable and over extraction of medicinal plants from forests have led to their degradation and decline in natural forests. Seeing the growing demand for traditional medicines in domestic and global markets, various initiatives have been taken up for in-situ conservation and ex-situ cultivation of medicinal plants which are high in demand under herbal industries.

National Medicinal Plants Board (NMPB) under the AYUSH Ministry in Government of India has the mandate to promote research and development of herbal resources in the country. The focus is on conservation and sustainable collection and use of natural bio-diversity as well as domestication of wild flora used in herbal industry. These steps in the past few decades have been responsible for gradual reduction of dependence of herbal industries on use of natural bio-diversity. Earlier the herbal industry used to meet almost 90-95% of its requirements from natural

sources (wild collection) which has now come down to less than 80% or so. In order to conserve and ensure sustainable collection of wild medicinal plants the management decentralization through Joint Forest Management Committees (JFMCs) is also being supported by NMPB and MFP Federations of medicinal plant rich states like Madhya Pradesh and Chhattisgarh. For in-situ conservation, medicinal plants conservation and development areas (MPCDAs) have been promoted across the country. In addition to this, various other conservation and development measures have been taken up by forest department under CAMPA fund and through support form multi-lateral and bi-lateral agencies.

In India, contract farming has been promoted between industries and farmers. In this model, more than Government, the initiatives have been industry led which can be systematically taken up at large scale with intervention of NMPB. Total consumption of herbal raw drug in the country for the year 2014-15 has been estimated at 5, 12,000 MT. It is also reported that about 20% of the total production is sourced through cultivation of medicinal plants (NMPB, 2019) and the rest is from wild collection. The total demand of herbal raw drugs is expected to grow to 6,50,000 MT by the year 2020 in India.

China is also very rich in medicinal plant biodiversity with more than 6,500 Chinese herbs. There are 162 botanical gardens in China, harboring 20,000 species in China.[4] These provide an important reserve of plant resources for sustainable economic and social development in China. Domestic demand for industry products has increased from $25.8 billion in 2014 to an estimated $43.6 billion in 2019. Chinese introduced an integrated approach of strengthening pre-production, production and post production practices which resulted in to all-round growth in creating a robust production and processing system in place. At production stage, promotion by domestication and cultivation of herbal medicines through natural fostering model involving small and marginal farmers has been a very successful and a model for emulation. Promotion of Good Agriculture Practices (GAPs) through involvement of multiple stakeholders including industries has been tried. Strict compliance with GAPs and investment on research with linkage of production with industry has been a successful model. At post production stage, this involves aggressive marketing aiming at export of TCM through certification, branding, using overseas Chinese Diaspora and the Belt and Road Initiative (BRIs).

Promotion of TISM and TCM

To promote TISM, Government of India has established dedicated Central Council one for each AYUSH sector to promote research. There are seven National Institutes (two for Ayurveda and one each for other systems), two North-eastern institutes to cater to needs of a specific area, two Pharmacopoeia Laboratories, one Pharmacopoeia Commission for Indian Medicine, a NMPB

[4] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6112327/

and a public sector undertaking for manufacture of standardized Ayurvedic and Unani medicines. Investors and corporate houses are also increasingly investing in infrastructure for development of AYUSH sector. India allowed 100% foreign direct investment (FDI) under AYUSH sector.

The education and research in Ayurveda is now receiving more attention by way of institutional strengthening and investment in research and development. India has made significant progress and developed expertise and facilities for organic synthesis, isolation and structure elucidation, biological screening, toxicological testing and pharmacokinetics. India has also mastered the agro-technology for cultivation of medicinal plants.[5] Good Field Collection Practices (GFCP) and Good Agriculture Practices (GAPs) to ensure quality of MAPS however, to make it popular a more systematic approach is required for increasing the area of application and extension. The Government has initiated re-structuring of medical education giving same emphasis on development of professionals with specializations in TISM as it has so far been for western system of education and research in medical sciences. The Government is investing in creating AYUSH medical colleges and dispensaries (Ayurvedic, Homeopathy and others) with Under-graduates, PG, and Doctoral courses at par with traditional medical colleges.

Ministry of AYUSH and WHO are also cooperating on promoting the quality, safety and effectiveness of service provision in traditional and complementary medicine (2016-2020). The area of collaboration a) development of Benchmarks for training in Yoga, b) development of benchmark for practice in Ayurveda, Unani and Panchakarma, c) development of Basic (essential) terms for T&CM, d) Project on the establishment of a WHO database for global T&CM practitioners and e) Support the establishment of a network of international regulatory cooperation for T&CM practice. The Ministry (AYUSH) is also in an agreement with WHO to develop documents for global positioning of Ayurveda. All these steps are expected to bring positive results in the sector.

Government has introduced good and rigid policies of quality management for plant based drug manufacturing units like ISO 9000 certification, Good Laboratory Practices (GLP), Good Manufacturing Practices (GMP), Total Quality Management (TQM) and validated instruments and services by the industries

For promoting processing and manufacturing of AYUSH medicines, industrial development has been taken up. Number of Licensed Drug Manufacturing Units (i.e. Licensed Pharmacies) under AYUSH system are 8954 in 2018 due to drive undertaken to close non GMP compliant units in some states. Of these, 7718 were registered under Ayurveda system and remaining viz. 1236 belong to other systems. However, most of the licensed drug manufacturing units are small and

[5] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1297513/

medium size and only about 50 companies have revenue of INR 100 crores or more accounting for more than 85 per cent of revenue generated by the sector. Industry estimates reveal that these 50 companies reported revenue of INR 22500 (approximately) for FY 2017-18. The government working on the concept of developing industrial cluster to make available common R & D facility to small industries and augment manufacturing of AYUSH medicines. 10 AYUSH Industry Clusters were sanctioned during the 11th Plan Period (2007-12). Out of these, 3 Clusters, one each at Kerala, Punjab and Rajasthan have been completed. These clusters needs further support and investment to become hub for manufacturing and export of quality AYUSH medicines.

China has been keen in developing their indigenous medicine system under the advance healthcare program of the country. The country has been evolving its regulatory mechanism and has stepped up investments in innovations, research and development. They have fast-paced on investment and taken advantage of knowledge from other markets to advance the growth of TCM, both domestic and worldwide. Scientific approaches were utilized and inculcated with prominence given to research, which is a major component to establish credibility of any science.

To expand the market of TCM, the United States Food Drug Administration (FDA) has continuously deregulated the restrictions on TCM drug sales. The government began to classify prescription and OTC drugs in 1999. To date, 60,000 TCM and ethnic minority medical drugs have been approved, and 2088 pharmaceutical enterprises that have been approved by the Good Manufacturing Practice (GMP) of Medical Products are manufacturing Chinese patent medicines. The dosage forms of TCM medicines have increased from a traditionally limited number of forms such as pills, powders, ointments and pellets into more than 40, including dropping pills, tablets, pods and capsules, indicating marked improvement in the technological level of Chinese medicinal drug production, and initial establishment of a modern Chinese medicine industry based on the production of medicinal materials and industrial production and tied together by commerce.

China has strengthened the quality control in microorganisms, pesticide residues, heavy metals and arsenic salts, there is still a large gap between Chinese and international standards. A systematic and transparent preparation of large data information platform of TCM preparation is key to comprehensive mining of the vast amounts of information on TCM and its preparation field, professional processing of data—drawing of scientific knowledge map, tracing patent data, digging and analyzing of clinical trial data and marketed drug data, drawing the navigational chart of TCM and its preparation in the era of big data. The establishment of the platform will effectively integrate all aspects of TCM research and development, serve the needs of multiple demand groups including enterprises, government regulators, academic research institutions,

and so on, and greatly shorten the development time of new varieties of Chinese medicine and its preparation.

As part of a new health drive, Chinese authorities are stepping up research into TCM and are encouraging scientists to look for its next magic cure. It is encouraging originality in TCM and explores the market value of existing research. Chinese researchers publish 3,000 scientific papers every year, which deepen research into the different herbs, substances, and working mechanics of TCM. Researchers are trying to enhance TCM precision and steps are being taken to converge it with western medicine. Evidence-based medicine is a widely-used approach in medical practice that is intended to optimize decision-making in treating individual patients by emphasizing the use of evidence from well-designed and well conducted research. Under this approach, clinical evidence serves as the main basis for evaluating effectiveness and safety of treatment. The country is taking up a systematic approach towards these ends.

The DNA barcode 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. 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 standardized gene identification era.[6]

China has also opened up its medical industry to foreign investment. Multinational pharmaceutical companies have large-scale deployment of R&D centres in China. In June 2008, the Academy of Military Medical Sciences and Phytopharm, a British company in plant medicine, signed a cooperation agreement on "NJS" (a new type of Chinese medicine) with "patent licensing", marking the first time that a Chinese patent for innovation in TCM went abroad. This is also the first time that China has authorized the use of IP of Chinese medicine by international companies.[7]

Trade and Export Promotion

As per a published report of NMPB, 2017, out of 6500 medicinal plant species traditionally used by Indian communities, only 1622 botanicals corresponding to 1178 plant species are found to be in all India trade. Of these 42% are herbs, 27% trees and 31% are shrubs & climbers. Only 242 species witness high volume trade (>100 MT) annually (Goraya & Ved, (2017). India exported USD

[6] https://www.researchgate.net/publication/323082723_Internationalization_of_traditional_Chinese_medicine_Current_international_market_internationalization_challenges_and_prospective_suggestions

[7] https://link.springer.com/chapter/10.1007/978-981-13-8102-7_10

330.18 million worth of herbs during 2017-18 with a growth rate of 14.22% over the previous year.[8] Also, the export of value-added extracts of medicinal herbs / herbal products during 2017-18 stood at USD 456.12 million recording a growth rate of 12.23% over the previous year.[9] India is the second largest exporter of Ayurveda and alternative medicine in the World, with its biggest markets being Western Europe, Russia, USA, Kazakhstan, UAE, Nepal, Ukraine, Japan, Philippines and Kenya.

The market system of MAPs trade is still not well developed and lacking proper facilities and regulations. A long presence of middlemen in supply chain without having adequate storage and transport facilities to handle medicinal plants caused poor quality of raw materials.

Promotion of Ayurveda has been an important area for Ministry of AYUSH during the last few years. Ministry of AYUSH has signed Country to Country MoUs with 18 countries for cooperation in field of Traditional Medicine and Homeopathy, 19 MoUs for undertaking Collaborative Research/ Academic collaboration and 13 MoUs for setting up AYUSH Academic Chairs in foreign Universities. 31 AYUSH Information Cell have been set up in 28 countries to disseminate authentic information about AYUSH systems.

The Traditional Medicine Delhi Declaration" was adopted as the resolution of the WHO Regional Committee for South-East Asia as proposed by AYUSH, and is now adopted by the countries of whole South-East Asia region, which is an achievement in itself. However, the challenges identified for internationalization of AYUSH includes unclear therapeutic material basis and mechanism, difficulty of quality control, low preparation level, registration/policy barriers, and shortage of intellectual property. Inadequacy of advanced equipment and technology for processing AYUSH products is a disadvantage especially to manufacture quality products under strict standards. Packaging, design and promotion as well as marketing strategy of AYUSH is in most cases not up to the standards; there are also concerns over the content of heavy metals and pesticide residues exceeding the national standards.

To cater to the increasing demand domestically and globally China has adopted multiple strategies for promotion of trade and export of TCM. Its developed integrated market systems in natural medicinal plants production regions to give a platform to multiple players – collectors/farmers, traders, processors and exporters to buy and sell raw, crud drugs and finished products. Primary processing facility is linked with market which can be used by the primary producers/collectors for cleaning, grading, packaging their produce. The traders and processors are provided office space and state of the art storage facility to carry out trading and storage activities.

[8] http://pib.nic.in/newsite/PrintRelease.aspx?relid=187278

[9] https://pib.gov.in/Pressreleaseshare.aspx?PRID=1558955

In addition to this, e-commerce is emerging channel for trade of TCM products. For example, the 111 Inc, China's largest online pharmacy and healthcare service provider started trading its American Depositary Shares on the Nasdaq stock market. The E-commerce giant Alibaba Health Information Technology Ltd. enters the rigidly-regulated pharmaceuticals market through purchase of a drugstore chain, Wuqiannian Medicine Co. Ltd., for US$ 2.5 million which sells OTC medicines and liquid tonic made of TCM.

China introduced the concept of "internationalization of TCM" in 1996 to remove the barriers in exports which comprised of two major aspects: (1) it is important to expand the volume of import and export in order to push forward the "going abroad" of TCM, to promote the sustainable development of its international trade and to foster the TCM market share across the countries; (2) the legal status of TCM in overseas countries has to be appropriately established to ensure reasonable market entry and to enable sustainable development of TCM under the protection of the local laws and regulations.[10]

China has focused on deepening reforms and opening-up in the international arena in its promotion of trade and exports related to health care. TCM has become an important area of health and trade cooperation between China and the Association of South East Asian Nations (ASEAN), European Union (EU), Africa, and Central and Eastern Europe and a key component for people-to-people exchange between China and the rest of the world. Hong Kong, Japan, USA and EU are major export destinations of TCMs. While EU showed major growth (49.15%) in TCM herbs/plant extracts; Hong Kong, Japan and USA were export markets for Chinese Patent Medicines (54%). Trade in Chinese medicinal products has consistently maintained a rapid growth.

The responsibility of TCM Exports brings together the SATCM, Ministry of Foreign Trade and Economic Cooperation, and the State Administration of Import and Export Commodity Inspection to issue yearly statements of exportable TCM and TCM producers collaboratively. The collaborative efforts and support of different kinds of organizations ensures that the regulation is more likely to be followed than other regulations originating from a single department, council, or ministry.

Under the Belt and Road Initiative (BRI) China included health dimensions too along with development connectivity with different countries. The initiative calls for creating 30 centers by 2020 to provide TCM medical services and education, and to spread its influence. The ties have been successful, the TCM exports BRI countries has increased by 54% between 2016 and 2017, to a total of US$295 million. The country has signed specialized TCM cooperation agreements

[10] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5807832/

with over 40 countries, regions and organizations and opened hundreds of TCM institutes in more than 30 countries and regions. Especially for small companies, engaging in international trade has been made easier through the initiative.[11]

Globally TCM has spread to 183 countries. According to the WHO, 103 member-states have given approval to practice of acupuncture and moxibustion; 29 have enacted special statutes on traditional medicine, and 18 have included acupuncture and moxibustion in their medical insurance provisions. TCMs have been registered in countries such as Russia, Cuba, Vietnam, Singapore and United Arab Emirates. Growth of TCM abroad has been materialized through better quality control, R&D, promotion of TCM education abroad and use of international trade and health platforms for TCM promotions.[12] China exported TCM of about 3.6 billion USD in 2017 and export is increasing @ of over 10% year on year basis.

In China's public health system TCM is an integral part and an important part of the ongoing Government policy development, both in terms of medicinal products and hospital/physician practice which is evident in China's health reimbursement system, including doctor's visits.

Establishing an internationally recognized standard is also key for the industrialization of TCM. An international standard for TCM will legitimatize the use of the medicine all over the world. China is improving its own national standards. National survey of TCM herbs are carried out across the country soon. TCM researchers have also stepped up the studying of ancient recipes.

Recommendations

China has been ahead in development of MAP sector especially promoting ex-situ cultivation and popularizing TCM globally. As a result, the trade and export of TCM in manifold than TISM. India has taken several initiatives to develop MAP sector and promote TISM domestically and globally. There are several important steps which India needs to further take to promote TISM.

India needs to adopt an integrated approach which systematically focus on i) production and management of MAPs including development of integrated value chain and market system so as to ensure supply of quality raw material for industries, ii) Research including technological intervention to develop and manufacture AYUSH medicines of universal acceptance and iii) integration of TISM with domestic and global mainstream healthcare system. Some of the important steps that needs to be taken up to achieve the goal are as follows-

- India has also actively taken pro-active stance by formulating policies and programmes to popularize the TISM from village to cities. However, the development faces difficulty in

[11] http://iththailand.net/upload/BRI_and_health_and_beyond_-_conf_doc.pdf
[12] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4940763/

the field compliance of various legal provisions that needs to be firmly enforced so as to ensure quality of TISM products.

- The policy regulations are focussed on conservation and management of MAPs but it is not adequately addressing the issues of production of raw material as per the need of industries. It is highly recommended that contract farming practiced in India should take appropriate learning from natural fostering model of China with appropriate modification.
- The education system is very slowly recognizing the TISM at par with western medical education. Policy shift and change of mind-set of proponents of western medicine system is urgently required for universalization of TISM. The existing barrier and undue preferences in-favour of western medicine should soon be balanced.
- Certification of process and products have been in place. However, due to prohibitive cost the growers, gatherers and industry are reluctant to take certification route. People centric participatory group certification needs to be promoted to make it cost effective and which could be acceptable in the international markets.
- GFCP, GAP and GMP are well known in India but its field compliance is still lacking in majority of the cases. These have to be facilitated by NMPB.
- Clinical trials have been recommended for making the entry of drugs into international markets. However, very little has been done in this respect. This aspect should be examined by AYUSH because this aspect is reported to be very expensive small and medium sized herbal drug manufacturers who are large in number in India.
- The Cluster of Herbal Drug Manufacturers was launched by AYUSH in 8 states out of which only three have made some progress. Considering their necessity it is recommended that the concept of cluster or SEZ type facility need to be created.
- The TISM is not getting their due recognition overseas markets because they are sold as supplements rather than medicines. The standards of TISM needs to be upgraded and matched with international standards so that they can find place in international healthcare system.
- India needs to take initiatives for supporting the neighboring countries which also practice various form of AYUSH traditionally, in framing adequate regulatory framework to use AYUSH. In addition to this, AYUSH research and education also needs to be promoted through partnership with similar institutions of other countries.
- The market of MAPs is unorganized in India and It is therefore recommended that India should also develop such marketing complexes in bulk production areas. This will help the producer, trader, industry and exporters. The country has recognized a number of Mandis but they should also be developed as markets for import and export of MAPs in the lines of TCM markets developed by China.

Chapter 1

Introduction

1.1. Background

The new philosophy of health care throughout the world is moving from illness to wellness, from treatment to prevention as well as early diagnostics and from generalized approach to personalized medicine. Alternative medicines are slowly taking up important space in world health market. The market growth is being stimulated by nature-based products, based on the presumption that these products cause lesser side effects than modern medicines and its comparatively lower costs.

The Global Herbal Medicine Market is expected to register a Compound annual growth rate (CAGR) of 5.88% to reach USD 1, 29,689.3 million by 2023. Today about 80% of the world's population rely primarily on plants and plant extracts for healthcare.[13] The projection made by World Health Organization (WHO) states that the global herbal market would grow to $5 trillion by 2050 (Ekor Martins, 2014).[14]

Alternative medicine disciplines such as Traditional Indian System of Medicines (TISM) and Traditional Chinese Medicine (TCM) are now gaining more popularity in the western world being recognised as natural products having no side-effects. Both TISM and TCM mode of treatments are centered around the patient rather than on the disease with promotion of health and treatment of diseases in a holistic fashion as the focus is on both (Bhushan Patwardhan, 2005). Many of their herbal sources used as medicines under TISM and TCM are common and both the systems follow similar philosophies for classification of individuals, materials and diseases.

Looking at the demand for such alternative medicines, the search of novel models in integrative medicine has begun with the WHO taking the lead, indicating the need for collaborations between traditional systems such as TISM and TCM with contemporary western biomedicine. In India and China, the WHO has taken systematic steps to bring the respective Traditional and Complementary Medicine (T and CM) of each country to the forefront in the world market so that a large section of world population can access healthcare services which have been cost effective healthcare options without any side-effect on health.

[13] https://www.medgadget.com/2019/08/herbal-medicine-market-global-industry-outlook-2019-size-estimation-share-business-growth-competitive-landscape-to-reach-usd-1-29-billion-till-2023-arkopharma-bayer-ag-beovita-hishimo-pharma.html
[14] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3887317/

1.2 Herbal Sector in India and China

Traditional Indian System of Medicines (TISM):

Ayurvedic medicine is one of the world's oldest holistic ("whole-body") healing systems. It was developed more than 5,000 years ago in India. It's based on the belief that health and wellness depend on a delicate balance between the mind, body, and spirit. Its main goal is to promote good health, not fight disease. But treatments may be geared toward specific health problems.

There has been an upsurge in use of herbal medicines that has led to a sudden increase in herbal manufacturing units. Besides this, there is also a growing demand for natural products including items of medicinal value/pharmaceuticals, food supplements and cosmetics in domestic markets also. In India, there are well-recognized as well as medium scale manufactures of herbal drugs. In addition, thousands of Vaidyas also have their own miniature manufacturing facilities.

There is a complex of large number of manufacturing units using herbal material for various purposes. Whereas the largest number of such manufacturing units are registered as 'pharmaceuticals', there are others that are engaged in making plant based cosmetics and food supplements. Even within the pharmaceutical units, there are manufacturers of Ayurveda, Siddha, Unani and Homeopathic formulations with a few even making western medicines. Another group of manufacturing units is engaged in making extracts and distilling oils for use by other industries and for exports. Raw materials for all these diverse industries are largely derived from wild sources.[15]

AYUSH Sector in India includes:

- Ayurveda
- Yoga
- Naturopathy
- Unani
- Siddha
- Homeopathy
- SOWA-RIGPA

According to Ayurvedic theory, everyone is made of a combination of five elements: air, water, fire, earth, and space. These elements combine in the body to form three energies or life forces, called doshas: vata, kapha, and pitta.

Under AYUSH sector, the treatment of disease can broadly be classified as:

[15] https://nistads.res.in/all-html/Indian%20Herbal%20Sector.html

- Shodhana therapy (Purification Treatment)
- Shamana therapy (Palliative Treatment)
- Pathya Vyavastha (Prescription of diet and activity)
- Nidan Parivarjan (Avoidance of disease causing and aggravating factors)
- Satvavajaya (Psychotherapy)
- Rasayana therapy (use of immuno-modulators and rejuvenation medicines)

Traditional Chinese Medicines (TCMs):

In TCM, most of the disease diagnosis and principles of medical application are based on a particular Chinese philosophy that is aligned with Confucianism and Taoism. The theory of TCM refers to Yin and Yang, the five elements, zangfu, channels-collaterals, qi, blood, body fluids, methods of diagnosis, differentiation of symptom-complexes, etc. Yin and Yang are opposite and complementary sides of the nature in the universe, and, according to Chinese philosophy, everything could be described by Yin and Yang. In TCM, Yin refers to the material aspects of the organism, and Yang refers to functions. It is the interpretation that the disease is caused by the imbalance of Yin and Yang in the human body. The rationale of Chinese medicine is to bring Yin and Yang back into balance, which results in overall health and cure versus the disease.

In addition, in ancient Chinese theory, everything in the universe consists of five elements (metal, wood, water, fire and earth). All organs and tissues were assigned to different elements, which are differentiated by their properties. This is the special Chinese system theory that forms a basis for TCM. Chinese medicine is very different from Western medicine, and the methodology of disease treatment cannot be explained in the same way as in modern medicine, as it is a type of treatment that is based on experience and a special philosophy.

Traditional Chinese Medicine is divided into the following— 1) Chinese patent medicines, 2) decoction pieces and 3) Chinese herbs. Chinese patent medicines are defined as any Chinese herbal medicines formulated into a finished dose form, while decoction pieces are mainly Chinese herbs, which are processed further. Historically, Chinese patent medicines account for about 50 per cent of all traditional Chinese medicines sold; but lately decoction pieces account for an increased share following their faster growth.

Apart from the TCM as practiced in China, traditional medicine systems practiced by the ethnic groups also form an important feature of Chinese medicine systems. By the end of 2003, there were 157 ethnic hospitals in China. Of these, 55 were hospitals of Tibetan medicine, 41 hospitals of Mongolian medicine, 35 hospitals of Uyghur medicine, one hospital of Dai medicine and 25 hospitals of other types of ethnic medicine.

TCM treatments can be categorized as follows:

- Drug therapy includes patent medicines, decoction pieces and herbs.
- Acupuncture is the practice of inserting needles into the skin, subcutaneous tissue, and muscles at the particular acupuncture points.
- Moxibustion is a therapy that involves burning moxa (mugwort root) made from dried Artemisia vulgaris (spongy herb) to facilitate healing.
- Tuina is a Chinese massage therapy.

1.3. Brief History of Herbal based Health Care in India and China

History of TISM:

The origins of Ayurveda have been traced to around 6,000 BCE when they originated as an oral tradition. Some of the concepts of Ayurveda have existed since the times of Indus Valley Civilization. The first recorded forms of Ayurveda as medical texts evolved from the Vedas. Ayurveda is a discipline of the upaveda or "auxiliary knowledge" in Vedic tradition. The origins of Ayurveda are also found in Atharvaveda, which contains 114 hymns and incantations described as magical cures for disease. There are various legendary accounts of the origin of Ayurveda, e.g. that it was received by Dhanvantari (or Divodasa) from Brahma. Tradition also holds that the writings of Ayurveda were influenced by a lost text by the sage Agnivesa.

Ayurveda is one of the few systems of medicine developed in ancient times that is still widely practiced in modern times.

There are three principal early texts on Ayurveda, the Charaka Samhita, the Sushruta Samhita and the Bhela Samhita. The Sushruta Samhita is based on an original from the 6th century BCE, and was updated by the Buddhist scholar Nagarjuna in the 2nd century CE. The Charaka Samhita, written by Charaka, and the Bhela Samhita, attributed to Atreya Punarvasu, is also dated to the 6th century BCE. The Charaka Samhita was also updated by Dridhabala during the early centuries of the Common Era.

The Bower Manuscript (dated to the Gupta era, between the 4th and the 6th century CE) includes of excerpts from the Bheda Samhita and its description of concepts in Central Asian Buddhism. In 1987, A. F. R. Hoernle identified the scribe of the medical portions of the manuscript to be a native of India using a northern variant of the Gupta script. The Chinese pilgrim Fa Hsien (c. 337–422 AD) wrote about the healthcare system of the Gupta empire (320–550) and described the institutional approach of Indian medicine. This is also visible in the works of Charaka, who describes hospitals and how they should be equipped.

Other early texts are the Agnivesha Samhita, Kasyapa Samhita and Harita Samhita. The original edition of the Agnivesha Samhita, by Agnivesa, is dated to 1500 BCE, and it was later modified by Charaka. Kasyapa Samhita includes the treatise of Jivaka Kumar Bhaccha and is dated to the 6th

century BCE. Some later texts are *Astanga nighantu* (8th Century) by Vagbhata, *Paryaya ratnamala* (9th century) by Madhava, *Siddhasara nighantu* (9th century) by Ravi Gupta, *Dravyavali* (10th Century), and *Dravyaguna sangraha* (11th century) by Chakrapani Datta, among others.

The main classical Ayurveda texts begin with accounts of the transmission of medical knowledge from the Gods to sages, and then to human physicians. In *Sushruta Samhita* (*Sushruta's Compendium*), Sushruta wrote that Dhanvantari, Hindu god of Ayurveda, incarnated himself as a king of Varanasi and taught medicine to a group of physicians, including Sushruta. Ayurveda therapies have varied and evolved over more than two millennia. Therapies are typically based on complex herbal compounds, minerals and metal substances (perhaps under the influence of early Indian alchemy or *rasa shastra*). Ancient Ayurveda texts also taught surgical techniques, including rhinoplasty, kidney stone extractions, sutures, and the extraction of foreign objects.

The earliest classical Sanskrit works on Ayurveda describe medicine as being divided into eight components (Skt. *aṅga*). This characterization of the physicians' art, "the medicine that has eight components" (Skt. *cikitsāyām aṣṭāṅgāyāṃ* चिकित्सायामष्टाङ्गायाम्), is first found in the Sanskrit epic the *Mahabharata*, c. 4th century BCE. The components are:

- *Kāyachikitsā*: general medicine, medicine of the body
- *Kaumāra-bhṛtya* (Pediatrics): Discussions about prenatal and postnatal care of baby and mother, methods of conception; choosing the child's gender, intelligence, and constitution; and childhood diseases and midwifery.
- *Śalyatantra*: surgical techniques and the extraction of foreign objects
- *Śhālākyatantra:* treatment of ailments affecting ears, eyes, nose, mouth, etc. ("ENT")
- *Bhūtavidyā*: pacification of possessing spirits, and the people whose minds are affected by such possession
- *Agadatantra*/*Vishagara-vairodh Tantra* (Toxicology): It includes subjects about epidemics, toxins in animals, vegetables and minerals. It as well contains keys for recognizing those anomalies and their antidotes.
- *Rasāyantantra*: rejuvenation and tonics for increasing lifespan, intellect and strength
- *Vājīkaraṇatantra*: aphrodisiacs and treatments for increasing the volume and viability of semen and sexual pleasure. It also deals with infertility problems (for those hoping to conceive) and spiritual development (transmutation of sexual energy into spiritual energy).[16]

[16] https://en.wikipedia.org/wiki/Ayurveda

History of TCM:

Traces of therapeutic activities in China date from the Shang dynasty (14th–11th centuries BCE). According to a 2006 overview, the "Documentation of Chinese materia medica (CMM) dates back to around 1,100 BCE when only dozens of drugs were first described. By the end of the 16th century, the number of drugs documented had reached close to 1,900. And by the end of the last century, published records of CMM had reached 12,800 drugs."

Stone and bone needles found in ancient tombs led Joseph Needham to speculate that acupuncture might have been carried out in the Shang dynasty. This being said, most historians now make a distinction between medical lancing (or bloodletting) and acupuncture in the narrower sense of using metal needles to attempt to treat illnesses by stimulating points along circulation channels ("meridians") in accordance with beliefs related to the circulation of "Qi". The earliest evidence for acupuncture in this sense dates to the second or first century BCE.

The *Yellow Emperor's Inner Canon (Huangdi Nei Jing)*, the oldest received work of Chinese medical theory, was compiled around the first century BCE on the basis of shorter texts from different medical lineages. Written in the form of dialogues between the legendary Yellow Emperor and his ministers, it offers explanations on the relation between humans, their environment, and the cosmos, on the contents of the body, on human vitality and pathology, on the symptoms of illness, and on how to make diagnostic and therapeutic decisions in light of all these factors. Unlike earlier texts like *Recipes for Fifty-Two Ailments*, which was excavated in the 1970s from a tomb that had been sealed in 168 BCE, the *Inner Canon* rejected the influence of spirits and the use of magic. It was also one of the first books in which the cosmological doctrines of Yinyang and the Five Phases were brought to a mature synthesis.

The *Treatise on Cold Damage Disorders and Miscellaneous Illnesses (Shang Han Lun)* was collated by Zhang Zhongjing sometime between 196 and 220 CE; at the end of the Han dynasty. Focusing on drug prescriptions rather than acupuncture, it was the first medical work to combine Yinyang and the Five Phases with drug therapy. This formulary was also the earliest public Chinese medical text to group symptoms into clinically useful "patterns" (*zheng*) that could serve as targets for therapy. Having gone through numerous changes over time, the formulary now circulates as two distinct books: the *Treatise on Cold Damage Disorders* and the *Essential Prescriptions of the Golden Casket*, which were edited separately in the eleventh century, under the Song dynasty.

Nan Jing (Chinese medicine) was originally called "The Yellow Emperor Eighty-one Nan Jing", the book is rumoured to be authored by Bian que in eastern Han dynasty. This book has been compiled in the form of question and answer explanations. The book is based on basic theory

and has also analyzed some disease certificates. The book is credited as developing its own path, while also inheriting the theories from Huangdi Neijing. The content includes physiology, pathology, diagnosis, treatment contents, and a more essential and specific discussion of pulse diagnosis. It has become one of the four classics for Chinese medicine practitioners to learn from and has impacted the medical development in China.

Shennong Ben Cao Jing is the earliest medical book in China. Written during the Eastern Han Dynasty between 200 and 250 CE, it was the combined effort of TCM practitioners in the Qin and Han Dynasties who summarized, collected and compiled the results of pharmacological experience during their time periods. It was the first systematic summary of Chinese herbal medicine. Most of the pharmacological theories and compatibility rules and the proposed "seven emotions and harmony" principle have played a huge role in the practice of medicine for thousands of years in Chinese medicine. Therefore, it has long been a textbook for doctors and pharmacists to learn Chinese pharmacy, and it is also one of the necessary books for medical workers in China.

The *AB Canon of Acupuncture and Moxibustion* (*Zhenjiu jiayi jing* 針灸甲乙經, compiled by Huangfu Mi sometime between 256 and 282 CE) assembled a consistent body of doctrines concerning acupuncture; whereas the *Canon of the Pulse* (*Maijing* 脈經; ca. 280) presented itself as a "comprehensive handbook of diagnostics and therapy."

In 1950, Chairman Mao Zedong made a speech in support of traditional Chinese medicine (TCM) which was influenced by political necessity. In 1952, the president of the Chinese Medical Association said that, "This One Medicine, will possess a basis in modern natural sciences, will have absorbed the ancient and the new, the Chinese and the foreign, all medical achievements—and will be China's New Medicine!"

Then came the Cultural Revolution (1966–1978). Traditional Chinese medicine was strongly affected during this period. The development of traditional medicine in China was part of the pursuit of national identity during the Cultural Revolution. During this period, the Chinese government made large investments in traditional medicine to try to develop affordable medical care and public health facilities. Modernity, cultural identity and China's social and economic reconstruction are the main aspects of the Cultural Revolution. Compared to the colonial and feudal past, this movement tried to define a new and modern China. The Chinese government has established a grassroots health care system as a step in the search for a new national identity and is trying to revitalize traditional medicine. During the Cultural Revolution, the Ministry of Health directed health care throughout China and established primary care units. Chinese physicians who are trained in Western medicine also learn traditional medicine, while traditional healers receive training in modern methods, dynamically integrate modern medical concepts and methods, and revitalize some of the appropriate aspects of traditional medicine. Therefore,

traditional Chinese medicine was re-created in response to Western medicine during the Cultural Revolution.

During the Cultural Revolution in 1968, the Communist Party of China supported a new system of health care delivery for rural areas. Each village was assigned a barefoot doctor (a medical staff with basic medical skills and knowledge to deal with minor illnesses) and is responsible for providing basic medical care. The medical staff combined the values of traditional China with modern methods to provide health and medical care to poor farmers in remote rural areas.

The various historical physicians in China include include Zhang Zhongjing, Hua Tuo, Sun Simiao, Tao Hongjing, Zhang Jiegu, and Li Shizhen.[17] Two of the earliest Chinese medicine books, the 'Huang-Di-Nei-Jing' (770–221 BC) and the 'hen-Nong-Ben-Cao-Jing' (25–220 AD) had great influence on the TCM development in the long history of China. Decoction of herbs, the most important preparation method of Chinese medicine, was first invented and further developed between 2000 and 474 BC. After the 1950s, advanced research into TCM began, which was aimed at meeting the needs of the growing Chinese population and also at reaching the standards of safety, efficacy and quality of Western medicine.[18]

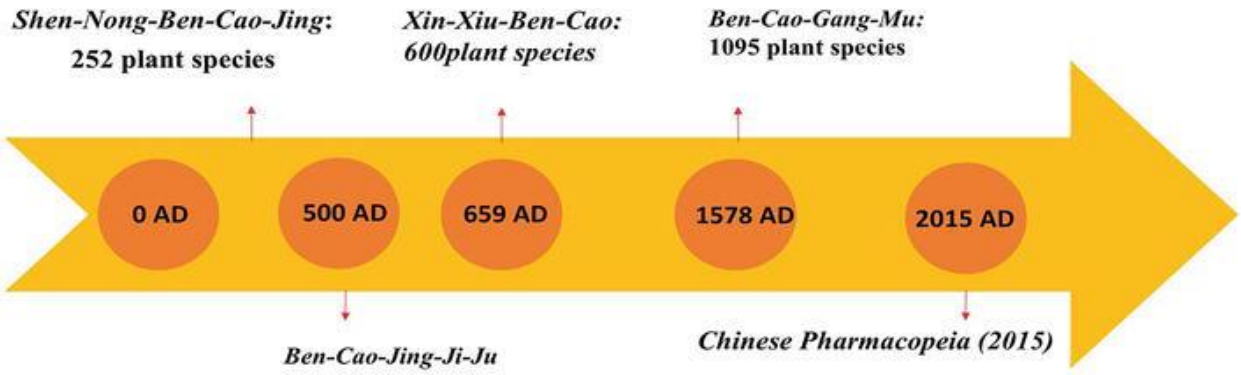

Figure 1: Timelines of some ancient Chinese medicine books

1.4. Demand Scenario of Herbal Products: Local and Global in India and China

With the improving economy, enhanced purchasing power, trade facilitation and inclination towards using alternative options, the preference for use of natural products as curative option is ever increasing. Many Pharmaceutical companies are re-strategizing in favour of natural drug discovery and development. In the global market, efforts are being put in for monitoring the quality of traditional medicine being sold in international market. The growing business of herbal

[17] https://en.wikipedia.org/wiki/Traditional_Chinese_medicine

[18] https://www.intechopen.com/books/plant-extracts/traditional-chinese-medicine-from-aqueous-extracts-to-therapeutic-formulae

drugs is being regulated by international bodies. Various Governments as well as certification bodies and health authorities have taken interest in providing standardized botanical medications. Scientific research in this area of medicine is being taken up in the context of rigorous science, sophisticated research, train researchers, disseminate information to the public on the modalities that work and explain the scientific rationale underlying discoveries.[19]

According to the International Union for Conservation of Nature (IUCN) and the World Wildlife Fund (WWF), there are between 50,000 and 80,000 flowering plant species used for medicinal purposes worldwide. The biodiversity richness vis-a-vis the proportion of most collected and used medicinal plants among them for different countries have been illustrated in diagram-1. Critically analysing the above diagram it can be deduced that although China has highest number of plant species among all countries compared, in respect of medicinal richness India has the maximum number of species of medicinal values. Probably on this account alone, there is a saying that every plant growing in the forest or elsewhere in India is having one or the other medicinal value. Only thing is that there is lack of proper documentation of each and every plants having medicinal importance.

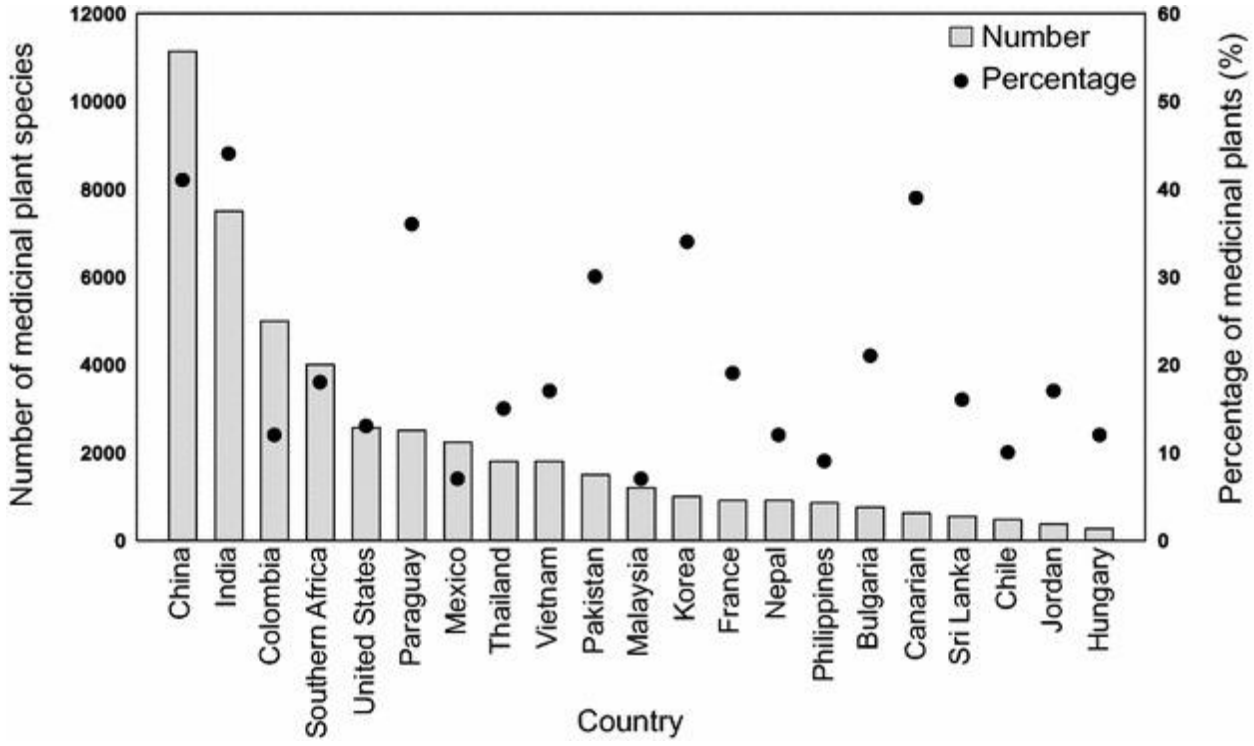

Diagram – 1: Number and percentage of medicinal plant species in different countries

(Sources from Rafieian-Kopaei, Hamilton, Marcy et al., and Srujana et al.)

[19]https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1297513/

The *light bars* indicate the number of medicinal plant species, and the *dark dots* indicate the percentage of medicinal plants compared with the total number of plant species.

The most widely used traditional medicine systems today include those of China, India, and Africa.[20] China, India, Ghana, Mexico, Russia and South Africa are also countries where traditional medicine system is used for healthcare reasons.[21] Countries such as the South-east Asia, Australia, New Zealand, Europe, Brazil, Canada, US and Africa have a demand for procurement of traditional medicine from countries like India and China.

India is one of the 17 mega-biodiversity countries contributing about 7% of the world bio-diversity. The variation in agro-climatic conditions (India has 15 agro-climatic zones) favour the richness of bio-diversity as a result of which the medicinal plants are found occurring from Himalayan to marine and desert to rain forest ecosystems.However away from forest areas very important medicinal plants are also found occurring as weed (eg; *Calotropis* spp*., Argemone mexicana, Adhatoda vasica, Allium Cipa, Dhatura metel, Cyprus rotandus* etc.)[22]

Out of 17,000-18,000 flowering plant species found in different eco-systems (forest, desert, marine, agro-ecosystems and different types of wastelands in India), about 7000 plant species have been reported being used as medicinal plants (NMPB, 2019).

Ayurveda, Siddha and Unani systems of medicine have more than 90% formulations which are plant based.

Table 1: Analysis of Plant Parts used in Ayurvedic Industry

Part Used	Percentage
Roots	29.5
Rhizome	4.0
Leaves	5.8
Flowers	5.2
Fruits	10.3
Seeds	6.6
Stems	5.5
Bark	13.5
Wood	2.8
Whole Plant	16.5

Source: FRLHT, Bangalore, 1997

[20] https://www.sciencedirect.com/topics/agricultural-and-biological-sciences/traditional-medicine
[21] https://academic.oup.com/heapol/article/31/8/984/2198144
[22] https://www.nmpb.nic.in/content/medicinal-plants-fact-sheet

To assess the current Demand and Supply scenario of medicinal plants, NMPB has extensively surveyed the herbal market of India in collaboration with ICFRE, Dehradun. The estimate of consolidated commercial demand of herbal raw drugs for the year 2014-15 has been estimated at 5,12,000 MT. Estimated Exports of Herbal Raw Drugs, including Extracts has been estimated 1,34,500 MT in 2014-15. Estimated Consumption by Domestic Herbal Industry has been estimated 1, 95,000 MT 2014-15.[23] An Estimated 1, 67,500 MT of Herbal Raw Drugs are also Used by Rural Households every year. About 1178 medicinal plant species recorded in the practices of trade. Out of which, 242 plant species are used in annual quantities of more than 100MT.[24]

China is also very rich in medicinal plant biodiversity with more than 6,500 Chinese herbs. Taking these huge natural medicinal resources into use, TCM system has been prevalent throughout east and south-east Asian countries, including Japan, Korea and Vietnam. It encompasses many different practices, including Chinese herbal medicine (CHM), acupuncture, moxibustion, Tui Na, dietary therapy, Tai Chi and Qi Gong. Instead of this diversity, Chinese Herbal Medicine is the mainstay and principal form of TCM practice.

As per data of China Chamber of Commerce for Import & Export of Medicine & Health Products, China exported 358,000 tons of traditional Chinese medicine, up 0.7 percent year-on-year. Export value was $3.6 billion, up 2.1 percent in 2017. TCM market is rapidly developing since later 1990s in China. It has successfully established its hold over the TCM market, and is progressively being recognized for its efforts put in so far in the sector. In the modern world market, TCM encompasses a wide range of items: traditional Chinese medicinal materials, decoction pieces, Chinese patented medicines, herbal extracts, and health care products which are used locally as well as exported outside China.

India stands as the 2nd largest exporter of herbal medicines only after China. Both the countries are producing over 70 percent of the herbal medicines demand across the globe. India exported raw herbs worth USD330.18 million during 2017–18 with a growth rate of 14.22% over the previous year (MoC&I, 2019). The export of value-added extracts of medicinal herbs/herbal products during 2017–18 stood at USD456.12 million recording a growth rate of 12.23% over the year before (MoC&I, 2019).

Instead of all these advantages, India is the 2nd largest exporter of herbal medicines only after China, both the countries producing over 70 percent of the herbal medicines demand across the

[23] https://www.nmpb.nic.in/content/medicinal-plants-fact-sheet

[24] https://www.nmpb.nic.in/content/demand-and-supply-position-medicinal-plants

globe. India exported raw herbs worth USD330.18 million during 2017–18 when these figures are compared with China's export of TCM in 2017 at $ 3.6 billion, India is much more behind China in terms of production and export of traditional medicines.

The present study entitled- 'Development and Trade of Medicinal and Aromatic Plants (MAPs): Learning from Comparative Analysis of MAPs Export of India and China' which is being undertaken by Institute of Livelihood Research and Training (ILRT) and commissioned by Rajiv Gandhi Institute for Contemporary Studies (RGICS) attempts to understand and analyse the major initiatives of India and China to promote medicinal plants/herbal products and enhance its trade globally.

1.5 Rationale for the Study

As already discussed the culture and trend of use of medicinal plants based herbal health care and nutrition system is spreading world over. This has created ample opportunities for the local communities who are involved in production and collection of MAPs to increase their income level by catering to the growing demand of herbal products in domestic and international markets. If we take example of India, nearly 250 million people especially the tribal live in and around forests and gather various forest products including MAPs from the forests for both self-consumption and commercial purposes. A systematic approach towards development of MAP sector and creating an eco-system of promoting trade and export of MAPs could result in terms of multiplier impacts and benefits at various levels.

Chinese introduced an integrated approach of strengthening pre-production, production and post production practices which resulted in to all-round growth in creating a robust production and processing system in place. At production stage, promotion by domestication and cultivation of herbal medicines through natural fostering model involving small and marginal farmers has been a very successful and a model for emulation. Promotion of Good Agriculture Practices (GAPs) through involvement of multiple stakeholders including industries has been tried. Strict compliance with GAPs and investment on research with linkage of production with industry has been a successful model. At post production stage, this involves aggressive marketing aiming at export of TCM through certification, branding, using overseas Chinese Diaspora and the Belt and Road Initiative (BRIs).

This way China recorded impressive growth of TCM and thus they are ahead of India with respect to their popularity and access to international market more than India. This happened due to their aggressive state policy. China pursued TCM as an important and equivalent part of an integrated system of medicine. Further the Chinese adopted another strategy of treating TCM at par with western system of medicines in medical education.

China's domestic demand for TCM is also surging along with its increasing demand for TCM exports for international consumption. India is yet to catch up with Chinese share of international market.

A comparative study of India and China of developing MAPs sector with a view to promoting its trade and export could benefit not only the primary collectors and producers of MAPs but all other stakeholders of the value chains. Both the countries can learn from each other's experiences of promoting inclusive growth and conservation of natural resources by linking the livelihood of primary forest produce gatherers, who contribute in collection of MAPs from forests and small and marginal farmers by involving them in domestication and production of MAPs and linking with global supply chain. This Study will add to the repertoire of India-China studies for obvious reasons. It will also give some answers as to how both the countries can increase their place herbal based health care system in the World basing on their historical, intellectual and natural resource base, and what can be done about it.

1.6. Objectives of the Study

The broad objective of the proposed study is to understand the initiatives undertaken in India and China for promoting trade and export of MAPs, results of different interventions and learning from each-others experience to take appropriate measures towards further development and promotion of export of MAPs. The specific objectives are-

- To understand the current scenario of development and trade of MAPs in India and China.
- To assess the level of production, trade and export of MAPs in both the countries as a result of the various initiative undertaken.
- To understand and compare the efforts and initiatives of Governments and other agencies in promotion of MAPs development and trade in respective countries.
- To assess the impacts and benefits of development at various levels for development of MAPs sector and future trends.
- To draw lessons from each-others experiences and make recommendations to apply suitable interventions in India for further development of MAPs sector to promote share in the international markets.

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Chapter 2

Research Methodology

2.1. Universe of Study

The study is analytical in nature which warranted collection and analysis of secondary as well as primary data and facts relating to legal and policy framework for MAP sector both in India and China, production and trading/export of MAPs in India and China as well as Processing and Industrial development of the sector in both the countries. The study objective was to compare the factors which contributed towards higher growth of TCM in China when compared to the TISM in India. Thus, appropriate research methods will be used to gather and analyze both quantitative and qualitative data.

2.2. Research Questions

The study attempts to find out answers to following questions-

- What is the production level of MAPs? Their sources- forests, cultivation on agriculture land or import? What kind of MAPs is being exported by India and China? Their comparative competitiveness and acceptability among international consumers?
- What are the issues related to sustainable management of MAPs in India?
- What is the level of domestication of MAPs in both the countries? What kind of roles is being played by gatherers and farmers?
- What kind of legal and policy framework have been adopted by India and China for development of MAPs sector and enabling conditions for increasing export of MAPs?
- What kind of governmental policies are in place in two countries to enhance the livelihoods of forest produce gatherers and small farmers?
- What kind of efforts- programs/schemes are in place in India and China to organize the production, processing and trade of MAPs?
- What kind of incentives exists in two countries for development of MAPs for meeting internal and external demands?
- What kind of specialized export promotion schemes are in existence?
- What kind of efforts has been made for Internationalization of Traditional Indian System of Medicines (TISM) and Traditional Chinese Medicines (TCM) by India and China respectively?
- What are the Trust building measures among International consumers (certification, product and process)?

- What has been the role of industries both domestic and multi-national corporations (MNCs) in promoting processing and trade of herbal products in domestic and international markets?

2.3. Study Framework

A mixed approach i.e. combination of Secondary and Primary research to achieve the desired objectives of the study was adopted. The Secondary Research was based on quantitative data, records, documents and information available in public domain. As a part of the primary research, the team carried out in-depth stakeholders' consultations and one to one interviews with identified stakeholders/officials through structured questionnaires and interview guidelines. The study has covered various important stakeholder views through consultation and personal interviews. The study has covered more than 15 stakeholders.

The list of stakeholders consulted is as follows:

Government Stakeholders

1) Ministry of Ayush, Delhi
2) National Medicinal Plant Board, Delhi
3) Indian Council of Medical Research, Delhi
4) Chhattisgarh Minor Forest Produce Federation (CGMFP)
5) Chhattisgarh State Medicinal Plant Board (CGSMPB)
6) Madhya Pradesh State Minor Forest Produce (Trading & Development) Cooperative Federation (MP MFP Federation)
7) Minor Forest Produce Processing and Research Centre (MFP-PARC)

Traders and Exporters

1) The Central Herbal Agro Marketing Federation of India (CHAMF)
2) Organic India Pvt Ltd., Lucknow

Pharmaceutical Industries

1) Shree Baidyanath Ayurved Bhavan Pvt. Ltd.
2) AIMIL Pharmaceuticals
3) Maharishi Pharmaceuticals Private Limited
4) Kudos Ayurveda
5) Emami Limited
6) Multani Pharmaceuticals

Councils

1) India China Economic and Culture Council, Delhi

International Organisations/ Bilateral Agencies

1) TRAFFIC, The Wildlife Trade Monitoring Network, Delhi

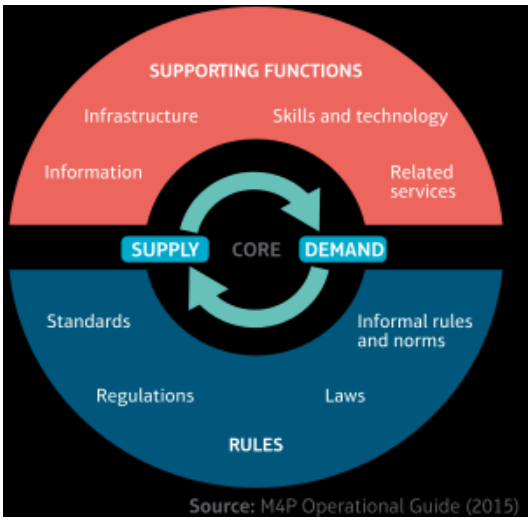
University

1) Pharmaceutics Department and Department of Ayurveda, Banaras Hindu University, Varanasi

Recommendations and strategies to overcome the identified challenges is suggested through the study. Actionable to strengthen the value chain and to prevent recurrence of the problem is given.

To understand the MAP sectoral structure in two countries, a set of quantitative and qualitative methods and tools which have been introduced and adopted by VCB-N CoEs is used. The value chain study procedures and methods introduced by VCB-N on VCD and MSD under the TOT training was applied in this study.

The Doughnut Module was applied to understand the components and dynamics of value chain and market system development of MAPs in the two countries. This gives a clear explanation – based on the three common components of any market system: the core market, supporting functions and the rules.



The market system 'doughnut'

Taking the guidance from the Doughnut model, following scan is applied under the study to understand the development and promotion of export of MAPs in both the countries.

Legal Framework and Policy Scan: This has focus on the legal framework adopted and policy measures undertaken by both the countries for development and also promoting trade and export of MAPs. The role played by such initiatives in terms of creating enabling environment for development of MAPs sector and its internationalization.

Market Scan: This would focus on current and future demand for MAP in the coming decades, the potential market sources, the potential consumers of the MAP products, the different market players.

Sectoral Scan: A 360 degree scan is undertaken. The sectoral scan covered the whole TCM value chain, i.e. medicine plant collection and production, processing, marketing and trading and export, etc. The study focused on production – trading and exports.

Programs and Schemes Scan: Various programs and schemes have been launched for development, processing and promote trading of MAPs. Outreach of the program and schemes, involvement of different stakeholders is analyzed. The output and outcome of such initiatives in terms of higher production and productivity, value added production, availability of different products of MAPs, volume of trade, income and growth trends, etc is studied.

Supply Chain and Stakeholder Scan: Development of supply chains- from local to global, role and involvement of different stakeholders, trading practices, roles at different stages and benefit sharing mechanisms, initiatives for strengthening the supply chain, etc is analyzed in the study.

Product Scan: Research and development initiatives, scientific validity of medicinal value, technology, product development for export markets, quality control measures, comparative competitiveness of the products etc are analyzed in the study.

MAPs Trade Scan: Overall production and trade of different MAPs both raw and finished products, key drivers of international MAP trade, strategies and interventions made for promoting trade especially export, incentives for export, trade and export trends, key issues, lessons and opportunities are examined in the study.

2.4. Study Methodology

To achieve the objectives and apply various scans, systematic review process with meta-analysis and narrative is used under the present study. Systematic review process involve analysis and synthesis of the current knowledge generated on the sector. The research questions would form the basis on which certain inclusion and exclusion would be identified, relevant literature identified from a range of information sources – which includes scholarly articles – sector specific

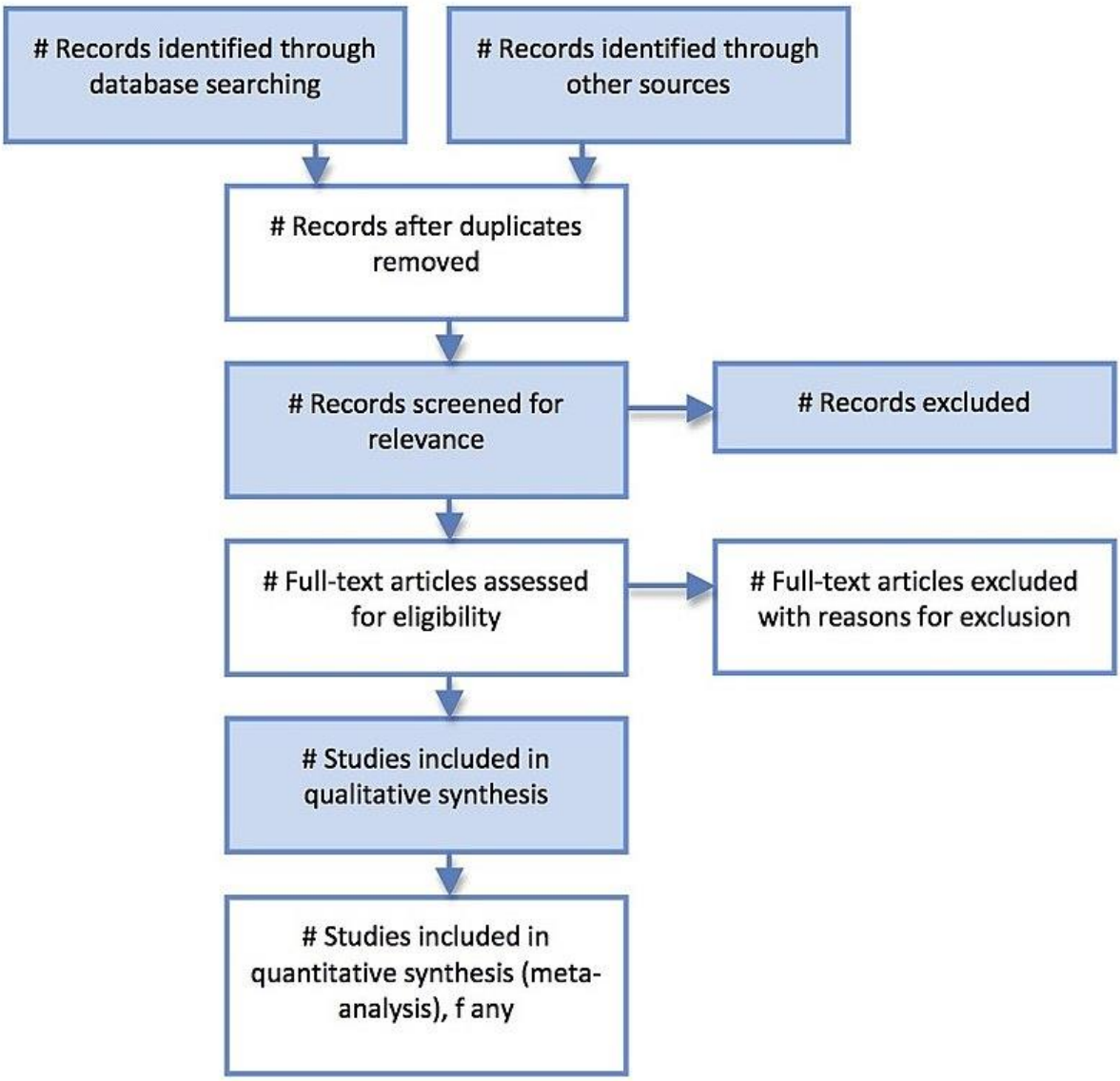
professional literature, trading and business magazines, academic and industry related books etc. Systematic reviews are a type of literature review that uses systematic methods to collect secondary data, critically appraise research studies, and synthesize findings qualitatively or quantitatively. Systematic reviews formulate research questions that are broad or narrow in scope, and identify and synthesize studies that directly relate to the systematic review question. They are designed to provide a complete, exhaustive summary of current evidence relevant to a research question.

Research Methodology

1. Primary Survey	Meeting with various stakeholders such as Government representatives, government councils, various international Institutions and bilateral agencies, traders and industrial houses engaged in research and development, cultivation, processing and export of MAPs from India
2. Secondary source of information	Review of Literature – Printed and Grey
3. Customized Questionnaire	Government representatives, Producer, Processors, Traders and Exporters
4. Data – Production, Processing, Trade and Export	Data gathering from indiastat.com, database of Ministry of Commerce and Industry
5. States Covered	Madhya Pradesh, Chhattisgarh
6. Analysis of existing data	Systematic Review, Content Analysis, Narrative Analysis, Discourse Analysis and Grounded Theory
7. Draft Report	Report
8. Final Report	Report

Systematic processes will be adopted for collection and review of relevant data and facts which is depicted through Preferred Reporting Items for Systematic Reviews and Meta-Analyses

(PRISMA)25 The PRISMA flow diagram, depicting the flow of information through the different phases of a systematic review.



The first step in conducting a systematic review was to create a structured question to guide the review.

The second step was to perform a thorough search of the literature relevant to research and different research questions. Listing of all the databases and citation indexes that were searched such as Web of Science, Research gate, India Stats, data.gov.in, Embase, and PubMed and any individual journals that were searched.

[25]https://en.wikipedia.org/wiki/Preferred_Reporting_Items_for_Systematic_Reviews_and_Meta-Analyses

The third step focused on inclusion or exclusion of literature and data. The titles and abstracts of identified articles were checked against pre-determined criteria for eligibility and relevance to form an inclusion set. This set was related back to the research problem. Each included study was assigned an objective assessment of methodological quality preferably by using methods conforming to the research questions of the study.

The fourth step focuses on systematic reviews often, but not always, use statistical techniques (meta-analysis) to combine results of eligible studies, or at least use scoring of the levels of evidence depending on the methodology used for analysis of quantitative and qualitative data and facts.

2.5. Data Collection

Secondary Data:

Secondary data and information are key to answer the various questions the present study attempts to answer, therefore various secondary information and data pertaining to legal framework and policies about MAPs in India and China, Government programs/schemes related to MAPs, circulars, orders, progress reports, data related to production, trading, processing, import and export of MAPs, evaluation reports, value chains of MAPs, involvement of different stakeholders and their role, initiatives undertaken for promotion of export of MAPs and herbal based health care in international markets, role of industries, research and publications on MAPs and their trade, etc., was gathered from different sources. Checklists were prepared for collection of all these data.

The secondary information and data were gathered from various sources such as-

Government documents: various Government documents related to legal aspects of MAPs, policy and program documents, schemes for development of MAPs and promote processing and trade, promotion of international trade and treaties, etc.

Official statistics: Statistics related to MAPs collected by governments and their various agencies, bureaus, and departments. These statistics are useful to researchers because they are an easily obtainable and comprehensive source of information that usually covers long periods of time.

Industry documents: Documents, annual reports and reports of industry associations on commercialization and industrial development of MAPs, investment in MAPs sector, product development and quality standards, production and trade of different MAPs, growth trends, constraints, etc. Industries and their associations prepare documents and reports in various areas of MAPs which can be useful secondary data and information on MAPs.

Technical Reports: Technical reports are accounts of work done on research projects on MAPs. A report may emanate from completed research or on-going research projects. The technical reports provide research results on various aspects of MAPs such as production, health benefits, processing and product development, quality and hygiene, etc.

Scholarly Journals: Scholarly journals generally contain reports of original research or experimentation written by experts in specific fields related to MAPs. Articles in scholarly journals usually undergo a peer review where other experts in the same field review the content of the article for accuracy, originality, and relevance.

Literature Review Articles: Literature review articles assemble and review original research dealing with a specific topic related to MAPs. Reviews are usually written by experts in the field and may be the first written overview of a topic area. Review articles also discuss and list all the relevant publications from which the information is derived.

Trade Journals: Trade journals contain articles that discuss practical information concerning various fields related to import and export of MAPs, trade policies and incentives for promotion of MAPs trade, trade barriers, consumer markets in developed countries, preferences, sentiments and demand trends.

Export Data: Export Data would be gathered from the database of Ministry of Industry and Commerce. Trends in Sectoral and Sub-sectoral exports would be captured.

Reference Books: Reference books provide secondary source material on MAPs and their trade. In many cases, specific facts or a summary of a topic is all that is included. Handbooks, manuals, encyclopedias, and dictionaries are considered reference books.

Primary Data:

Primary information and data was gathered from trading firms, processing industries and export houses. Consultation and interview were done with different stakeholders both Government and other organisations involved at various stages such as production, policy making, research and development, processing, trading and export of MAPs.

Various methods were used for data collection-

Interview and Consultations with key Stakeholders: Interview and consultations were done with key stakeholders such as policy makers, planners, traders, processors, exporters, researchers, etc. A comprehensive list of different stakeholders of both the countries was prepared. For interview and consultation, semi-structured interview schedules were prepared and administered among the different stakeholders through face-to-face and online medium.

Focused Group Discussions (FGDs): FGDs was conducted with various stakeholder groups involved in similar activities under the MAPs sector. This was done to understand the various initiatives by Central and State Governments for development of MAPs and promoting their trade and exports and their subsequent impacts.

2.6. Data Analysis

Since the present study is based on both primary and secondary data and facts, adequate methods were used in analysis and interpretations to present the results is a meaningful form, such as the Systematic Review, Content Analysis, Narrative Analysis, Discourse Analysis and Grounded Theory were all used as methods for analysis of the qualitative data gathered.

Desk review of all the documents of secondary data was done to understand existing production and trade including export of MAPs in India and China, initiatives undertaken for promotion of trade and development of MAPs, involvement of various stakeholders and income level at various level, etc.

2.7. Limitations of the study

In the present study, a direct stakeholder consultation was planned in China with the Government, international agencies, research organisations, industrial houses and traders and farmers engaged in medicinal plant cultivation processing and trade. But due to the outbreak of Corona Virus pandemic in the country, the research team were unable to travel to the country for first hand information gathering with the primary stakeholders. This inhibited the study results to some extent, though attempt was made to get all details possible through secondary literature review and telephonic conversations as well as consultation with traders and Pharmaceutical companies engaged in trade and export of TCM to and from China.

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Chapter 3

Legal and Policy Initiatives for Promotion of Traditional Medicines in India and China

Since time immemorial the traditional systems medicines have been practiced for preventive and curative healthcare in both India and China. Both the countries are rich in term of availability of bio-diversity especially availability of medicinal and aromatic plants (MAPs) and supply about 70% raw material in herbal based healthcare system in the world. Assessing the importance of MAPs in ensuring primary healthcare to large number of population and potential for development of the sector for local economy building especially promoting livelihoods of the poor forest produce gatherers and smallholder farmers, various legal and policy initiatives have been taken up by Government in both the countries to develop the MAP and herbal based healthcare including promotion of export. This chapter focuses on comparative policy level interventions taken up in both India and China to improve the acceptability, domestic spread, production, conservation, export and international recognition and approval. Some proposed policy interventions have been suggested along with the short-comings in India, to take up the case of TISM at par the rigorous stand that has been taken up by China for TCM promotion.

3.1. Legal and Policy Framework for Traditional System of Medicines in India

There have been a symbiotic relationship between forest and forest dwelling communities in India. The forest dwelling communities especially the tribal have been dependent on forest for both commercial and consumption including healthcare needs. Government has taken up several legal and policy initiatives time to time for management of MAP resources, enhancing livelihoods of forest dependent communities, promoting herbal based healthcare and trade and export of traditional medicines.

3.1.1. Legal and Policy Initiatives for Management MAP Resources

There are several laws and policies that are of relevance for protection, conservation and promotion of medicinal plants sector in India put forward by the Government. The governance of production, processing, export of medicinal plants and herbal based healthcare come under jurisdiction of various ministries and agencies in India which framed different policies time to time.

Forest Act, 1927: The first step in this direction is Forest Act of 1927 which consolidated the law relating to forests, the transit of forest-produce and the duty leviable on timber and other forest-produce. This Act provides a legal regime for protection of forests. It has categorized forests as Reserve and Protected forests)Bhattacharya, 2015)

National Forest Policy, 1952*:* India's first forest policy of 1952 recognized the protective role of forests and discarded the notion that forestry has no intrinsic right to land. It reinforced the right of the state to exclusive control over the forest protection, production and management (Hobley, 1996). It stipulated that the country should aim at having at least one third of its total land area under forests. The policy advocated the extension of forestry beyond the forest area, to meet local and national demands. The policy provided guidelines for management and control of private forests, curtailment of shifting cultivation and creation of village forestry.

Wild Life Protection Act, 1971: The Wild Life (Protection) Act, 1972 provides protection to wild animals, birds and plants and for matters connected therewith or ancillary or incidental thereto. Most of the states in the country have promulgated separate legislations to meet specificities of the respective states in lien with this act.

The Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) 1975: CITES is an international agreement between governments with the aim to ensure that international trade in specimens of wild animals and plants does not threaten their survival. The species covered by CITES are listed in three Appendices, according to the degree of protection they need. Appendix I include species threatened with extinction. Trade in specimens of these species is permitted only in exceptional circumstances. Roughly 5,800 species of animals and 30,000 species of plants are protected by CITES against over-exploitation through international trade. They are listed in the three CITES Appendices. The species are grouped in the Appendices according to how threatened they are by international trade.

In India, for cultivation of CITES Appendix I species, the nursery where the plants acquired are maintained and multiplied must be registered with the Assistant CITES Management Authority. CITES Appendix I and Wildlife (Protection) Act Schedule VI plants cultivated this way are eligible for export, subject to obtaining a transit pass from the concerned DFO if the plants were cultivated on sites within forests, or a Certificate of Cultivation from a District Agriculture, Horticulture or Forest Officer if cultivated at sites outside forests. Foreign trade in respect of species listed in Appendix II and III of CITES whether wild or cultivated is regulated only to the extent that the exporter needs to have a Certificate of Legal Possession issued by jurisdictional DFO, and the export is subject to CITES provisions.[26]

National Commission on Agriculture Recommendation, 1972: The most significant change in forestry sector occurred in the mid-1970 with the recommendations of National Commission on Agriculture (NCA) in 1972 which opened window for social forestry. It recommended large scale

[26]https://www.researchgate.net/publication/335095621_Trade_in_Medicinal_and_Aromatic_plants_of_India_An_overview/

plantations in degraded forest areas in the community and the forest lands through social forestry.

Forest Conservation Act 1980: This law is applied to all the lands which are notified as forests in the government records and is not restricted to reserved and protected forests. It restricts the powers of the state governments by making it mandatory for them to seek permission from the central government for any non-forest use of the forest lands including de-reservation of the forest and diversion of the forest land.

Environment Act, 1986: The Environment Act 1986 established that no person carrying on an industry, operation or process shall discharge or emit any environmental pollutant in excess of standards prescribed by the Government. The standards of emission or discharge of environmental pollutants from the industries, operations or processes are specified in Schedules 1 to 1V of the Environment (Protection) Rules. The Central Government has established several environmental laboratories for the purposes of the Environment (Protection) Act. It ensuring effective provision is made for public participation in environmental planning and policy formulation, particularly at the regional and local level.

Forest Policy 1988: The National Forest Policy 1988 changed the scenario of forestry in India and concept of people's participation and sustainable management approaches came into being. This policy initiated a process of reforms at the local policy and clearly laid down the procedure for people's involvement in forest conservation and management through appropriate village level institution and under a proper scheme. The policy emphasized on environment stability, maintenance of ecological balance and protection of rights and concessions of the tribal people. The policy emphasized on integrated area development programmes to meet the needs of the tribal people in and around the forest areas (Bhattacharya, 2015).

Joint Forest Management (JFM) Guidelines, 1990: With the promulgation of National Forest Policy 1988, India had taken a revolutionary shift in the approach of forest management from regulatory to participatory. The ecological security became the prime objective and focus was given for providing livelihood to the forest dependent communities. India has initiated the implementation of this policy in a big way to involve local communities in the conservation, protection and management of forests through Joint Forest Management (JFM) institutions in 1990 and expanded this programme to more than 22 million hectares of forests with the involvement of approximately 21 million people (Bhattacharya, 2015).

PESA (Panchayat Extension to the Scheduled Areas) Act, 1996: For enhancing the contribution of forests towards poverty alleviation through empowering people with the ownership of NTFPS (PESA, 1996), the Parliament of India passed Provisions of the Panchayats (Extension to the Scheduled Areas) Act, 1996 to extend the provisions of the 73rd Constitutional Amendment 1993

to the Schedule V Areas of the country. The PESA Act empowered the Panchayats with the ownership rights of the natural resources including MAPs. It was envisaged that sustainable management of these resources, with the development of value addition chains will improve the income of the Panchayats as well as that of primary collectors and processors.

Biodiversity Conservation Act, 2002: The Biological Diversity Act 2002 has been enacted in pursuance of the United Nations Convention on Biological Diversity 1992. The main objective is to conserve Indian biological diversity and regulate access to Indian biological resources as well as ensure equitable benefit sharing arising from the utilization of those resources. The Act is of particular relevance when addressing issues relating to the intellectual property rights over biological materials including medicinal plants and knowledge relating to biodiversity or its elements.

The Act creates a three-tier structure of authorities to manage the biodiversity of the country. This includes the National Biodiversity Authority (NBA), the State Biodiversity Boards at the state level and the Biodiversity Management Committees at the local level.[27] Various sections of the Act deal with regulations related to obtaining permission for export and trade of biological resources. Section 38 of the Act empowers the Central government to notify red-listed species and prohibit or regulate collection thereof for any purpose in consultation with the concerned State government. Further, as per Section 3 of the Act, foreign nationals and non-residential Indians are required to obtain prior approval from the National Biodiversity Authority to access biological resources for research, or for commercial utilization, or even for bio-surveys. It also suggests measures for their rehabilitation.

Another important dimension of the BD Act is 'Guidelines on Access to Biological Resources and Associated Knowledge and Benefit-Sharing Regulations, 2014' ("ABS Regulations"). It was issued following the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to CBD, which came into force in 2014. 385 species are exempted from the BD Act, dated 2016. Accordingly, the products derived from these species are also treated as normally traded commodities.

Forest Right Act, 2006: Another milestone has been achieved in 2006 by the enactment of a national level legislation, The Scheduled Tribes and other Traditional Forest Dwellers (Recognition of Forest Rights) Act, 2006, for assigning habitation and occupation rights on forests along with responsibility of conservation of biological resource and maintenance of ecological balance to community. This Law recognizes the rights of occupation of forests by tribes and forest dwellers and empowers them for management of forests used by them as common property resources. It is estimated that about 20% of the government controlled and managed forestland

[27]http://awsassets.wwfindia.org/downloads/lecture_notes_session_9_1.pdf

will come under the occupational titles recognized under this law. The recognition of right of common use conforms to the policy prescription of participatory forest management and also accepted principles of biodiversity conservation as well as community involvement in conservation (Bhattacharya, 2015).

National Biodiversity Strategy and Action Plan, 2007: In order to establish national certification standards and protocols for improving access to international market and to get green premium price, the GoI has approved the Criteria and Indicators(C&I) for Sustainable Management of NTFPs bulk of which is MAPs resources. The National Biodiversity Strategy and Action Plan (NBSAP) 2007, suggests detailed strategies for the conservation and sustainable use of medicinal plants.

It further stressed on MAPs inclusion in National Forestry Information System and in National Working Plan Code, 2014. It also underlined the need for Nation-wide long-term genetic improvement programmes for indigenous species, screening of Indian species for fast growing, short rotation alternatives for traditional species to be used in industry and launch of protocols for survey, inventory, and management planning for medicinal and aromatic plants in forests.

New Draft National Forest Policy (NFP), 2018: The Central government has come up with a new draft National Forest Policy (NFP), 2018 which takes into account a reality that has become the defining feature of the world today—climate change which if passed as a law has immense potential to change the MFP sector challenges to opportunities. The previous NFPs focused on production and revenue generation of forests (NFP, 1894 and NFP, 1952) and environmental stability and maintenance of ecological balance (NFP, 1988). NFP, 2018 will focus on climate change mitigation through sustainable forest management.

Listing the objectives, the NFP 2018 specifically mentions that livelihoods of people need to be improved based on sustainable use of ecosystem services. It further goes on to emphasize on management of protected areas and other wildlife rich areas with the primary objective of biodiversity conservation and for enriching other ecosystem services. Mountain forests are to be conserved and managed for sustainable flow of ecosystem services. It also lays emphasis on incentivizing agro forestry and farm forestry facilitating assured returns.

Laying down the principles of Forest Management, the NFP 2018 says that management of natural biodiversity has to be done for maximizing ecosystem services and also proposes to strengthen and extend the network of national parks and sanctuaries for biodiversity conservation.

Management of NTFP including medicinal plants forms another major pillar of the strategy of NFP. The Policy says that *"Non-Timber Forest Produce (NTFP) such as medicinal and aromatic plants, oil seeds, resins, wild edibles, fibre, bamboo, grass etc. provide sustenance to forest*

dependent communities by supplementing their food and livelihood security. Such produce should be managed sustainably ensuring increased employment and income opportunities for the local communities. Value Chain approach that is climate-smart and market oriented and embedded in sustainability would be made compulsory and part of the business plans related to NTFP."

Biodiversity conservation forms one of nine pillars of the strategy. Recognizing that natural forests are rich repositories of biodiversity in the country, the Policy proposes to take scientific measures for systematic documentation of biodiversity in sync with NBD Act and promote modern techniques of ex-situ conservation for the preservation of Relic, Endangered and Threatened (RET) species.

Developing a national forest ecosystems management information system is one of the six new thrust areas in forest & tree cover management of the policy. Recognizing lack of adequate data on forestry sector that is needed for planning and management the Policy plans to develop national forest ecosystems management information system and make it operational using the latest information and communication technology. The information will be made available in public domain.

For strengthening wildlife management, the Policy will take measures on assessment of species for survival and recovery measures based on population and habitat viability parameters would form an integral and regular part of management planning and practices. For tradable biodiversity a strong regime of inventory, assessment of status, and sustainability will be made part of the working/ management plans. Import and trade of exotic species, their uses and upkeep shall be subjected to strict regulations to ensure that the native biodiversity does not face genetic contamination. Zoological gardens, botanical gardens and biodiversity parks would be designed with modern and interactive methods for effective communication/interpretation about the value of flora and fauna aspect of the awareness creation and nature education. Zoos and rescue centers would also be used for harboring rescued species and conservation breeding.

The Policy also plans to enhance forest industry interface by supporting strengthening of partnership that forest industries have established with farmers.[28]

The Eleventh Five Year Plan for 2007-2012 took into consideration a number of important aspects related to the MAP sector, the Planning Commission emphasized for Promotion of organized trade in MAP, need based MAP cultivation with assured buy-back/promotion of contract farming and increased availability of MAP planting materials and development of improved varieties and hybrids.

[28] http://www.indiaenvironmentportal.org.in/files/file/Draft%20National%20Forest%20Policy,%202018.pdf

Contract farming can be taken up in order to streamline the process of providing a market for the produce to the farmers in order to bring security for their produce before they go for cultivation of MAPs, the lack of which is one of the major reasons why farmers do not forge into cultivation of medicinal plants in India, but prefer horticulture crops over it, though it might not fetch them a very good price. The commodity specific clusters can be distinguished and MAP plan and policy of that area should be worked out accordingly with the assistance of the industrial house interested to collaborate in that area. But before coming forward with these Company led models, it is important that the value chain players be developed strategically and efforts should be put in to streamline the supply chain. With a holistic look at the entire picture, in the planning efforts, the chances of successful results will improve.

The policy and legal regime in the forestry sector as envisaged by the government will keep focus on poverty alleviation through forestry, increasing productivity, enabling environment for private sector to grow more trees, ecological security of the nation, empowerment of communities along with their capacity building and biodiversity conservation.

3.1.2. Policy provisions for Traditional Medicines based Healthcare Promotion

There has been a symbiotic relationship of communities and forest in India. Huge availability of medicinal plants created base for herbal healthcare which is in vogue for a long. However, in modern times, western medicines based healthcare acquired prominence in mainstream healthcare system in the country. The significance of Indian Systems of Medicine and Homoeopathy was first brought in the National Health Policy (1983) and later emphasized in the National Population Policy-2000 and National Health Policy (2002) and ultimately in comprehensive terms in National AYUSH Policy, 2002. It was envisaged in the policy statements that Ayurveda, have a substantial role because of its advantages, such as diversity, modest cost, low level of technological input and the growing popularity of natural plant based products, especially in the under-served, remote and tribal areas (National Health Policy, 2002). The policy envisaged the consolidation of documentary knowledge of Ayurveda to protect it from commercial exploitation, piracy and misappropriation by foreign entities. It promotes measures to ensure affordable health services and drugs which are safe and efficacious. Integration of AYUSH in the healthcare delivery system and national programs to ensure optimal use of the vast infrastructure of hospitals, dispensaries and physicians were focused in the policy. Re-orientation and prioritization of research in Ayurveda to validate drugs and therapies to address in particular the chronic and new emerging lifestyle related diseases was given importance in the policy. Optimal utilization of Ayurveda has been taken up for the mainstreaming of its services through

National Rural Health Mission, which is now upgraded into flagship program called National Health Mission.[29]

The National Policy on Indian Systems of Medicine & Homeopathy (ISM &H) of 2002 is also significant as the policy clearly states that the conservation of medicinal plant resources and revitalization of Local health traditions are important thrust areas for promoting ISM & H in the country.

3.1.3. Legal Framework for Regulation of TISM:

The Drugs and Cosmetics Act of 1940 and the Drugs and Cosmetics Rules of 1945 govern the traditional medicines in India. The drugs under the Drugs and Cosmetic Act cover varieties of therapeutic substances, diagnostics and medical devices. As per the Act, Ayurvedic, Siddha or Unani drug includes all medicines intended for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, and manufactured exclusively in accordance with the formulae described in, the authoritative books. The rules have the role of regulating the import, manufacture, distribution and sale of drugs and cosmetics. The primary objective of the Act is to ensure that the drugs and cosmetics sold in India are safe, effective and conform to prescribed quality standards.

In India, no products derived from traditional systems can be manufactured without a license from the State Drug Control Authorities. In 1993, an expert committee appointed by the Indian Government developed guidelines for the safety and efficacy of herbal medicines which were intended to be incorporated into the Drugs and Cosmetics Act and rules. It was proposed that no new herbal medicines other than those authorized by the licensing authorities be allowed to be manufactured or marketed, except for those mentioned in and manufactured in compliance with the formulae given in the "authoritative" books for Ayurveda, Siddha and Unani herbal medicines. [30] This was in response to the lack of clinical trials and need for proven trails of medicines before it reaches domestic and international market.

In its latest addition, The Drugs and Cosmetics 4th Amendment Rule 2008 provides guidelines for evaluation of ASU drugs (Rule 170). The new rule classifies the ASU medicines into four broad categories according to which clinical study requirement is prescribed. For the ASU drugs manufactured in accordance with formula, as per the definition given in Section 3(a) of DCA, and medicines based on aqueous extracts of medicinal plants for indications, as per text, no evidence of safety and efficacy (clinical evidence) is required. However, for proprietary ASU drugs, Indian ethno-medicine–based drugs, and hydro-alcoholic extract–based drugs, safety and efficacy studies are mandatory (Sahoo Niharika et al, 2013). Clinical study is also necessary for medicines

[29] https://www.researchgate.net/publication/306351005_Government_Policies_and_Initiatives_for_Development_of_Ayurveda#pf7
[30] https://apps.who.int/medicinedocs/en/d/Jwhozip57e/4.5.html

based on aqueous extracts for new indications.[31]This aspect of the law should be reconsidered looking at the emphasis the international community gives to proper clinical trials in the sector in order to promote exports.

The Second Schedule of the Act lays down standards of quality that need to be taken care of. Similarly it lays specifications for misbranded, adulterated and spurious drugs and cosmetics. The Act also empowers Central Government to prohibit import of those drugs and cosmetics as it deems fit. But at the same time allows import of 'small' quantities of these for the purpose of examination, test or analysis or for personal use.

The Act also empowers the Central Government to prohibit import of any drug or cosmetic in public interest if it is satisfied that it's use is likely to involve any risk to human beings or animals, if it does not have the therapeutic value claimed for it or contains ingredients and in such quantity for which there is no therapeutic justification. Similarly, import of misbranded, spurious, adulterated, improperly labeled and harmful drugs and cosmetics is also prohibited.

Similarly the Government has the power to prohibit manufacture, sale and distribution of those drugs and cosmetics which don't conform to the quality standards set and/ or involve any risk to human beings or animals or that any drug does not have the therapeutic value claimed or purported to be claimed for it or contains ingredients and in such quantity for which there is no therapeutic justification and that in the public interest.

There is also a detailed provision for penalizing the concerned entity for performing functions in contradiction to the provisions of the Act, not keeping documents and records as prescribed in the rules related to the Act, non-disclosure of information as required by the Act. Inspectors appointed under the Act have been given wide ranging powers to inspect the premises, the process and even confiscate the drugs and cosmetics which do not conform to the quality standards set out by the Government.

Pharmacopoeia Commission of Indian Medicine & Homoeopathy and Ayurvedic Pharmacopoeia Committee are in place to develop the quality standards and Standard Operating Procedures for Ayurvedic medicines, which are mandatory for the manufacturers to comply with. Central and State Governments have established Drug Testing Laboratories for Ayurvedic medicines and their raw materials and 55 laboratories so far are approved or licensed in the country in accordance with the Drugs & Cosmetics Rules, 1945 for quality testing of Ayurvedic drugs. Quality certification schemes for Ayurvedic medicines are also administered as per WHO Guidelines and International Standards by Central Drug Standards Control Organization (CDSCO) and Quality Council of India (QCI) respectively. Like allopathic medicines Ayurvedic medicines are also covered under the provisions of Drugs & Magic Remedies (Objectionable Advertisements) Act,

[31]https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3868382/

1954 and Rules thereunder. Central Government has initiated pharmacovigilance system for safety monitoring of Ayurvedic medicines etc and grant in aid is provided through National AYUSH Mission to strengthen quality control activities in the states (Ministry of Ayush, 2018).

Drugs & Cosmetics Act, 1940 and Rules thereunder as on date do not have explicit provisions for the clinical trials of Ayurvedic medicines. Rule 158-B of the Drugs & Cosmetics Rules, 1945 does provide the requirement of pilot study to generate proof of safety & effectiveness of certain categories of Ayurvedic medicines. Ministry of AYUSH has published Good Clinical Practice Guidelines for conduct of clinical trials on Ayurvedic, Siddha and Unani medicines on voluntary basis.

Amendment of regulatory provisions is a continuous process and it is taken up in accordance with the felt needs and emerging trends in the quality control of natural medicinal products. Lot of thrust has been given to check manufacturing companies for compliance to Good Manufacturing Practices, prescribed Shelf-life and evidence of safety and effectiveness of drugs. Government has sanctioned additional senior level posts of regulatory positions and steps taken to set up a vertical structure for AYUSH drugs in the Central Drug Standards Control Organization headed by Drugs Controller General. Financial support is provided to the states to strengthen infrastructural and functional capacities for production, testing and quality enforcement of Ayurvedic and other traditional medicines.[32] (Katoch Dinesh, Sharma, Banerji, Biswas et al, 2016 -Journal of Ethnopharmacology).

3.1.4. Provisions of Intellectual Property Rights (IPR) under TISM:

In Ayurveda, plants are integral part of treatment and it has been used in many formulations like Churna, Kwath, tablets etc since time. Ayurveda is based on indigenous and original knowledge developed from thousands years and also codified in authentic literature like Bhava Prakasha, Charak Samhita. As mentioned in literature, Ayurveda is created by Lord Brahma and its knowledge passed on to present generation by Rishi. Thus knowledge of Ayurveda comes under traditional knowledge (TK) which needs protection and preservation so that future generation can benefit out of it. In present time, Ayurveda is practices in all part of country and treating simple to complex ailment of human body. Therefore, it is required to preserve and document TK created in past, which could lost in present time; but also to develop a system which sustain knowledge created by continuous practice of TK. Thus aspect of development in Ayurveda needs legal protection to avoid its exploitation from commercialization and fraudulent objectives.

An invention is the creation of intellect and applied to capital and labour, to protect something new and useful. Such creation becomes exclusive property of the inventor or grant of patent. The

[32] file:///C:/Users/Lenovo/Downloads/Government-policies-and-initiatives-for-development-of-Ayurveda_2017_Journal-of-Ethnopharmacology.pdf

patentee's exclusive property right over the invention is an intellectual property right (Wadhera, 2007). Traditional knowledge (TK) such as Ayurvedic medicine is knowledge accumulated from thousand years and as per patent rules, to get a patent, it must be new invention which could have industrial application. So, it is difficult to grant patent to knowledge of Ayurvedic medicine which is 'public domain'.

India has its own legal framework to protect an invention but not sufficient to protect TK. India award patent to new inventions under Indian Patent Act, 1970. Under this law patent can be granted to process but not to product. This provision in law had a huge advantage to Indian companies which captured market of developing countries by manufacturing generic drugs. After continuous pressure from US drug manufacturer, Indian parliament passed The Patent Amendment Act 2005, to bring Indian Patent Acts in full conformity with global patent structure. Section 3 of Indian Patent Acts, 2005 outlines conditions in which an invention cannot be patented.

According to Section 3(p):

An invention which in effect, is traditional knowledge or which is an aggregation or duplication of know properties of traditionally known component or components.

This section prevents misuse of Traditional Knowledge (TK) like Ayurvedic medicine to get patented. This section prevents any readymade formula of Traditional Ayurvedic medicine to get patented. Moreover, this provision does not prohibit any substantial improvement over traditional medicine to get patent after meeting prescribed criteria. This new amendment bring assuredly that patent will be granted to only those invention which would be genuine and novel and could be used for industrial application.

Up to March 2013, 86 applications were filed by foreign entities and 523 applications were filed by Indian entities for grant of patent products, formulation, compositions & processes in the field related to traditional Ayurvedic medicine, medicinal plants and herbal based formulations. Of these, 26 patents have been granted for to foreign entities and 93 patents to Indian entities.

But still, Patent Acts does not have provision to preserve Tradition Knowledge (TK). In the absence of any clear provision, how far Indian Patent Acts, 2005 will protect Ayurvedic medicine from its commercial exploitation. National and foreign companies are competing to take advantage of knowledge of Ayurvedic medicines which are in public domain because lack of single authority to look after this issue. To address this issue, Council for Scientific and Industrial Research (CSIR) a government body set up "Traditional Knowledge Digital Library" whose mandate is to assimilate non-documented and scattered literature on TK and to formally document it so that Indian patent office and foreign patent office can screen patent claims on criteria of novelty and ingenuity. Currently, TKDL is available in five languages; English, French,

German, Japanese and Spanish. TKDL is made available to patent office of many countries so that they can conduct search on subject matter before granting patent.

Furthermore, to protect invention based on biological resources, Government of India has clause of Section 6(I) of the Biological diversity Act, 2002 which requires an applicant to obtain the previous approval of the National Biodiversity Authority before applying for a patent for an invention. The process for granting such approvals by the National Biodiversity authority is carried out in consultation with the State Biodiversity Boards, if necessary. Further, the patent act, 1970 requires an applicant who applies for such patents, to obtain necessary permission from the National Biodiversity Authority and submit the same to the office of CGPDTM before the grant of patent (Choudhary & Singh, 2012).

3.1.5. Policy Initiatives and Provisions for Trade and Export of MAPs:

To facilitate export of medicinal plants and herbal products, Ministry of Commerce framed EXIM Policy. The policy provisions for MAPs were decided in consultation with the Government of India and the Management Authority for CITES implementation in the country on the basis of threats to the wild population of these plants due to indiscriminate trade.

The export-import policy of India looks at the subject on the basis of the Convention of International Trade in Endangered Species of Wild Fauna and Flora (CITES), and schedule VI of Wildlife (Protection) Act, 1972 both of which essentially lists the same six species of plants. The Wildlife (Protection) Act, 1972 prohibits picking and uprooting of listed species growing in the wild. Outside the protected areas, provides only a regulatory mechanism for six endangered plant species. Out of these only one is of medicinal value. Limited concession has been given to scheduled tribes residing in the district for their *bona fide* use.

Export and transit of wild collected and cultivated MAPs is regulated under the Forest Produce Transit Rules listed under the Indian Forest Act, 1927. These rules apply to procedures that are related for storage, transit and export of MAPs. Under this Act, each State government has been vested with the power to create their own rules to regulate the transit of forest produce including MAPs. Transit rules also provide authority to State governments to prohibit the collection and trade of forest produce obtained from a species considered to be of conservation concern in that particular State. This is in addition to the federal regulations which are applicable across the country.

3.2. Legal and Policy Framework for TCM in China

China has adopted the policy of giving equal importance to TCM right from the beginning. It made all the efforts in this direction that TCM achieve the level of western medicines and acquires important position in providing healthcare not only in China but also overseas. Article 21 of the

Constitution stipulates that the state develops medical and health undertakings and develops modern medicine and traditional medicine in China. Since 1978, the Government provided support in areas of human resources, finance, raw material supplies and rigorously promoting the development of TCM.

Following are some of the major legislations and regulations:

3.2.1. The Drug Administration Law of the People's Republic of China, 1984

This is the main law regulating manufacturing, distribution and preparation of all medicines. Pursuant to Articles 21 and 22 of the Drug Administration Law, on 1 July 1985, the Ministry of Public Health issued and implemented a regulation for the Approval of New Drugs. The regulation included general principles concerning new drugs, their classification, research, clinical trials, approval, and manufacture. This law was amended in the year 2001.

3.2.2. Regulation on Protection of Wild Medicinal Resources, 1987

The fundamental aim of this is ensuring sustainable collection of wild medicinal resources and encouraging cultivation of medicinal plants. A number of national and local nature reserves were established; research was conducted on the protection of rare and endangered Chinese medicinal resources; and artificial production or wild tending was carried out for few scarce and endangered resources. The purchase and the export of wild medicinal materials, was put under the provincial governments.

National regulation of TCM accelerated in 1992 with the **Regulations 122 on Protection of TCM which came into effect in 1993.** This regulation aims to raise the quality of all varieties of TCMs, promote the development of TCM medicine and protect the legal rights and interests of enterprises engaging in the production of TCM. Formerly, businesses could patent specific medical compounds, including TCM compounds. The Regulations on Protection of TCM protect all TCM products prepared or produced in China with minimal filing hassle. Unfortunately, due to undeveloped intellectual property laws and the general lack of awareness regarding intellectual property rights, few TCM providers patented their products in the early TCM development stage of the country. In estimation, it was foreigners who owned more than 70% of the intellectual property rights in herbal medicine globally which is the case, in other countries like India, where the indigenous traditional medicines have faced similar consequences.

3.2.3. Policy and Provisions for TCM based Healthcare Promotion

Guiding Opinions on Rural Health Reform and Development, 2001:

This sets agenda for providing primary healthcare services in rural areas. It advocated for adopting prevention oriented approach of healthcare for farmers and thus, opened window for

TCM based healthcare system in rural areas. In the training of rural health technicians, it was made necessary to strengthen the knowledge and skills of TCM (Commission, 2001).

Regulation on Traditional Chinese Medicines, 2003

This law regulated establishment of medical institutions, research and practices related to TCM, and liabilities and penalties in case of failure to subscribe to prescribed rules for the same, taking care of the need for such regulations before it got out of hands. China has strived to put in place all standards and regulations, early, so it does not have to work for taking care of the negative repercussions later as an outcome of wrong policies and programmes.

TCM was prioritized again in 2012, where the Party and the government granted greater importance to its development, making a series of major policy decisions and adopting a number of plans with this regard. The government reinstated the necessity to pay equal attention to the development of TCM and Western medicine. It also supported the development of TCM and ethnic minority medicine.

The 12th Five-Year Plan (2011-2015) explicitly states 'supporting the development of TCM and emphasizes also on paying equal attention to TCM at par with modern medicine, developing TCM medical treatment and preventive health-care services, promoting inheritance and innovation of TCM, and developing TM education and medical institutions among others. It also proposes to strengthen development of legal system on standardization and information availability of the TCM.

TCM has played a very important role in the reform of the country's medical care system. In the course of advancing the reform, TCM's distinct strengths, such as its unique role, its flexible ways of treatment and relatively low cost in disease prevention and healthcare, and its clinical effectiveness have been to a large extent made-use-of to supplement the benefits of reforms for people. The municipalities and local governments have been encouraged to make direct monetary investments in the modernization of TCM.

County-level governments and above are instructed to set up TCM institutions in public-funded general hospitals and mother and child care centers. Private investment is encouraged in these institutions. All TCM practitioners must pass tests. Apprentices and previously unlicensed specialists with considerable medical experience may only begin practice when they have recommendations from at least two qualified practitioners and pass relevant tests. Therefore the standards were made stricter for the professionals to practice TCM.[33]

[33] https://www.who.int/traditional-complementary-integrative-medicine/WhoGlobalReportOnTraditionalAndComplementaryMedicine2019.pdf?ua=1

This law has put TCM and Western medicine on equal footing in China, with better training for TCM professionals, the goal is for TCM and Western medicine learn from each other and complementing each other. It provides for setting up of TCM institutions in public-funded general hospitals and mother and child care centers by county-level government and above. Private investment will also be encouraged in these institutions. It provides for compulsory test for all TCM practitioners. The state supports TCM research and development and protects TCM intellectual property. Special protection will be given to TCM formulas that are considered state secrets.

Special protection will be given to TCM formulas that are considered state secrets. Use of technology and expansion of TCM in dealing with emergency public health incidents and diseases prevention and control should increase. The state will protect medical resources including protection and breeding of rare or endangered wildlife. Enhanced supervision of raw TCM materials, banning the use of toxic pesticides. International exchanges and cooperation on TCM should expand.

The Development Plan for TCM related Health Services (2015-2020):

Released by The General Office of the State Council, according to the plan, the key tasks includes the vigorous development of TCM related health boosting and healthcare services, the acceleration of the development of TCM-related medical services, and the support for the development of rehabilitation services with the characteristics of TCM. Specific tasks come under the plan such as support for the establishment by social efforts of regulated TCM-related health boosting and healthcare institutions, the fostering of a number of well-known reputable and technically-established TCM health boosting and healthcare service groups or chain organizations; and the encouragement of insurance companies to develop commercial healthcare insurance products such as TCM-related health boosting and healthcare/ preventive healthcare insurance, as well as a variety of medical insurance and disease insurances. The Plan emphasizes that social capitals shall have access to any area of TCM medical and health services which are not expressly banned from being accessed by social capitals. The Plan encourages social capitals to invest in and operate TCM-related medical and healthcare projects.[34]

The Healthy China 2030 Plan:

It is an important national medium- and long-term strategic plan in the health sector. It is an important medium for implementing the country's commitment to the UN 2030 Agenda for Sustainable Development. It is important to integrate healthcare delivery system moving from an extensive development mode based on scale to an intensive one focusing on quality and

[34] https://china.lexiscn.com/latest_message.php?id=175391

efficiency. The emphasis is on prevention and control of health care ailments and services. Efforts will be towards complementary development of both TCM and Western medicine, as well as overall enhancement of healthcare delivery.

3.2.4. Legal and Policy Framework for Processing and Industrial Development

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

Regulation on Traditional Chinese Medicines, 2003

This law regulated establishment of medical institutions, research and practices related to TCM, and liabilities and penalties in case of failure to subscribe to prescribed rules for the same, taking care of the need for such regulations before it got out of hands. China has strived to put in place all standards and regulations, early, so it does not have to work for taking care of the negative repercussions later as an outcome of wrong policies and programmes.

TCM was prioritized again in 2012, where the Party and the government granted greater importance to its development, making a series of major policy decisions and adopting a number of plans with this regard. The government reinstated the necessity to pay equal attention to the development of TCM and Western medicine. It also supported the development of TCM and ethnic minority medicine.

The National medium and long-term Programme for Science and Technology Development (2006-2020):

This programme sets out inheritance, innovation, modernization, and internationalization of TCM as the four basic tasks for Ministries involved in policy- making. It has further established therapy, evaluation technologies and standards of researching TCM with research development and manufacturing technologies of modern TCM as goal. It calls for a combination of classic heritage of TCM with innovations of life-science to develop TCM, therefore inculcating the best of the old and new sciences. The focus is on translating TCM into clinical effectiveness. For this, it proposes a new research model, i.e., translational Chinese medicine, to utilize global scientific and technological resources, and to facilitate Chinese medicine globalization. This step is instrumental in making TCM more acceptable for the global population.

Traditional Chinese Medicine Law, 2017:

This law is intended to provide a sound policy environment and legal basis for TCM development. It sets regulations for the TCM sector and criteria for practitioners to generate greater credibility

and competency in the sector. Among others, it also calls for protection of TCM as 'state secrets'. The law covers medical services; protection and development of Chinese medicine; education of professional talent; scientific research; heritage and cultural transmission and protection; and supporting measures; and legal obligations. The law describes establishment and improvement of regulatory system, governing TCM; and IPR protection and full supply chain quality control of medical materials.

Use of technology and expansion of TCM in dealing with emergency public health incidents and diseases prevention and control is increased. The state will ensure enhanced supervision of raw TCM materials and bans the use of toxic pesticides in production of raw material. There is expansion of international exchanges and cooperation on TCM. This law focused on encouraging TCM going global (SATCM, 2017).

The Strategic Plan on the Development of Traditional Chinese Medicine (2016-2030):

This plan makes TCM development a national strategy with systemic plans for TCM development in future. These decisions and plans have mapped out a grand blueprint that focuses on the full revitalization of TCM, accelerated reform of the medical and healthcare system, the building of a medical and healthcare system with Chinese characteristics, and the advancement of the healthy China plan, thus bringing in a new era of TCM in the country.[35]

Innovation and Development Planning Outline for Traditional Chinese Medicine (2006-2020): It called for a diversified and multichannel investment system in support of progress of the TCM, which can be formed, among others, by means of international cooperation assets.

In 2016, the state council developed a national strategy that promised universal access to the practices by 2020 and a booming industry by 2030. That strategy included supporting TCM tourism, which steers large numbers of people to clinics in China. The government planned to build 15 TCM 'model zones' similar to the one in Hainan by 2020. Beijing and Hainan pioneered TCM tourism and are actively targeting domestic and international health travelers.

The 13th Five-Year Plan (2016-2020): For bio-pharmaceutical industry which prioritizes development of medicines for major diseases, biotech medicines, new vaccines and cell therapy preparations, as well as major medical technology like 3D printing was introduced.

By 2020, China has plan to improve the medicine quality of a large number of bio-pharmaceutical enterprises to get in line with international standard and at least 100 pharmaceutical preparation enterprises obtain the authentication of American, European, Japanese countries and also the World Health Organization (WHO). Based on international medicine standard, China is promoting

[35] http://www.chinadaily.com.cn/china/2016-12/06/content_27584111_5.htm

3-5 traditional Chinese medicines to complete registration in American and European countries, and accelerate the pace to get access to the international market.

3.3. Analysis and Discussions

Both India and China have taken up various initiatives to develop legal and policy frameworks for development of MAP sector and promoting herbal based healthcare domestically and globally.

In India, the policies / legislations made whether at central or the state level have orientation to conservation, propagation, cultivation and institutionalization etc. The Standard Operating Procedures, the quality standards and the policy framework is still in its evolving phase. Not a single policy discusses about post harvesting, logistics, infrastructure and marketing aspects. Medicinal plants are still considered as a Minor Forest Produce (MFP), which again opens up a series of problems. The process of documentation and procedures to be followed for exports are complicated and time-taking which should be simplified. Since the transportation cost of perishables from landlocked states is very high, a provision to include inter-State movement in the Tax Assessment can be considered with suitable ceilings such as minimum distance/quantity/ value/ commodity. The MAPs sector comes under the jurisdiction of multiple Ministries and authorities ranging from Ministry of Environment and Forest, Ministry of AYUSH, Ministry of Agriculture and Farmer's Welfare, Ministry of Commerce and Industry, Ministry of Tribal Affairs, Ministry of Panchayat and Rural Development, etc. which made various legal and policy provisions in their respective areas. Lack of synergy in legal and policy framework of different legal authorities hinder the growth of TISM sector in the country.

According to industry experts, insufficient regulatory guidelines for different aspects of productions are an important reason for quality issues with herbals medicinal products. National Medicinal Plant Board (NMPB) developed India specific Good agricultural practices and good field collection practices in line GACP developed by World Health Organization (WHO). But main problem is poor implementation of guidelines in field and forest both. There is little awareness about these guidelines among manufacturer and traders in herbal medicines. Even companies who are following it find it difficult to implement it completely.

The application of GMP is critical for quality of the herbal medicines. The technical and nontechnical environment with regards to possible risk of adulteration and contamination, personnel, effectiveness of an independently run quality assurance system, and documentation are also critical aspects of GMP (Sahoo & Manchikanti, 2013, pp. 957-963). Schedule T of Drugs & Cosmetic Act, 1940 is deals quality control of products but need greater emphasis on quality assurance and documentation process.

Western system of medicines dominated the healthcare system in India due to its promotion from the colonial era. After independence, the same trend continued. In 1970s, Government started focusing on promotion of traditional Indian system of medicines. Overtime, India has taken several steps to protect and promote the Indian System of Medicines. However the expansion of ISM domestically and in the international market is much short of expectation. Although we claim, based on our historical anecdotes on the popularization and efficacy of ISM, we have not been able to compare favorably with China in domestic popularization and access to global market. China has made provisions for promotion of TCM in its Constitution. It talks about giving equal importance to TCM in comparison to western medicines. China has made various policy provision to integrate TCM into the education and healthcare sector. TCM was given priority in rural healthcare system through institutionalizing TCM under the grass-root healthcare. It made policy provision to treat TCM at par with western medicines and combined both the healthcare system at education, management and practice levels.

The systematic planning and outreach approach towards TCM development is evident through the policies and programmes adopted by China. China plans to provide every Chinese citizen access to basic TCM services by 2020, and by 2030 TCM services will cover all areas of medical care. The ambitious "Healthy China 2030" plan estimates that the value of the TCM market may reach 5 trillion RMB by 2030 (US$ 737.9 billion). In the domestic arena, TCM has been incorporated into the national economic and social development plans by local governments, and 28 provinces have started formulating local TCM regulations. North China's Hebei province has completed and enacted the regulation.[36]China made policy provisions for encouraging multi-national bi-pharmaceuticals to directly engage with farmers in contract farming of medicinal plants. Similarly, it has made policy provisions for multi-national bio-pharmaceutical to establish joint venture with Chinese TCM industries for co-development, production and marketing of TCM domestically and globally.

In India, although the sector has a number of legislations and policies, but the practice is alarmingly disorganized; thereby raising serious concerns regarding the quality of practice, provision of medicines and the standard of education imparted in the institutions. There have been various cases reported of fake medicines being sold and fake claims made, which have an adverse image on the status of the medicine system.

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[36]https://www.sciencedirect.com/topics/pharmacology-toxicology-and-pharmaceutical-science/traditional-chinese-medicine

Chapter 4

Production Promotion of Medicinal Plants in India and China

India and China both are rich is bio-diversity and contribute highest number of medicinal plants (about 70%) used for making herbal medicines under TISM and TCM. The demand for traditional medicines are growing domestically and globally. To conserve the valuable herbal wealth and augment production of medicinal plants both countries have undertaken several measures. The present chapter focuses on the initiatives taken up by India and China for development MAPs.

4.1. Production of Medicinal Plants in India

India is one of the 17 mega-biodiversity countries contributing about 7% of the world bio-diversity. The variation in agro-climatic conditions (India has 15 agro-climatic zones) favour the richness of bio-diversity as a result of which the medicinal plants are found occurring from Himalayan to marine and desert to rain forest eco-systems. About 18% of these medicinal plants are confined to Himalayan and Trans Himalayan zone including North East India while around 4% is restricted to Western Ghats and 0.5% is found only in the Desert zone. The rest of the species (around 77%) have a wide range of distribution across the other bio-geographic zones of the country[37]. In addition to this, away from forest areas very important medicinal plants are also found occurring as weed (e g; *Calotropis* spp*., Argemone mexicana, Adhatoda vasica, Allium Cipa, Dhatura metel, Cyprus rotandus* etc*.*)[38]

Out of 17,000-18,000 flowering plant species found in different eco-systems (forest, desert, marine, agro-ecosystems and different types of wastelands in India), about 7000 plant species have been reported being used as medicinal plants (NMPB, https://www.nmpb.nic.in/content/medicinal-plants-fact-sheet, 2019). In India, most of the medicinal herbs are collected through wild harvesting (70-80% of the total demand of industry).

Table 2: Medicinal plants: species diversity and representative species of different biogeographic zones of India (Ved et al. 2001)

Biogeographic region	Estimated no. of medicinal plants	Examples of some typical medicinal species
Trans Himalayas	700	*Ephedra geradiana* Wall., *Hippophae rhamnoides* L., *Arnebia euchroma* (Royle) John
Himalayan	2500	*Aconitum heterophyllum* Wall. ex Royle,.*Ferula jaeshkeana* Vatke and *Saussurea costus* (Balc).

[37] https://medcraveonline.com/APAR/bio-diversity-and-conservation-of-medicinal-and-aromatic-plants.html#table3

[38] https://www.nmpb.nic.in/content/medicinal-plants-fact-sheet

		Lipsch., *Nardostachys grandiflora* D.C. *Taxus wallichiana* Zucc,. *Rhododendron anthopogon* D.Dun and *Ponax pseudoginseng* Wall.
Desert	500	*Convolvulus microphyllus* Seib ex Spreng.,*Tecomella undulata* (Sm.) Seem., *citrulus colocynthis* (L.), Schrader and *Cressa crertica* L.
Semi-Arid	1000	*Commiphora wightii* (Arn.) Bhandari, *Caesalpinia bonduc* (L.) Roxb, *Balanites aegyptiaca* (L.), Delilie and *Tribulus rajasthanensis* Bhandari & Sharma.
Western Ghats	2000	*Myristica malabarica* Lam., *Garcinia indica* (Thou.) Choisy, *Utleria salicifolia* Bedd and *Vateria indica* L.
Deccan Peninsula	3000	*Pterocarpus santalinus* L.f., *Decalepis hamiltonii* Wigh & Arn, *Terminalia pallida* Brandis and *Shorea tumbuggaia* Roxb.
Gangetic Plain	1000	*Holarrhenaq pubescens* (Buch-Ham.) Wall. ex DC., *Mallotus philippensis* (Lam.) Muell –Arg., *Pluchea lanceolata* C.B. Clarke and *Peganum harmala* L.
North-East India	2000	*Aquilaria malaccensis* Lam., *Smilax glabra* Roxb., *Ambroma augusts* (L.) L.f. and *Hydnocarpus hurzii* (King) Warb.
Islands	1000	*Claophyllum inophyllum* L. *Adnanthera pavonina* L., *Barringtonia asiatica* (L.), Kurz and *Aisandra butyracea* (Roxb.), Baehni.
Coasts	500	*Rhizophora mucronata* Lam., *Acanthus ilicifolius* L., *Avicennia marina* Vierth and *Sonneratia caseolaris* (L.) engl.
Total	14200	

Source: FAO[39]

4.1.1. Conservation of MAPs under Forest Areas

Indian forest are major sources of various precious medicinal plants which occur naturally in the forest areas. The communities living in and around forest areas are gathering MAPs since time immemorial and using the same for self-health needs as we as sale in market. As per various estimates about 80% MAPs required by the industries come from natural forest. The communities have been collecting the MAPs in the traditional manner. Plant parts like leaves, bark, roots, fruits, seeds or even whole plant is indiscriminately collected from wild sources without taking care of their sustainability aspect. Many of the important species are on the list of RET (Rare, Endangered and Threatened) and some are on the verge of extinction due to unsustainable collection and habitat destruction. Demand for herbal products are increasing rapidly in domestic and international markets, as a result over-extraction of MAPs is being done by the local communities in order to fulfil growing demand of industries and to maximise their household income. The climate change phenomenon, the agricultural crops are facing frequent

[39] http://www.fao.org/3/ad871e/ad871e09.htm, Retrieved on 15 Feb 2020

failures as a result of which the gatherers are required to collect more wild materials than they used to do in normal crop years.

In order to conserve the MAPs, Government has taken-up several steps. These include framing laws for protection and conservations of natural habitats and bio-diversity, promotion of in-situ conservation including through involvement of local communities under joint forest management regime. National Bio-diversity Act and Rules (2002 – 04) made thereunder had provided for sustainable management and use practices for conservation and sustainable development of MAP resources.

Under the protection and conservation drive, protected areas such as national parks, wildlife sanctuaries, conservation reserves and community reserves were created and managed across the country keeping in view the need for protection and conservation of different species of flora and fauna.

Table 3: Protected Areas of India (July, 2019)

Protected Areas	Number	Total Area (km^2)	Coverage % of Country
National Parks (NPs)	104	40501.13	1.23
Wildlife Sanctuaries (WLSs)	551	119775.80	3.64
Conservation Reserves (CRs)	88	4356.49	0.13
Community Reserves	127	525.22	0.02
Protected Areas (PAs)	**870**	**165,158.54**	**5.02**

Source: National Wildlife Database, Wildlife Institute of India

The protection and conservation initiatives of the Forest Department and associated agencies have contributed significantly towards the conservation initiative of bio-diversity. The obvious result has been overall increase in the wildlife including the tiger population in the country.

4.1.2. Conservation and Production of Medicinal Plants through Five Years Plans

Health sector planning is one among the 13 sectors identified by Government of India for planning till the 12th Five Year Plan. AYUSH sector forms the part of health sector planning. Under the AYUSH section, detailed description regarding the medicinal plants is delineated during each Five Year Plan.[40]

During the first 5-year plan, it was felt that the systematic investigation into the herbal plants is a hard hitting job as the same is delineated in the classical texts of Ayurveda. The major areas of investigation included identification, nomenclature, geographical distribution,

[40] Planning Commission, Govt. of India. Available from: http:// www.planningcommission.gov.in/ aboutus/history/ index. php?about=aboutbdy.htm.

and the localities, where the individual herbs can be grown to the best advantage. Museums were also recommended to ensure access of information regarding all areas of herbs to the researchers and the students of Ayurveda and other indigenous system of medicine. Early action regarding the collection, storage, and distribution of Indian medicinal herbs were also recommended during first 5-year plan. It was proposed during the first 5-year plan that the investigations and research pertaining to the medicinal plants should be carried out jointly by the Central Institute for Ayurveda Research and Central Drug Research Institute, Lucknow. These should be carried out under the expert supervision of subject specialist in coordination with central agencies.[41]

The Central Institute of Research in Indigenous System of Medicine that was set-up in 1953 started working on certain areas of medicinal plants such as identification of crude ayurvedic drugs, plants, and herbs and problems associated with their cultivation. A large number of indigenous drugs are used at household level; hence, during the **third 5-year plan**, it was proposed to establish herbaria with few selected herbs locally available in the first instance in individual development blocks. Until the **ninth 5-year plan**, the department had initiated schemes for the development and cultivation of medicinal plants.

The main objective of the **ninth 5-year plan** was to augment the production of raw herbs of plant origin by providing central assistance for their cultivation and development. Several states such as Himachal Pradesh had set-up herbal gardens and linked them to production units of drugs for Indian System of Medicines and Homeopathy (ISM and H). The department has utilized three gene banks (at Delhi, Lucknow, and Trivandrum) under the Department of Biotechnology to store 2000 species of medicinal plants (Germ plasma) required for ISM and H drugs. At the village level, cultivation of medicinal plants through appropriate utilization of waste land in active collaboration with Agriculture Department, Krishi Vijnana Kendra and Department of Rural Development was proposed during the ninth plan.

Important strategies for the preservation, promotion, and cultivation of medicinal plants were made in the **tenth 5-year plan** to establish medicinal plant conservation areas covering all ecosystems, forest types, and subtypes. It proposed that ex-situ conservation of rare and endangered medicinal plants might be tried out in established gardens managed by Department of Agriculture, Horticulture, or Forests. During this plan, it was proposed that the gene banks created by the Department of Biotechnology should store the germ plasma of all medicinal plants and establish “vanaspati vans” in degraded forest areas. Strategies were made to engage technically qualified non-governmental organizations to take up the task of improving the awareness and increasing availability of plant stock and involve in the promotion of agro-techniques for cultivation of medicinal plants. Proposals were also made to establish

[41] Planning Commission Report on 1st Five-Year Plan. New Delhi: Government of India; 1951.

traditional knowledge digital library so that information on medicinal plants and their use in the country could be accessed readily and medicinal plant board for integrated development of the medicinal plants.[42]

The NMPB was functioning with a very small component of staff as an extension of the Department. Manifold increase in expenditure was made in **eleventh 5-year plan** to restructure the NMPB as an autonomous body and provide sufficient manpower to undertake its wide mandate. Two centrally sponsored components; one for cultivation, processing, and marketing of medicinal plants started from the outlay of NMPB. This will have sub-components for financial allocation: Cultivation of prioritized medicinal plant species over 75,000 hectares; raising of 50 lakh seedlings; setting up of Centralized Seed Centre and Nursery for cultivating planting materials for 15 states; setting up of six medicinal plant zones in agro-climatic zones of the country; and market development assistance fund for plan building and marketing support. The second existing central sector component is regarding program for in situ conservation, creation of gene bank for medicinal plants, ex situ conservation of prioritized medicinal plants, research and development for quality standards, and certification and program for information, education, and communication.[43]

During the **twelfth 5-year plan**, despite the efforts by the NMPB to support the projects for the conservation, cultivation, and storage of medicinal plants, only 20% of the 178 major medicinal plant species traded as raw drugs are largely sourced from cultivation.

4.1.3. CAMPA: An another Conservation and Development Initiative

The development and industrial projects such as dams, mining, industries, roads, etc., require diversion of forest land. A Compensatory Afforestation Fund Management and Planning Authority (CAMPA) has been constituted to promote afforestation and regeneration activities for compensating for forest land diverted to non-forest uses. In states State CAMPA has been constituted to receive CAMPA funds collected from user agencies towards compensatory afforestation, additional compensatory afforestation, penal compensatory afforestation, Net Present Value (NPV) and all other amounts recovered from such agencies under the Forest (Conservation) Act, 1980. These funds are utilized for compensatory afforestation, assisted natural regeneration, conservation and protection of forests, infrastructure development, wildlife conservation and protection and other related activities[44]. The forest department involves JFMCs in conservation interventions under the CAMPA fund.

Although CAMPA scheme did not specify any special emphasis on development of any particular category of plants or products, the general improvement of habitat condition after plantations of degraded forests and wastelands did support the growth of MAPs also.

[42] Planning Commission Report on 10th Five-Year Plan. New Delhi: Government of India; 2002
[43] Planning Commission Report on 11st Five-Year Plan. New Delhi: Government of India; 200
[44] http://moef.gov.in/forest-wildlife/forest-3/

4.1.4. Research and Development Initiatives for Production Promotion of MAPs

Research and Development Initiatives through ICAR:

The journey of research on MAPs in Indian Council of Agriculture Research (ICAR) system started under Plant Introduction Division of IARI way back in the fourth plan. In 1972, All India Coordinated Research Project on Medicinal and Aromatic Plants (AICRPMAP) was initiated under the ICAR to boost the research on cultivation of important plant species, considering their future importance in the global scenario.

After gaining experience of doing research on MAP for two decades, the ICAR took another historic decision to establish a **National Research Center for Medicinal and Aromatic Plants** (NRCMAP) at Anand in 1992. The idea was to give a blend of basic, strategic and applied research for popularization of the MAP cultivation in view to make the quality raw drug available to the various end users. In view of the progress made by the NRCMAP and looking into the ever growing demand of the MAP sector in primary health care as well as herbal industry, ICAR upgraded NRCMAP to **Directorate of Medicinal and Aromatic Plants Research (DMAPR)** on November 24, 1992. The aim was to facilitate efficient forward and backward integration of basic, strategic and applied research in various agro-climatic regions.

In Crop Production, work has been carried out on crops including Isabgol (*Plantago ovata Forsk.*), Opium poppy (*Papaver somniferum Linn.*), Senna (*Cassia angustifolia Vahl*), Periwinkle (*Catharanthus roseus (Linn.) G. Don*), Safed musli (*Chlorophytum spp Ker.*), Liquorice (*Glycyrrhiza glabra Linn.*), Sarpagandha (*Rauvolfia serpentina Beth. ex Kurz*), Foxglove (*Digitalis purpurea Linn. and D. lanta Ehrh*), Aswagandha (*Withania somnifera Danunal*), Khasi Kateri (*Solanum viarum Dunal*), Long pepper (*Piper longum Linn.*), Henbane (*Hyoscyamus niger Linn.*), Palmarosa (*Cymbopogon martinii var. Motia*), Vetiver (*Vetiveria zizanioides (l.) Nash*), Mints (*Mentha spp*), Babchi (*Psoralea corylifolia Linn.*), Kalmegh (*Andrographis paniculata Nees*), Lavender (*Lavender officinalis Chaix*), Melisa (*Melissa officinalis Linn.*), Salvia (*Salvia scalarea Linn.*), Giloe (*Tinospora cordifolia*).

Under Crop Improvement focus is on Plant Genetic Resource (PGR) Management and Varietal Development. Importance of PGR activities were recognized in the project and was taken up on priority at all the AICRP centers for exhaustive collection, evaluation, conservation and documentation of germplasm of medicinal and aromatic plants. This activity has also been included in the mandate of the ongoing National Agricultural Technology Project of Plant Biodiversity. Valuable genetic stocks of Aswagandha (48), Geranium (6), Isabgol (47), Khasi kateri (7), Long pepper (64), Liquorice (5), Periwinkle (8), Valeriana (40), Vetiver (37), Guggal (50), Henbane (14), Kacholam (12), Mucuna (44), Safed musli (52), Aloe (72), Asparagus (9), Gentiana (12), Tinospora (12), Heracleum (10), Jasmine (109), Patchouli (7), Sylibum (10) and Coleus (13)

are maintained at various AICRP centers and NRCMAPs. The evaluation and characterization of these accessions are in continuous process.

In Varietal Development Multi-location evaluation trials conducted under the AICRP on MAPs have resulted in the identification and release of twenty five new improved varieties of medicinal plants of fourteen species and seven varieties of aromatic plants of six species.

Table 4: Development of New Varieties of MAPs

S. No.	Crop	Variety	Developed At	Year Of Release
Medicinal Plants				
1	*Chlorophytum borivilianum (Safed musli)*	JS405	Mandsaur	2004
2	*Cassia angustifolia (Senna)*	Anand Late Selection	Anand	1989
3	*Diascoria floribunda*	FB(C)-1	Bangalore	1974
4	*Diascoria floribunda*	Arka Upakar	Bangalore	1980
5	*Digitalis lanata (Foxglove)*	D.76	Solan	1991
6	*Glaucium flavum (Yellow Horned Poppy)*	H47-3	Solan	1991
7	*Glycyrrhiza glabra (Liquorice)*	Haryana Mulhatti-1	Hisar	1989
8	*Hyoscyamus muticus (Egyptian Henbane)*	HMI-80-1	Indore	–
9	*Lepidium sativum (Cress)*	GA-1	Anand	1998
10	*Rauvolfia serpentina (Sarpagandha)*	RI-1	Indore	–
11	*Papaver somniferum (Opium poppy)*	Jawahar Aphim 16	Mandsaur	1984
12	*Papaver somniferum (Opium poppy)*	Kirtiman	Faizabad	1990
13	*Papaver somniferum (Opium poppy)*	Jawahar Aphim 16	Mandsaur	1997
14	*Papaver somniferum (Opium poppy)*	Jawahar Aphim 16	Mandsaur	1998
15	*Papaver somniferum (Opium poppy)*	Chetak Aphim	Udaipur	1994
16	*Papaver somniferum (Opium poppy)*	Trisna	Delhi	–
17	*Piper longum (Long pepper)*	Viswam	Trichur	1996
18	*Plantago ovata (Isabgol)*	Gujarat Isabgol- 1	Anand	1976
19	*Plantago ovata (Isabgol)*	Gujarat Isabgol- 2	Anand	1983
20	*Plantago ovata (Isabgol)*	Haryana Isabgol-5	Hisar	1989
21	*Plantago ovata (Isabgol)*	Jawahar Isabgol-4	Mandsaur	1996
22	*Solanum laciniatum*	NH 88-12	Solan	1991
23	*Solanum viarum (Khasi Kateri)*	Arka Sanjeevani	Bangalore	1989
24	*Solanum viarum (Khasi Kateri)*	Arka Mahima	Bangalore	1992
25	*Withania somnifera (Aswagandha)*	Jawahar Asgand-20	Mandsaur	1989
26	*Withania somnifera (Aswagandha)*	Jawahar Asgand-134	Mandsaur	1998

Aromatic Plants				
1	*Cymbopogon flexuosus (Lemon Grass)*	NLG-84	Faizabad	1994
2	*C. martinii Var. Motia (Palmarosa)*	Rosha Grass-49	Hisar	1989
3	*C. martinii Var. Motia (Palmarosa)*	CI-80-68	Indore	–
4	*Jasminum grandiflorum (Jasmine)*	Arka Surabhi	Bangalore	1993
5	*Mentha spicata (Spearmint)*	Punjab Spearmint-1	Solan	1991
6	*Valeriana jatamansi (Mushakbala)*	Dalhousi Clone	Solan	1994
7	*Vetiveria zizanioides (Vetiver)*	Hyb-8	Mandsaur	–

In Crop Protection limited work on disease and insect pest management has been done. Under its Field Gene Bank component, the DMAPR is maintaining 830 Germplasm of species of MAPs in our gene bank. These are:[45]

Table 5: Germplasm Development of MAPs

Species Name	No. of Germplasm
Aloe spp.	55
Andrographis paniculata	60
Asparagus spp.	80
Cassia angustifolia	50
Chlorophytum borivilianum	54
Commiphora wightii	154
Cymbopogon martini	07
Desmodium gangeticum	52
Gymnema sylvestre	43
Plantago ovata	84
Tinospora cordifolia	35
Urgenia spp.	12
Withania somnifera	140
Total	**830**

R & D Initiatives through Council for Scientific and Industrial Research:

Council for Scientific and Industrial Research (CSIR), has also played a significant role in cultivation of medicinal plants, through Central Institute of Medicinal and Aromatic Plants (CIMAP), Lucknow. CIMAP focuses on agro-technology as well as basic studies; improvement and enhancement of the resource base, and chemistry and related research regarding product development from plants.

[45] https://www.dmapr.org.in/category/research/ as accessed on March 07, 2020.

The Central Government also initiated a five year program (1992-1997) implemented by the Ministry of Agriculture to accelerate research and development of medicinal plants. With the support of 16 state agricultural universities, state horticulture and agriculture departments, regional research laboratories and the International Crop Research Institute for the Semi-Arid Tropics (ICRISAT), the GOI is establishing herbal gardens, nursery centers and demonstration seed production centers nation-wide.

4.1.5. Establishment of National Medicinal Plants Board (NMPB) to Promote MAP Sector

The Medicinal Plants Board was setup under Ministry of AYUSH in 2000 as central agency to coordinate and manage issues related to promotion of medicinal plants in the country. The Board has been given the responsibility of coordinating with Ministries/Department/ Organizations/State/UT Governments for development of medicinal plants in general and specifically undertaking various activities relating to promotion of in-situ and ex-situ cultivation and conservation of medicinal plants; demand and supply analysis for medicinal plants; data base generation and information dissemination; advice for policy formulation; support for value addition, trade and export of medicinal plants; Capacity building of primary collectors and producers, implementing various schemes with state authorities; undertaking and awarding scientific, technological research and cost effectiveness studies; Development of protocols for cultivation and control; Encouraging the protection of Patent Rights and IPR; etc.

Schemes of AYUSH for Development of MAP Sector:

Ministry of AYUSH along with NMPB initiated set of schemes for development of MAPs and herbal based healthcare in country. The Central Sector Scheme on Conservation, Development and Sustainable Management of Medicinal Plants are looking to streamlining several aspects to the related subject, these initiatives will help organize information and plan activities systematically through its reference. Some of these aspects are as follows:

1) Documenting trade practices
2) Generating information on wholesale prices, arrivals and trends in different markets to benefit both growers and buyers
3) Establishing communication network for speedy collection and dissemination of market data for its efficient and timely utilization
4) Preparing farmer's advisories and issuing the same for the Benefit of farmers towards optimizing returns
5) Developing Databases of Cultivators and Cultivars
6) Integrating and mainstreaming of Medicinal Plants through call centres including Kisan call centres initiatives of Ministry of Agriculture

7) Putting in place an appropriate pricing regime in respect of produce sourced from wild v/s cultivation in favour of cultivated material so as to encourage cultivation and reduce pressure on the natural resources
8) Streamlining of HS Codes
9) In order to cater to the domestic market needs of ASU industry, promotion of primary producer companies (PPCs) would be taken-up in a focused manner.
10) Promotion and information dissemination through IT dedicated mechanisms for procurement of MAPs
11) Network of Agri Mandis for MAPs
12) Database of Cultivators
13) Contract Extractions (PHM)
14) Specialty Warehousing & Supply Chain development
15) Integration of all Portals with techno Trade Exchange
16) Integration with Krishak Call Centres, KVKs etc.[46]

Schemes and guidelines for financial assistance in different areas of medicinal plants sector is covered under Promotional and Commercial schemes applicable both for Government and non-government organizations. (i) **Promotional scheme** mainly includes survey, conservation, herbal gardens, extension activities, demand-supply studies, R&D, value addition, etc.; and (ii) **Commercial scheme** mainly includes production of quality planting material, large scale cultivation, post-harvest technology studies, innovative marketing mechanism, etc.

Scheme for Conservation, Development and Sustainable Management of Medicinal Plants, being taken up by the Ministry of AYUSH:

The outreach and acceptability of AYUSH systems, both nationally as well as globally, are dependent on uninterrupted availability of quality medicinal plants based raw material. Ministry of AYUSH has provided a comprehensive scheme and guideline for development of medicinal plants sector. It focused on promotion of cultivation of MAPs through cluster development in the vicinity of forest areas where the ago-climatic condition suits for particular medicinal plant species. The schemes attempt to support cultivation of medicinal plants in the farming systems involving farmers and their collectives, promote Good Agricultural and Collection Practices (GACPs) to promote standardization and quality assurance and thereby enhance acceptability of the AYUSH systems globally and increase exports of value added items like herbal extracts, phyto-chemicals, dietary supplements, cosmeceuticals and other AYUSH products. It Support setting up processing clusters through convergence of cultivation, warehousing, value addition and marketing and development of infrastructure for entrepreneurs to set up units in such clusters.

[46] https://www.nmpb.nic.in/content/schemesproposals

Implement and support certification mechanism for quality standards, promote partnership, convergence and synergy among stakeholders involved in R&D, processing and marketing in the public as well as private sector at national, regional, state and sub state level[47].

Scheme for in-situ Resource Augmentation:

Assisted natural regeneration or artificial re-generation of local populations of medicinal and aromatic plant species for conservation of genetic diversity of medicinal plants, thereby complementing the other biodiversity preservation and climate change mitigation interventions being implemented by the country as part of its international obligations.

The major activities being undertake under this schemes have been summarized below-

In-situ resource augmentation of medicinal species through assisted natural regeneration. Artificial re-generation of local populations of medicinal and aromatic plant species is particularly important in case of species where wild populations have dwindled on account of habitat degradation, and unsustainable harvest. Active interest and engagement of rural communities in such a conservation program is instrumental to address sustainability of the medicinal plant sector as a whole, hence financial support is provided for community mobilization through entry point activities.

4.1.6. In-situ Conservation and ex-situ Cultivation of MAPs

Medicinal plants are not only the main resource base for traditional medicine and herbal industry but it also provided livelihood, health and food security to a large population dependent on it. In the recent times there has been an increasing demand for medicinal plants both for domestic as well as global level. Therefore, in order to meet the increasing demand MAPs, the Board has been focusing on both in-situ conservation and ex-situ development.

In-situ conservation deals with the conservation of the wild genetic resources/genetic diversity in natural habitat. This is done through the conservation of forest areas. Further, in the forest areas a number of conservation initiatives were taken which include establishment of Medicinal Plants Conservation and Development Area's (MPCDA's) which has been in short also known as Medicinal Plants Conservation Areas (MPCAs). It also provides strength/up-gradation of already existing MPCA's by means of survey & inventory, documentation, protection and main streaming in habitat management approaches (NMPB, 2019). The management of these MPCAs were not continued after cessation of funding support. As a result, some MPCAs although could be traced in the forest areas a number of them have been obliterated, included in the felling coupes. In

[47]National AYUSH Mission, Operational Guidelines, Medicinal Plants, Department of AYUSH, Government of India

both cases, the status of improvement of MAPs is not reported and therefore, it is difficult to make any judgement thereof.

Table 6: Development of MPCDAs

States	2013-2014		2014-2015		2015-2016		2016-2017	
	Released Amount	No. of MPCDAs	Released Amount	No. of MPCDAs	Released Amount	No. of MPCDAs	Released Amount	No. of MPCDAs
Jharkhand	-	-	60.00	4.00	-	-	-	-
Karnataka	-	-	64.40	1.00	-	-	-	-
Maharashtra	12.00	4.00	43.32	7.00	-	-	-	-
Madhya Pradesh	-	-	-	-	343.89	10.00	40.00	10.00
Tamil Nadu	61.00	8.00	-	-	-	-	30.00	4.00
West Bengal	84.00	7.00	-	-	-	-	31.20	7.00
India	**157.00**	**19.00**	**167.72**	**12.00**	**343.89**	**10.00**	**101.20**	**21.00**
Source : Lok Sabha Unstarred Question No. 746, dated on 07.02.2017[48].								

In response to an un-starred Lok Sabha question number 746 dated 07.02.2017, the information on number of MPCDAs in 06 states have been replied by Ministry of AYUSH. However, the information for many prominent medicinal plants rich states such as Chhattisgarh, Arunachal Pradesh, Uttrakhand, Odisha, etc., have not been included. In fact, MPCDAs were created under centrally sponsored scheme throughout the country. However, the information on their status is not available at NMPB website.

Under MPCDA (Medicinal Plants Conservation and Development Areas) which is a centrally sponsored scheme implemented by NMPB during 2014-15 to 2015-16 and 2016-17, the Board spent a sum of Rs. 45.67 crores, 27.8 crores and 42.87 crores respectively[49]. From this it is clear that the investment was not uniform in past three years. Further, the impact of these investments in term of conservation and ecological conditions of MPCDAs is not recorded. In fact, the details of MPCDAs created over past decade and half are not available. There is need to have detailed accounts of conditions of MPCDAs so as to enable NMPB take a view on their continuation or otherwise. In the absence of details of past assessment on aspects of species conservation and their benefits to the sector it is difficult to assume that everything is good condition.

Ex-situ development includes cultivation of medicinal plants outside forest areas, creation of medicinal plant gardens, nurseries, home-gardens, school nurseries, private nurseries, etc.

[48] Selected State-wise Funds Released and Number of Medicinal Plants Conservation and Development Areas (MPCDAs) Supported under Central Sector Scheme for Conservation Development and Sustainable Management of Medicinal Plants in India (2013-2014 to 2016-2017), Lok Sabha Unstarred Question No. 746, dated on 07.02.2017

[49] https://pib.gov.in/newsite/mbErel.aspx?relid=169918

Under schemes promoted by NMPB cultivation of 55 plant varieties are eligible for 30 per cent subsidy, 27 for 50 per cent subsidy and 13 plants for 75 per cent subsidy.[50] The Board has also promoted establishment of 397 nurseries across India through its various project.[51]

During the period 2008-09 to 2015-16 the Board has supported 1065 projects for cultivation of 105 species covering an area of 184,365.54 ha. Species wise coverage of area reveals that top three species have been Ashwagandha (*Withania somnifera*), Coleus (*Coleus barbatus Benth*) and Tulsi (*Ocimum sanctum*) and bottom three are Pathinugam, Patang (*Caesalpenia sappan*) and Baibidang. Area covered by these species under the projects supported by NMPB is given below:

Table 7: Coverage of area by top three and bottom three species under NMPB supported projects

S. No.	Species	Cumulative Area (ha.)
	Top three species (area wise)	
1	Ashwagandha (Withania somnifera)	28,081.94
2	Coleus (Coleus barbatus Benth)	21,249.11
3	Tulsi (Ocimum sanctum)	19,892.84
	Bottom three species (area wise)	
1	Pathinugam	1.00
2	Patang (Caesalpenia sappan)	0.99
3	Baibidang	0.40

State wise coverage of area as detailed in table below reveals that Madhya Pradesh, Tamil Nadu, Karnataka, Andhra Pradesh and Nagaland are the top 5 states whereas Himachal Pradesh, Telangana, Bihar, Tripura and Jammu and Kashmir are at the bottom 5. [52]

Table 8: Area coverage in top five and bottom five states under NMPB supported projects

State	Area covered (in ha.)
Top five state in terms of area covered	
Madhya Pradesh	38367.22
Tamil Nadu	29529.37
Karnataka	21938.76
Andhra Pradesh	21183.27
Nagaland	19437.13
Bottom five state in terms of area covered	
Himachal Pradesh	434.30
Telangana	345.00

[50] https://www.nmpb.nic.in/content/medicinal-plant-component as accessed on 7th March 2020
[51] https://www.nmpb.nic.in/nursery-developed as accessed on 7th March 2020
[52] https://www.nmpb.nic.in/cultivation-status as accessed on March 7, 2020

Bihar	194.70
Tripura	45.00
Jammu and Kashmir	21.00

Box 1: Ex-situ MAP Development Initiative of Chhattisgarh SMPB

Ex-situ Development Initiative of Chhattisgarh Medicinal Plants Board: Case Study
The "Aonla Campaign" Project is undergoing for plantation of 12 Lakhs sapling and popularization of Aonla products.

Several herbal gardens are being promoted and developed through the Board in collaboration with the Government, Non-government and private sector. Institutional herbal garden are being promoted. There is scope for school herbal garden which are also being encouraged under the aegis of the Board. The tradition of oral knowledge of herbal healers is under threat as subsequent generation doesn't want to follow the profession. It is necessary to identify and recognize the traditional herbal healers. Their status is being identified & documented in different districts all over the State by the Board. Between the years 2011-2014, the Board & traditional healers together guided nearly 50,000 families to develop 'Home Herbal Gardens' in Chhattisgarh. The UNDP is also supporting the documentation of this knowledge through People's Biodiversity Registers. Training of traditional herbal healers is also being done regularly to keep them abreast with the trends and needs of the sector.

The Government has been promoting cultivation of medicinal plants in identified and designated areas within the districts of selected states which have the potential for it. Good Agricultural and Collection Practices (GACPs) are promoted for the purpose of meeting international certification and marketing standards.

The high value medicinal plants have poor density and required to be cultivated ex-situ on a larger scale and over extensive areas so that the pressure of collection from the wild is reduced. This is a safe bet as a conservation strategy but without sufficient original plant base for plantation, it can be a challenge. However, the availability of medicinal plant seedling of indigenous varieties along with commercial ones and existing seed banks are not sufficient. To ensure the production of quality planting material a number of training programmes have been organized across the country on medicinal plant cultivation, processing and marketing.

4.1.7. Conservation Initiatives through Multi-lateral and Bi-lateral Cooperation

The Government of India and State Governments have undertaken afforestation and regeneration programs with their own resources and also with support from multi-lateral and bi-lateral cooperation. Special projects have been taken.

Initiative of In-situ and Ex-situ Conservation of MAPs: GEF Project Implemented by MoEF, UNDP and NMPB (2008-15):

UNDP initiated an innovative project namely Mainstreaming Conservation and Sustainable Use of Medicinal Plant Diversity in Three Indian States which aimed to mainstream long-term conservation and sustainable use of India's medicinal plants into forest management policy and practice at the national, state and local levels in three Indian states: Arunachal Pradesh in north-eastern India, Chhattisgarh in central India and Uttarakhand in north-western India. These states represent India's enormous medicinal and aromatic plant diversity and are home to more than 30 Globally Significant Medicinal Plants (GSMPS). The project has demonstrated replicable models of in-situ and ex-situ conservation and promoted cultivation of highly traded Medicinal Plants. Institutional mechanisms have been put in place towards sustainable harvest and use of medicinal plants by facilitating the state governments in establishing Biodiversity Management Committees and building their capacities to prepare biodiversity registers and community protocols.

Twenty Medicinal Plants Conservation Development Areas covering 24,047 hectare, were developed in three project states which also includes conservation of 32 GSMPs. The three project states have undertaken plantation of various medicinal plants including GSMPs on 13,130 hectare.

The project led to incorporation of MAPs development and the practices of sustainable management under their planning processes (UNDP, 2015).

Conservation and Development of MAPs through JICA Assisted Forestry Projects:

Similarly, large scale project for forest resources conservation and management have been initiated with funding support from JICA (Japan International Cooperation Agency) since 1991 with an ODA Loan for 'Afforestation and Pasture Development Project along Indira Gandhi Canal Area' in Rajasthan. Since then, the support has been extended to 27 projects which include 25 ODA Loan projects and 2 Technical Cooperation projects. Japanese ODA loan has been extended to 14 states, which include Rajasthan, Gujarat, Tamil Nadu, Karnataka, Punjab, Haryana, Odisha, Himachal Pradesh, Tripura, Uttar Pradesh, Sikkim, West Bengal, Uttarakhand and Nagaland, making Japan the largest donor in the forestry sector in India. In is important to work for the livelihood of forest dependent communities many of them are tribal who have been dependent on forest for livelihood and health needs. JICA provided support for blending forest resource management with sustainable livelihood improvement of local communities through Joint Forest Management (JFM) approach (JICA, 2019). Apart from general forestry development activities, the project placed adequate emphasis on development and sustainable management of NTFPs including MAPs because it was related to improvement of livelihood base of communities.

Table 9: JICA Assisted Forestry Projects in India

S. No.	Name of Project	Loan Amount JPY Million	Loan Agreement (Year)	Loan Completion (Year)
1	Afforestation and Pasture Development Project along Indira Gandhi Canal Area	7,869	1991	2002
2	Afforestation Project In Aravalli Hills	8,095	1992	2000

3	Rajasthan Forestry Development Project	4,219	1995	2002
4	Gujarat Afforestation and Development Project (I)	15,760	1996	2004
5	Eastern Karnataka Afforestation Project	15,968	1997	2005
6	Tamil Nadu Afforestation Project (I)	13,324	1997	2005
7	Punjab Afforestation Project (I)	6,193	1997	2003
8	Punjab Afforestation Project (II)	5,054	2003	2009
9	Rajasthan Forestry and Biodiversity Project (I)	9,054	2003	2010
10	Haryana Integrated Natural Resource Management and Poverty Reduction Project	6,280	2004	2014
11	Tamil Nadu Afforestation Project (II)	9,818	2005	2015
12	Karnataka Forest Management and Biodiversity Conservation	15,209	2005	2015
13	Swan River Integrated Watershed Management Project	3,493	2006	2016
14	Orissa Forestry Sector Development Project	13,937	2006	2016
15	Tripura Forest Environmental Improvement Project	7,725	2007	2017
16	Gujarat Forestry Development Project Phase 2	17,521	2007	2017
17	Uttar Pradesh Participatory Forest Management Project	13,345	2008	2018
18	Capacity Development For Forest Management & Personnel Training Project (Executed by MoEF)	5,241	2008	2018
	Technical Cooperation Project			
19	Project for Capacity Building of State Forest Training Institutions and Central Academy for State Forest Services (CASFOS)		2009	2014

Box 2: Setting up of NTFPs based Centre of Excellence

Case of Tripura: Setting-up of NTFPs Centre of Excellence under JICA Assisted Forestry Project
Development of NTFPs for livelihood of forest dwelling communities was an important component of first phase of JICA project. This has also received emphasis in the second phase of the project also. Apart from development of several other medicinal plants in the state, the emphasis has been on Sugandhmantri (*Homalomena aromatica Schott*), a least attended but high potential economic plant resource of Tripura and other north-eastern states, Agar oil, Black Turmeric (kali Haldi), (*Cassia ceasia*) and many other medicinal plants. Other plants although managed for improved livelihoods were broom-grass and bamboo sticks for incense-sticks – Agarbati etc.

Centre of Excellence continues as an independent society created by Tripura government for development of medicinal plants and other NTFPs for employment and income of forest dwelling communities.

Box 3: Market Linkages of MAP Producer Farmers with Industry

Case Study of Uttrakhand: Market Linkages Development for MAPs
Memorandum of Understanding (MoU) with Patanjali he Project has signed a MoU with Patanjali, a leading FMCG company, based on Ayurveda. The MoU aims at developing Non-Timber Forest Products (NTFPs) and Medicinal Plant resource in each VP for creating a permanent source of revenue for them. Patanjali would provide necessary technical and market linkages for the same. This step will also go a long way in empowering VPs, which is one of the hallmarks of the Project.

4.1.8. Industry led Production Initiatives under Contract Farming Arrangement

Herbal industry has been used to procuring medicinal plants through a network of traders but the sector is developing an intellect for contract cultivation slowly. The increasing demand – supply gap and supply of adulterated raw material in some cases forced the herbal drug manufacturers in the country to create sources of regular supply of quality raw materials. Direct involvement of the industries in cultivation and procurement of raw materials is slowly becoming a rising trend.

The Arya Vaidya Sala, in Kottakal, Kerala, in addition to maintaining two large herbal gardens, has also undertaken research on the propagation of 10 species, the demand for which currently outstrips supply, or may soon do so. The company planned its research and production efforts in such as that they remain complementary to that of the government initiatives.

Other traditional drug manufacturers in India have also begun to invest in cultivation experiments and developments. Some of the companies are undertaking R&D programs through the creation of company foundations, such as the Zandu Foundation for Health Care in Mumbai and the Shree Dhootapapeshwar Ayurvedic Research Foundation in Bangalore and Panvel. These companies are actively involved in the development of cultivation methods of medicinal plants of importance to them, with the direct participation and partnership of local farmers and tribal

women. All such efforts will result in an increase in the number of medicinal plant species cultivated, particularly indigenous Indian species.[53]

Initiative of Dabur for Cultivation of Medicinal Plants:

Dabur has taken the lead in preserving and growing some of the herbs which are endangered and whose supply is going down. Its biodiversity initiatives involve farmers, tribal and forest-based communities across the country, taking them along in this mission to not just arrest the decline in the production of these rare herbs but also increase their population.

It has identified environmentally sensitive species of medicinal plants and herbs, and developed methodologies to address their sustainability concerns. The company uses 249 medicinal and aromatic plants (MAPs) for various Ayurvedic and natural preparations. Of these, they have identified 100 MAPs as being critical to their operations in terms of their availability, value and volume. Through its biodiversity initiatives, they have put in place direct interventions for either cultivating or sustainably collecting 58 of these 100 critical MAPs. In 17 species of MAPs, Dabur is 100% self-sufficient in a way that the entire requirement of these 17 herbs is managed through its biodiversity programme and interventions.

Under this programme, they engage with marginal farmers in cultivation of these herbs and MAPs, providing them visible economic opportunities and supplementing their income. They undertake special training programmes for farmers, villagers and tribal communities to train them on sustainable and environment-friendly cultivation processes.

Initiative of Himalaya for Cultivation of Medicinal Plants:

Similarly, another big name in the Indian herbal industry, the Himalaya Drug Company tied up with one of its key suppliers, Gram Mooligai Co. Ltd, to set up a 75-acre nursery of high active ingredient plant species near Madurai in Tamil Nadu. By 2015, Himalaya aimed to source 70% of its raw materials through cultivation. Besides paying a one-time fee of Rs. 7.5 lakh to Gram Mooligai, which supplies 60% of its raw stock, Himalaya has put in the cost of testing mass cultivation of some herbs. Gram Mooligai owned by medicinal plant gatherers and small cultivators logged sales in lakhs. It makes seeds of tested herbs available for free to farmers who could grow them in between their regular crops and supply the produce to Himalaya (Choudhary et al, 2012) (Choudhary, Goyal, Khokra , & Kaur, 2012).

[53]The Medicinal Plants Sector in India: A Review; Jason Holley and Kiran Cherla; South Asia Regional Office, IDRC, Canada; Medicinal and Aromatic Plants Program in Asia (MAPPA); New Delhi; 1998

Initiative of Semi Labs:

Reiterating its commitment to contract farming for medicinal plants, Semi Labs acquired more than 20,000 acres of land in various parts of the country. Company utilizes this land for growing nearly 20 varieties of medicinal plants. As part of company contract farming commitment, it provides technical expertise, facilitate loans and insures crops by entering into a buy-back agreement with farmers. The company spends nearly 10 per cent of its revenues on R&D, while it buys cultivated material worth more than Rs. 20 crore from farmers every year.[54]

Ageing populations in Europe or the US are moving towards herbal products for The company has already identified land in AP, Uttaranchal, Tamil Nadu, Karnataka and Maharashtra. Rs 3 crore has been earmarked for these land acquisitions. Company will utilise this land for growing nearly 20 varieties of medicinal plants. As part of company contract farming commitment, it will also provide technical expertise, facilitate loans and insure crops by entering into a buyback agreement with farmers. Company has already obtained permission from the government of Uttaranchal for contract farming of medicinal plants. Sami Labs spends nearly 9 per cent of its revenues on R&D, while it buys cultivated material worth Rs 20 crore from farmers every year (Choudhary, Goyal, Khokra , & Kaur, 2012).

4.1.9. Production Potential of MAP

The various initiatives taken up by NMPB, Corporates and other agencies to promote cultivation of MAPs have resulted in increasing number of farmers coming forward for MAP cultivation. However, the initiatives of cultivation of MAPs are scattered and also lacking economy of scale. In some of the states such as Rajasthan, Uttar Pradesh, Madhya Pradesh, Tamil Nadu, Punjab, Chhattisgarh, etc., farmers have taken up cultivation of MAPs. The state of Rajasthan has promoted cultivation of Ashwagandha, Isabgol, Kalmegh, Giloy, Aloe Vera, Aonla, etc. which resulted in meeting the demands of industries across the country. However, in the states which are located in Himalayan ranges including north-eastern states, central India and western ghats, wherein the MAPs production occur naturally the emphasis on cultivation has been on low key despite the area offering best habitat conditions for MAPs cultivation. This also applies to the states in central India where the wild material continues to make good bulk of the industries demand.

Despite the best efforts of NMPB and other agencies the cultivation of MAPs has not been commensurate with the pace of cultivation in China. The reported data from India is over 0.655 million hectares. The figure for China stands at 3.5 million hectares. The Chinese also have substantial natural forests which have a number of medicinal plants. However, they try to

[54] http://pharmaerudition.org/ContentPaper/2012/2(2)%2040-44.pdf

conserve and manage their wild resources much better with strict rules and regulations. At the same time they continue to expand area under cultivation so as to meet the growing demand of industries. India also has relevant rules and protocols to conserve and ensure sustainable management of wild resources but probably the compliance to many rules at field level is short of expectation.

Table 10: Production of MAPs in India

States	Area (In ' 000 Hectare)	Production (In ' 000 MT)	Productivity (In MT/Hectare)
Rajasthan	416.14	382.98	0.92
Tamil Nadu	15.14	232.73	15.37
Madhya Pradesh	38.16	90.79	2.38
Chhattisgarh	9.67	67.53	6.98
Uttar Pradesh	135.04	13.53	0.10
Andhra Pradesh	6.50	11.00	1.69
Karnataka	1.71	9.47	5.54
Punjab	13.20	2.79	0.21
Bihar	6.79	2.68	0.39
Haryana	0.32	1.08	3.38
Himachal Pradesh	1.12	0.91	0.81
Nagaland	0.13	0.88	6.77
Mizoram	0.77	0.78	1.01
Odisha	1.92	0.61	0.32
Telangana	0.05	0.44	8.80
Maharashtra	0.41	0.22	0.54
Assam	4.53	0.17	0.04
Arunachal Pradesh	0.24	0.16	0.67
Manipur	0.04	0.12	3.00
Jammu and Kashmir	3.83	0.01	0.00
Others	0.00	0.00	-
India	**655.72**	**818.89**	**1.25**

Source: Ministry of Agriculture and Farmers Welfare, Govt. of India. (ON2224)[55]

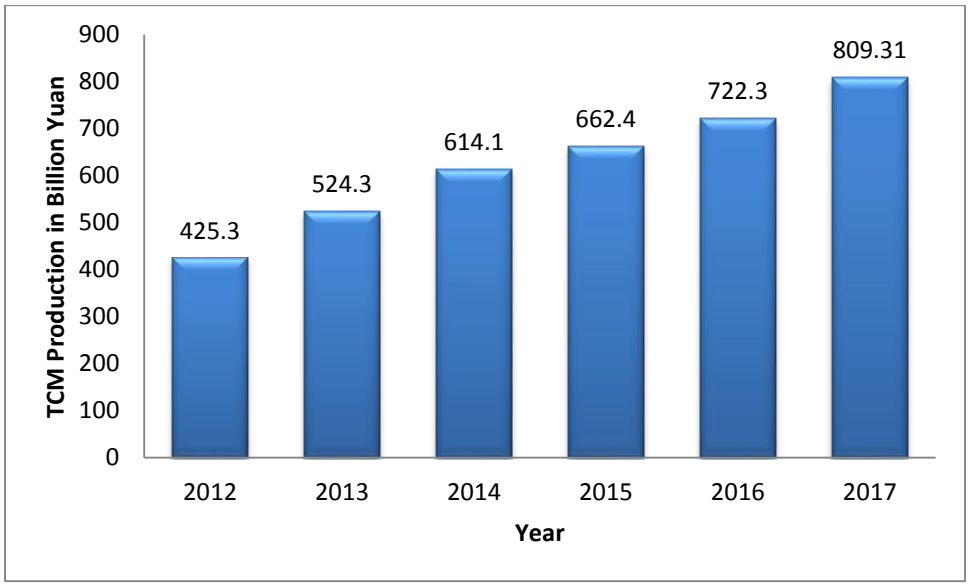
4.2 Production of Medicinal Plants in China

The country's production area of traditional Chinese medicines is more than 3,496,933.33 hectares, with large reserves (Liu, Wang, & Duan, 2018). But yet, the natural reserves in forests cannot meet the ever increasing demand. The wild herbal resources are also reducing every year. In China, about 1,800–2,100 of total 11,146 species of medicinal plants that have been endangered and 20% of all commonly used herbs were facing shortage. The species most in

[55] Selected State-wise Area, Production and Productivity of Medicinal and Aromatic Plants in India (2018-2019-3rd Advance Estimates), Ministry of Agriculture and Farmers Welfare, Govt. of India. (ON2224)

demand are the ones most negatively impacted. Most herbs can recover naturally, but the speed does not match with the consumption. (Li Xiwen et al, 2015)

Year wise TCM Production in billion Yuan



(Source: https://www.statista.com/statistics/988851/china-traditional-chinese-medicine-tcm-production-value/)

Although, in respect of cultivation, China is much ahead of India (China – 3.5 million ha against India's 0.65 million ha) both countries continue to have large dependence on wild resources. The compliance instruments on sustainable management are available in both countries but their field compliance is reportedly better in China than in India. Both countries access about 80% of industries requirements from natural forests.

In order to fulfill the growing industrial demand for raw material, the wild sources have their own limitation. Over exploitation led to degradation of natural resources and many of the important medicinal plant species have reached the stage of extinction. Therefore, Government has taken up several initiatives for promotion of cultivation of TCM other than wild harvesting of medicinal plants, the other techniques which have been adopted for cultivation are natural fostering methods used as production method of cultivation in vicinity of forest areas. Artificial breeding is another method which is being carried out for production, though it is done on a small scale. (Li Xiwen et al, 2015)

4.2.1. Regulatory regime for improving TCM production in China

Setting up protected areas has been found to be one of the most effective ways to protect biodiversity in situ. To better protect the TCM resources, the Chinese government launched the

overall plan of Chinese medicinal materials protection and development (2015–2020) in 2015[56]. Identifying conservation priority areas for threatened wild medicinal plants and animals is an important task of the plan.

Nature reserves in China are established mainly to protect representative natural ecosystems, rare wild animals and plants, or special significant natural sites, which cover approximately 14.8% of the country's total landmass.

To better protect plant diversity in China, the Ministry of Environmental Protection of the People's Republic of China (2013) organized an evaluation of the conservation status of plant species in China based on the International Union for Conservation of Nature (IUCN) Red List Categories and Criteria (Version 3.1, IUCN, 2001) and Application of the IUCN Red List Criteria at Regional Levels (Version 3.0, IUCN, 2003). In this evaluation, 3767 higher plant species (including species, subspecies, variety and form, the same hereinafter) were identified as threatened, including 583 critically endangered (CR), 1297 endangered (EN), and 1887 vulnerable (VU) species[57].

To protect its biodiversity, China had established 2729 nature reserves in approximately 1590 counties in mainland China by the end of 2014, including 428 national, 858 provincial and 1443 municipal nature reserves[58].

The government of China has brought forward several laws and regulations which were enacted and implemented for strengthening the protection of TCM wild medicinal resources; and artificial production or wild tending have been carried out for certain scarce and endangered resources. Farms producing raw ingredients must comply with State Drug Administration (SDA)-imposed standards in China.[59] The laws specifically note the additional requirements such as sourcing, cultivation, ecological environment, collection, handling, processing, and preparation information which are included in the pre-trial testing phase for TCM.[60] The Government promotes good regulatory practices to ensure supply of high-quality and affordable health products and continued research is facilitated for bettering technologies.

The Government adopted Good Agricultural Practices (GAPs) and Good Manufacturing Practices (GMPs). The GAP guidelines suggest selection of the correct germplasm with high content of stable active components. The cultivation practices offer Standard Operating Procedures (SOPs) for use of fertilizers,

[56] The State Council General Office of the People's Republic of China, 2015
[57] Natural Ecosystem Protection Office of Ministry of Environmental Protection of the People's Republic of China, 2014
[58] Chi Xiulian; China Academy of Chinese Medical Sciences Threatened medicinal plants in China: Distributions and conservation priorities, Yu Tian; Chinese Research Academy of Environmental Sciences et al.,2017
[59] https://www.hindujagruti.org/hinduism/global-market-position-ayurvedic-products
[60] China policies to promote local production of pharmaceutical products and protect public health. Geneva: World Health Organization

irrigation systems and disease management allied with insects and pest prevention and cure. GAPs also establish standards for noxious and harmful contaminants like heavy metals, pesticide residues and microbes in plants.

A vital step to address degradation of TCM resources is a detailed survey of the distribution and population sizes of plant resources throughout China. There are already a number of activities addressing the problem. These include the flora of China project, which is co-supported by the Chinese Academy of Sciences and the National Science Foundation of China. The project was started in 1989, and the resulting series of books (Wu Z-Y and Raven 1990–2009, Wu Z-Y et al. 1990–2010) is jointly edited by botanists from China and America. The series is based partly on a translation of the Chinese edition of the flora of China (Editorial Board of the Flora of China 1959–2004) but this version is updated and extended (Li D and Huang 2006), aiming to provide a thorough overview of plant species in China. In collaboration with eight additional agencies and with financial support from the Ministry of Finance, the Ministry of Environment Protection also set up the China Important Species Survey Project in 2004, with the goal of establishing the distribution and state of economically and environmentally important species and their habitats. These steps are taken with the aim to create solid knowledge platform, with in-depth inventories covering all protected areas, as well as all rare and endangered species.

There are already more than 140 botanical gardens distributed throughout China by 2005, these are part of ex-situ conservation approach of the country (Sang & Axmacher, September 2011).

4.2.1. Conservation and Production of Medicinal Plants in China

Wild Collection:

The Chinese government has taken up several steps to improve ecological environment for protecting the Chinese herbal habitat. The lack of wild herbal collecting plan, biomes' destruction, and degraded ecologic environment are becoming more and more serious. Some medicinal plants have been successfully cultivated, but their wild species can still no longer be found within the latest decades of years. Such circumstances can restrict the genuine medicinal plants selection from wild resources for breeding purpose. The fast degrading environment lowers the recovery speed of wild herbal plants out of which some cannot be recovered at all because of the damage to their natural environment.

For wild harvesting, the quality of medicinal herbs is determined by factors such as identification, time of harvesting, harvesting methods and transportation. Harvesting methods should avoid damage to harvested material and to surrounding herbs. The ideal quantity of harvested herbal material should be scientifically considered and balanced, to allow for sustainability. The period of harvesting is important as the effective chemical contents of herbs vary seasonally and climatically, which will impact on biological activity of the decoctions derived from the herbal

material. The effects of global warming on plant cultivation, sustainability and quality will also have to be considered in the coming years.[61]

The wild collection carried out is also not scientific. The cultivators generally have low education with little knowledge on sustainable utilization of resources. Therefore the method of wild collection alone cannot guarantee sustainable development of Chinese medicinal plant resources (Li, et al., 2014).

Cultivation:

In order to supplement the wild collection of medicinal plants, cultivation is being taken up on a large scale. In China, the area of herbal cultivation has increased from 400,000 hm2 in 1950s to 9,330,000 hm2 by the year 2014. There were altogether 200 herbs that can be artificially cultivated, 100 of which have achieved large-scale cultivation. The output of herbal production by cultivation has reached 400,000 tons per year. The yield of 200 usually used Chinese herbal medicine from cultivation accounted for more than 60% of the whole market demand per year in China. In particular some herbs such as ginseng and noto ginseng were provided absolutely by cultivation. [62]

Cultivation also has an economic benefit, with new industries and employment models emerging, and guaranteeing the supply for the expanding and substantial Chinese and/or global markets. However, negative impact is that the natural diversity of the gene pool for wild resources is reducing due to the standardization of mass cultivation practices (Zhang Bengang et al, 2010) which lead to variety degeneration. Pesticide residues and the heavy metal pollution due to cultivation under single species population are other problems arising out of large scale cultivation of medicinal plants. Higher costs can be associated with the construction of the special environment needed for mass cultivation, but the economic and ecological benefits of cultivation versus wild harvesting is also recognized (Zhang Bengang et al, 2010). Therefore research and scientific enquiries are ongoing for seeking more innovative methods for increasing medicinal plant production to meet the growing demands in China.

Natural Fostering Model of Production: Natural fostering mainly focuses on increasing the raw medicinal materials in its original habitats. It is a combination of wild collection and cultivation. It does not change the basic community trait of original habitat. Natural fostering unites industrialized production of TCM and ecological protection. This method has been carried out in many Chinese herbs, such as Fritillaria cirrhosa, F. unibracteata, Glycyrrhiza uralensis, G. inflate, G. glabra, Panaxginseng,Ephedrasinica,E.intermedia,Coptischinensis, C. deltoidea, C. teeta, Gastrodia elata, Saussurea involucrata, and Cordyceps sinensis. More than 19 Chinese herbs have

[61] https://www.kew.org/science/projects/chinese-medicinal-plants-and-their-materia-medica
[62] https://www.hindawi.com/journals/ecam/2015/218901/

been used to produce raw materials through natural fostering and among which 12 herbs have realized large scale production. The key advantage of natural fostering is that the herbal quality from its output is very close to that from wild collection. Profit motivation was the main reason to prompt farmers to implement this method of cultivation, for example, the income from fostering Coptis was 15 times higher than the one from planting crops. [63]

The method focus is not only to increase population density of the species but also to involve as little human intervention as possible in the process. In comparison to cultivation, it can to a large extent, reduce economic input, and can provide high quality raw materials without negatively influencing the natural environment. The biodiversity in fostering regions is also being increased. Forest breeding is also a method of natural fostering.

But this method cannot completely replace other methods of cultivation. Natural fostering method can be implemented in the species original habitat, and in many cases are mountainous and difficult regions, for which the cost of man-power and other requirements for production can be very high. It also has long production cycle and there are technological imperfections in the method which needs to be looked at first.[64] Its technology is still not mature and the germplasm for natural fostering has not been identified completely. The scale of production is not as large as artificial cultivation and stays at the primary phrase. There are number of experimental project of natural fostering in China, but they are still limited due to lack of basic studies.[65]

More attention has been directed on the value of combined method from a holistic perspective, exploring the feasibility to solve the conflict between biodiversity and economy. Therefore, the sustainability of Chinese herbal resources should depend on systematic combination of wild collection, cultivation, and natural fostering, with comprehensive consideration of medical demand and herbal growth characteristics.

[63] https://www.hindawi.com/journals/ecam/2015/218901/
[64] https://www.hindawi.com/journals/ecam/2015/218901/
[65] https://www.hindawi.com/journals/ecam/2015/218901/

(Zhang Bengang et al, 2010)

4.2.3. Initiatives for Promotion of Production of Medicinal Plants

Good Agriculture Practice (GAP)

In order to meet international standards and improve production, GAP is being implemented widely in China. This approach aims to standardize cultivation, collection and processing of TCM herbs, improving their quality and therefore being significant in the modernization and internationalization of TCM.

The State Food and Drug Administration of China (SFDA) put forward GAP for TCM for the first time in November 1998. GAP for Chinese Crude Drugs became official in 2002 and enacted in June of the same year. In order to effectively implement GAPS for TCM herbs, SFDA formulated and enacted the "Management Measures of Chinese Crude Drug GAP Certification" (Provincial) and "Chinese Crude Drug GAP Certification Evaluation Criteria" (Provincial) in September 2003, which symbolized the commencement of the standardization of TCM herb production in China.[66]

The Chinese Central Government has been given adequate support to implement GAP for TCM herbs, resulting in rapid development of GAP for TCM herbs and the Chinese TCM industry.[67]

- The government financially supported technical research of standardized planting (breeding) of species of TCM herbs with key technologies and R & D Programme of the 9th and 10th five year plan.

[66] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4213821/
[67] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4449915/

- In addition, standardized planting of TCM herbs and a related research program have been sponsored by the National Development and Reform Commission, SATCM, Ministry of Science and Technology. Owing to the generous support, there is remarkable progress on technical research of standardized planting of TCM herbs.
- Several influential books were published, such as Guidelines for Good Agricultural Practice for Chinese Crude Drugs. GAP production base of TCM herbs certification,
- The Government support has effectively mobilized enterprises to implement GAP since the "Management Measures of Chinese Crude Drug GAP Certification" was approved by the State Council. By the year 2010, 22 provinces/municipalities had established standardized TCM herb planting bases. A total of 99 GAP bases were formally adopted by GAP Certification covering 49 species of TCM herbs which are currently cultivated in these GAP bases.
- The area of plantations is also growing rapidly.
- GAP base certification effectively addresses the problem of substandard medicinal material production in China and helps to bring medicinal material production onto the track of standardization.
- GAP implementation is widely recognized by TCM enterprises and the cultivator's implementation of GAP for TCM herbs had a tremendous impact on people's traditional ideas, leading to "traditional Chinese medicine production being extensively changed from small-scale farmer's production".
- The cultivators are giving attention to the quality of TCM herbs, and the importance of their standardized production has become more salient.[68]

Implementation of GAP has changed the TCM herb production practice characterized formerly by disorderly development, lack of government regulation, and extensive farming that remained since the 1980s. It resolved many longtime problems with TCM herb production activities, such as germplasm resource background confusion, substandard production processes, and abuse of pesticides and chemical fertilizers.

GAP approach is an important measure for industrialization of TCM. Standardization, commercial scale and industrialized production of TCM herbs is a prerequisite for their use in pharmaceuticals companies. The whole process of production is regulated through GAP approach.

It involves the following:

1) Ecological environment of the production site: At the production base, producers should rationally select their production sites based on local conditions of soil fertility, soil contaminants, cultivation history, location and setting of the site, with special attention given

[68] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4449915/

to the recommended production area of geo-authentic crude drugs (Dao Di). A total of 99 bases of GAP for TCM herbs (49 species) were certified before 2010 by SFDA. The choice of the bases to plant TCM herbs by the GAP approach followed aspects related to GAP for the TCM herbs under consideration, that is, natural distribution area of the original species, cultivation and domestication history, the level of socioeconomic development, human culture, and social environment. For safety's sake, requirements have been imposed on the quality of soil, farm irrigation water, and animal drinking water of the production sites. The environmental conditions of the production sites should meet the requirements of the related national standards: "Atmospheric Conditions Standard (GB 3095-1996)", Grade 2 for air quality; "Soil Quality Standard (GB 15628-1995)", Grade 2 for soil; "Farm Irrigation Water Standard (GB 5084-92)", Grade 2 for irrigation; "Drinking Water Standard (GB 5749-85)" for animal drinking water.

2) Germplasm and propagation materials: At first, propagation materials should be identified accurately as to their relevant taxonomic rank. Homonyms and synonyms of TCM herbs are very common in TCM. Therefore, the adopted and Latin names of TCM herbs should be clearly recorded to avoid nomenclatural confusion. Secondly, the germplasm of propagation materials should be paid more attention to in practice. Many cultivars of medicinal plants with good agronomic traits have been selected and bred during the long cultivation history of China, such as Rehmannia glutinosa cv. "Jin Zhuang Yuan" and R. glutinosa cv. "Xiao Hei Ying". They have significant differences in stress resistance and yield. Finally, when certain species have different secondary metabolites in different populations, the propagation materials should be well chosen. The reason lies in the fact that different ecological factors could cause diverse secondary metabolic pathways.
3) Cultivation and feeding management: TCM herb cultivation management demands formulating standard operating procedures (SOPs) for the production technology. The contents of SOPs include a fertilizing program, irrigation technology, pest control measure, determination methods, and limitation standards of toxic and harmful substances in TCM herbs, as well as application of specific fertilizers for TCM herb cultivation and pesticide residue standards. Medicinal animal feeding and management also require developing SOPs, including the condition of facilities, health management, feed, feed additives, drinking water, disease prevention and control.
4) Harvesting and primary processing: Requirements are formulated on the harvesting period, harvesting equipment and processing sites, and post-harvest processing techniques. SOPs for harvesting and processing are required to be formulated. Wild medicinal resource utilization should be well planned according to the principle of sustainable use. Such methods as wild fostering, interval harvesting, planting young seedlings to replace harvested herbs, etc., are being explored for adoption to achieve the benefits both of medicinal resource conservation and economic interest. Based on scientific research and traditional experiences, any parts of

plant and animal organ or secretion could be used as TCM herbs depending on where the effective medicinal ingredients are accumulated. Collected parts should be not arbitrarily altered in the collection process. Appropriate collection time (season and years) and methods should be determined in accordance with the quality and yield of the plants. For example, the best collection time of Panax ginseng is at the sixth year of growth, which is proved by research comparing the accumulating value of the effective ingredient and yield of the medicinal part annually. Machines and tools for collection should be kept clean and free of contamination, and stored in a dry place inaccessible for insects, rodents, poultry, and livestock. In the course of collection and primary processing, non-medicinal portions and foreign matter should be removed, especially weeds and toxic substances. Damaged and perished parts should be excluded. After being collected, the medicinal parts should be selected, washed, cut, or trimmed. Those that need drying should be dried timely by using appropriate methods and techniques, with controlled temperature and humidity. The use of antioxidant agents and preservatives should be avoided. If used, they must conform to the national regulatory requirements on food additives (GB 2760-1996). Processing sites should be clean and well ventilated and fitted with awnings, canopies, and devices to prevent the entry of insects, rodents, poultry, and livestock. **Geo-authentic crude drugs should be processed according to traditional methods. Any change in methods should be based on sufficient experimental data, and should not affect the quality of the TCM herbs.**

5) Packaging, transportation, and storage: Specific requirements have been defined for packaging materials and methods, condition of the transporting containers and the warehouse for crude drug storage. Prior to packaging, crude drugs should be checked and substandard ones as well as foreign matter should be eliminated. The packaging materials to be used should be clean, dry, uncontaminated and undamaged, and conform to the quality requirements for crude drugs. On each package of the crude drugs, the product name, specification, production site, batch number, packaging date, and the name of producer should be indicated and a sign for qualified products should be marked. Fragile crude drugs should be packaged in hard boxes. Poisonous/toxic, narcotic, and precious crude drugs should be specially packaged, and appropriately marked. Containers should be well-aerated to keep the crude drugs dry, and moisture proof measures should be in place. Measures to prevent entry into the warehouse from insects, rodents, poultry, and livestock should be taken.
6) Quality management: Quality inspection is conducted according to the standards for TCM herbs approved by the government, including Pharmacopoeia of the PRC and Drug Standard of Ministry of Public Health of the PRC. Those TCM herbs without quality inspection of national standards should comply with related standards of local governments. The testing items should at least cover macroscopic characters and identification of crude drugs, impurities, moisture content, total ash content and acid insoluble ash content, extracts and efficacious contents. Pesticide residue, heavy metal, and microbiological limits should comply

with the Green Standards of Medicinal Plants and Preparations for Foreign Trade and Economy of Ministry of Commerce of the PRC. Personnel and facilities: The responsible persons for technology and quality management of a producer are the key personnel for implementing GAP for TCM herbs. They should meet the requirements for educational background, qualification, professional knowledge, and capability to resolve practical issues and problems in production and quality management processes.

7) Documentation: Management and SOPs, quality standards, testing rules, and quality control procedures should all be documented in detail and distributed to the relevant user and operators for training and implementation. These documents are targeted to ensure GAP implementation in a dynamic and orderly manner, as well as traceability of quality management of TCM herbs. [69]

4.2.4. Industrialization of TCM herbs supported through GAP implementation

Industrialization of TCM herbs was catalyzed by GAP implementation in the country. Standardization became the mainstream aspect of TCM herb production bases. According to preliminary statistics, Sichuan, Shaanxi, Gansu, Yunnan, Jilin, Henan, Anhui, and Guangdong provinces have completed more than 50 standardized TCM herb production bases.

Meanwhile, medium- and large-sized pharmaceutical industry establishments began building their own medicinal material plantations, which rapidly drove production of TCM herbs towards industrialization and effectively drew dispersed farmers together through market mechanisms. Thus, a modern agricultural production model consisting of company + plantation + farmers was introduced into the TCM herb production practice, thereby effectively facilitating intensive and large-scale production of TCM herbs in the country and resulting in rapid and sound development of TCM herb production.

The Wild tending techniques were applied in GAP for TCM herbs. Along with the implementation and promotion of GAP for TCM herbs, a number of medicinal materials which formerly had to rely on wild resources, such as Gastrodia elata, Pinellia ternata, Bupleurum chinense, Gentiana scabra, Ledebouriella divaricata, Schisandra chinensis, Citrus grandis, Tripterygium wilfordii, Pueraria lobata, Glycyrrhiza uralensis, Ephedra sinica, Cistanche deserticola, Saussureae involucratae, etc. have been introduced and cultivated on a large scale. The technology for wild tending, such as Fritillaria cirrhosa and Cordyceps sinensis, has been getting mature; GAP base construction has been rapidly developed. The plantations of Gastrodia elata, Gentiana scabra, and Schisandra chinensis have been adopted by national certification of GAP production bases of TCM herbs.

[69] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4213821/

The gradual internationalization of TCM, helped draw learning's from the international medical fields. **Through implementation and spread of GAP, many countries began understanding and accepting TCM, leading to a steady increase in the export of TCM products from China.**

4.2.5. Unique Agricultural (TCM) Production Model

In China, the medicine enterprises prefer building their factories close to the fostering area in order to reduce transportation cost. Most of the TCM production companies are beginning to recognize the supply crisis of raw medicinal materials.[70]

Currently, most of TCM herb plantations in the country run the operational model of company + plantation + farmers, in which the company usually cooperates with the research institutes to provide technical support and guide the whole process of production management of TCM herbs. Farmers are made to follow GAP requirements and given technical trainings as and when required.

The herbal geographical distribution covers different longitude, latitude, and altitude in China. Different ecological habitat causes different genuine medicinal materials. The government is also committed to encourage wherever possible, geo-authentic crude TCM drugs which are recognized by the general public for their long history, high quality, and curative effect; they are produced under certain natural conditions using particular production technology and processing techniques. Geo-authentic crude drugs are usually named after their places of origin, for example, Sichuan Coptis chinensis (Chuan Huang Lian), Zhejiang Fritillaria thunbergii (Zhe Bei Mu), Liaoning Schisandra chinensis (Liao Wu Wei), and Henan Dioscorea opposita (Huai Shan Yao). Suitable ecological environment, excellent germplasm resources, and time-tested production and processing techniques are the basic elements in formation and development of geo-authentic crude drugs.

Although the regulations of GAP for TCM herbs do not stipulate that TCM herbs have to be cultivated in the place of origin, it specifies that a "suitable location of cultivation shall be determined according to the requirements of growth and development of medicinal plants." Therefore the location of base and germplasm of TCM herbs are selected strictly according to place of origin and suitability of the species or cultivars so as to ensure the high quality of TCM herbs.

The formation of this model is mainly due to the economic structure in rural areas, a labor allocation system, and the natural environment of mountainous areas. This model is not the best one from the perspective of standardization as required by GAP.

[70] https://www.hindawi.com/journals/ecam/2015/218901/

Therefore, rural cooperatives, intensive farming and plantation, and specialized corporate planters have become the main direction of standardization of TCM herbs production.

The Chinese foreign direct investment (FDI) regulations have recently been updated to include removal of joint-venture requirements for cultivation of herbs for TCM production. TCM is looked as a new source of growth in China's economy, especially rural economy. The planting of Chinese medicinal herbs has become an important addition to the rural industrial structure benefitting the environment along with farmers' incomes. The provinces such as Hebei, Guizhou, Yunnan, Sichuan, Shaanxi and Shanxi have designated traditional medicine as a pillar industry in China.

4.3. Discussion and Analysis

According to IUCN and WWF there are between 15,000 and 18,000 flowering plant species used for medicinal purposes worldwide. The plant based raw materials are used for manufacturing herbal as well as allopathic drugs. In India, the herbal drug material has also been primary raw material for other forms of Indian System of Medicines (ISM) as well as AYUSH.

China has over 11,000 plant species which is highest in the world followed by India with about 7,500 plants. Although China has maximum number of plants India has maximum species known for a variety of medicinal uses. Further, In India there is common saying that every plant has one or the other medicinal use.

The richness of India’s flora and fauna is attributed to varied agro-climatic conditions. India enjoys (15 agri-climatic zones) which favours rich eco-system bio-diversity. As a result of favourable habitat conditions there are 14,200 plants found in 10 bio-geographic regions (FAO). The medicinal plants are found occurring from Himalaya to Marine and Desert to Rain-forest eco-system. In China, there are only four agro-climatic regions with more uniform habitat conditions. This is probably the reason that despite large number species found here have less number of plants used for medicinal purposes.

Medicinal plants generally been occurring in the natural eco-system namely natural forest, cultivated wastelands, wastelands, water bodies, deserts, etc. These natural eco-systems generally met almost entire supply of raw material to existing pharmacies and industries till about 1980s. Gradually, with the allopathic drugs becoming expensive and out of reach to 30 to 40% population in the rural hinter lands as also due to reported side effects of western medicines more and more herbal pharmacies and industries came of be established across the country. This put a lot pressure on supplies from natural forests. Many species became threatened and were categorized under RED list of IUCN. The herbal industries faced acute shorted of supply of raw material from natural forest and other search eco-systems. Mail practices such as raw material

adulteration, substitution, late Government to promote domestication and cultivation particularly of species having thin density and in large demands.

The central Government faced with the problem of short supply of raw material and also the forest degradation placed attention on conservation and sustainable of MAP resources through Five Year Plans. A number of initiatives in this direction were taken (up to 12th Five year Plan) to conserve the natural resources through sustainable management and used practices. The key question was to make available the raw material to industries and at the same time to protect the interest of gatherers to get remunerative price for their collection. These gatherers were mostly tribal communities, particularly women who constituted about 70% of all gatherers were dependent on MAP gathering from forest areas in their vicinity. Also, there have been emphasis in all Government schemes to ensure that local Vaidyas and Traditional Healers are not deprived of medicinal herbs for primary natural healthcare.

In order to address the above concerns, the Ministry of AYUSH established a dedicated institutional mechanism in the form NMPB at Central Government level. At state level, 36 SMPBs were promoted to be established for development of MAP resources. The Indian initiative for conservation of MAP resources has been strengthening of protected areas and MPCDAs, Voluntary Certification Scheme for ensuring good field collection practices (GFCP). These are being promoted by NMPB with the support QCI.

The classical Indian healthcare systems, however, continue to be largely dependent upon wild collected herbal raw material with nearly 80% of the species diversity and more than 70% of the volumes of herbal raw drugs consumed being sourced from the wild. NMPB's program to promote medicinal plant cultivation was noted to have made a significant contribution in facilitating the cultivation of medicinal plants in the form of providing financial support, building confidence and in supporting CBOs towards hand holding of the farmers. Cultivation of Red Listed species was noted to be still at an exploratory phase of cultivation, and would need more support to firmly entrench such cultivation in local agricultural processing.[71]

In India and China both the important development strategy for popularization of TISM and TCM were i) sustainable management and use of natural forest and other eco-system and ii) ex-situ conservation and cultivation. In India, contract farming has been promoted between industries and farmers. In this model, more than Government, the initiatives have been industry led. In case of China, the initiatives are through Government regulations and campaigning. China adopted

[71] https://www.nmpb.nic.in/sites/default/files/Projects/Medicinal_Plants_in_India_An_Assessment_of_their_Demand_and_Supply.pdf

the natural fostering which the farmers and their farms – industry and research institutes were linked for holistic cycle of production, processing and marketing. This unique model of ex-situ cultivation of medicinal plants using GAPs in partnership of farmers, industry and research institute have contributed significantly in productivity enhancement, quality production of MAPs as per industry needs and increasing income of primary producers. India can also think on similar lines for production of MAPs in their natural habitat.

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Chapter 5

Development of TISM and TCM

The demand for herbal products are increasing in domestic and global markets both on account of high cost and side effects of allopathic medicines and therefore, there is need to promote manufacturing high quality herbal healthcare products to meet the needs of increasing population worldwide. The also provides an opportunity to reduce Government expenses on public healthcare and open up a window for countries like India and China to develop their economy through promotion of manufacturing base and thereby livelihood for the rural communities. Assessing the same, both India and China have made various efforts for development of processing and manufacturing of traditional medicines. The present chapter deals with the initiatives taken up in India and China for manufacturing promotion and issues being faced for the same.

5.1. Development of TISM in India

5.1.1. Demand for Herbal Medicines

The Indian classical and the folk health care traditions have dependence upon the raw material derived from a large diversity of plant species on the basis of which several traditional and complementary medicines are made.

The first serious attempt at national level to assess the demand and supply of medicinal plants in the country was made by the National Medicinal Plant Board during 2001-02, when it commissioned a study through The Center for Research, Planning & Action (CERPA) to understand annual trade levels of selected 162 medicinal plant species. The NMPB, thereafter in 2006-07 commissioned a national study to assess demand and supply of medicinal plants in India. That study, carried out by FRLHT, for the first time brought various intricacies in the herbal sector to the fore and added to the understanding of the subject.

To assess the current Demand and Supply scenario of medicinal plants, NMPB has extensively surveyed the herbal market of India in collaboration with ICFRE, Dehradun. The estimate of consolidated commercial demand of herbal raw drugs for the year 2014-15 has been estimated at 5,12,000 MT. Estimated Exports of Herbal Raw Drugs, including Extracts has been estimated 1,34,500 MT in 2014-15. Estimated Consumption by Domestic Herbal Industry has been estimated 1, 95,000 MT 2014-15.[72] An Estimated 1, 67,500 MT of Herbal Raw Drugs are also used

[72] https://www.nmpb.nic.in/content/medicinal-plants-fact-sheet

by Rural Households every year. About 1178 medicinal plant species recorded in the practices of trade. Out of which, 242 plant species are used in annual quantities of more than 100MT.[73]

Consumption of herbal raw drugs by folk healers and traditional practitioners who prefer to dispense medicines has also been prepared. The average annual usage of herbal raw drugs by the sampled folk healers worked out to 109 kg but this data could not be extrapolated and added to the total demand of the herbal raw drugs in the country for want of reliable information on the total number of such folk practitioners in India.

The estimated annual demand of herbal raw drugs for the year 2014-15 has registered an increase of 62 percent in volume over the estimation of similar demand worked out by Ved and Goraya (2008) for the year 2005-06. The major increase has been in case of exports where the exported volume of botanical drugs increased from 56,500 MT in 2005-06 to 1, 34,500 MT in 2014-15, i.e. more than doubled with an increase of 138 percent. Isabgol (Plantago ovata), Chakoda/ Powad Beej (Senna tora) and Sonpaa (Senna alexandrina) were recorded as the top three exported botanical drugs with export volumes of >32,000 MT, >28,000 MT and >13,000 MT respectively during the year 2014-15. In respect of botanical drugs consumed by the domestic herbal industry, Ghritkumari (Aloe vera) with an estimated consumption of 15,700 MT (dry wt.) during 2014-15, was the highest consumed herbal raw drug. Amla (Phyllanthus emblica) with estimated consumption of 14,200 MT, Isabgol (Plantago ovata) with estimated consumption of 13,700 MT and Harad (Terminalia chebula) with estimated consumption of 6,000 MT during the same period, are the other important herbal raw drugs consumed in larger quantities.

Estimated Annual Trade Value of Herbal Raw Drugs in the Country:

The trade volume of 5,12,000 MT of botanical raw drugs, estimated to be consumed in the country during the year 2014-15, works out to around 7,000 crores (> one billion USD). The herbal raw drug sector in the country is on a path of growth riding on the growth of herbal based wellness industry, registering an annual growth of more than 10% between 2004-05 and 2014-15. The total demand of herbal raw drugs is expected to grow to 6,50,000 MT by the year 2020. In view of the increasing demand of wellness products, the export value of the herbal raw drugs has the potential to maintain the current rate of growth of about 20% per annum.

The major increase has been in respect of the export which has increased from 354.80 crore in 2005-06 to 3211 crore in 2014-15, registering more than eight fold increase in ten years. The

[73] https://www.nmpb.nic.in/content/demand-and-supply-position-medicinal-plants

trade value of herbal raw drugs consumed by the domestic herbal industry has also registered more than two fold increase as per the latest estimates.

Demand of Herbal raw drugs through the domestic herbal industry:

The domestic herbal industry has increasingly engaged in the manufacture of wellness related patent and proprietary OTC formulations towards addressing wellness related issues like obesity, diabetes, joint pains, skin care, hair care, etc. There was an increasing trend towards use of 'extracts' as evidenced from the use of extracts of about 500 species, with major use of extracts in wellness formulations.

The cultivation of medicinal plants by number of species and area under cultivation has shown an increase. The major species in cultivation were recorded to be Isabgol (Plantago ovata), Ghritkumari (Aloe vera), Vever (Chrysoopogon zizanioides), Senna (Senna alexnadrina), Ashwagandha (Withania somnifera), Bach (Acorus calamus), Tulasi (Ocimum tenuiflorum), Pippali/ Pippalmool (Piper longum), Kuth (Saussurea costus), Pushkarmool (Inula racemosa), Mentha (Mentha spp.). The major driver of cultivation seemed to be the units engaged in making 'extracts', the herbal units engaged in making very specific formulations that requires large volume of limited number of species with consistent quality, and the firms engaged in export of herbal raw drugs.

5.1.2. Processing and Industrial Development for TISM in India

5.1.2.1. Initiatives for Processing of Medicinal Plants under Five Year Plans

After independence, the traditional system of medicines attracted attention of Government as a large section of population especially rural communities continued to depend on this. Hence, AYUSH sector forms the part of health sector planning.[74] Government established Central Institute of Research in Indigenous System of Medicine in 1953 to undertake research in areas relating to crude ayurvedic drugs, plants/ herbs and problems associated with their cultivation. A large number of indigenous drugs are used at household level; hence, during the **third 5-year plan**, it was proposed to establish facilities for manufacturing and standardizing homeopathic drugs.[75] Clinical research on several drugs of various Indian systems of medicine, collection and propagation of medicinal plants, and standardization of drugs was encouraged during the **seventh and eighth 5-year plans**.[76]

[74] Planning Commission, Govt. of India. Available from: http:// www.planningcommission.gov.in/ aboutus/history/ index. php?about=aboutbdy.htm.

[75] Planning Commission Report on 3rd Five-Year Plan. New Delhi: Government of India; 1961

[76] Planning Commission Report on 6th Five-Year Plan. New Delhi: Government of India; 1980 and Planning Commission Report on 7th Five-Year Plan. New Delhi: Government of India; 1985

Pharmacopoeial committees were established on respective AYUSH drugs and by the end of eleventh 5-year plan standards for around 40% of the raw materials and around 15% of formulations have been published by these committees. AYUSH Department intends to convert pharmacopoeial committees of various systems into a modern pharmacopeial commission with adequate representation of stakeholders. This is directed toward the development of standards those are in line with internationally acceptable pharmacopoeial standards and quality parameters of Ayurveda, Siddha, and Unani drugs.

During the **twelfth 5-year plan**, it was observed that albeit considerable progress has been made in documenting identity and quality standards of herbal medicines, scientific validation of AYUSH principles, remedies, and therapies has not progressed. Despite the efforts by the NMPB to support the projects for the conservation, cultivation, and storage of medicinal plants, only 20% of the 178 major medicinal plant species traded as raw drugs are largely sourced from cultivation. During the twelfth plan, nine AYUSH industry clusters through "special purpose vehicle" having common facility centers for manufacturing and testing of AYUSH medicines are set-up in eight states.[77] Furthermore, the Indian Public Health Standards released by Government of India delineates that locally available medicinal herbs/plants should be grown around the sub center as per the guidelines of Department of AYUSH.[78][79]

The government had sanctioned **10 AYUSH Industry Clusters during the 11th Plan Period** (2007-12). Out of these, 3 Clusters, one each at Kerala, Punjab and Rajasthan have been completed. Development of AYUSH Cluster Scheme has been approved for continuation in the 12th Plan period (2012-17). The government will support 60 per cent of the project cost while the industry players need to take care of 40 per cent of the cost.[80] The Objectives of the scheme is to fill in the critical gaps in the sector especially related to standardization, quality assurance and control, productivity, marketing, infrastructure and capacity building through a cluster based approach preferably for classical ASU and Homoeopathic drugs. It also encourages creation of social capital for sustainability of collective initiatives.

The government has also set-up **Research Councils of Ayurveda, Siddha, Unani and Homeopathy** which are having 80 research centers across the country. In this regard, a public sector undertaking Indian Medicines Pharmaceutical Corporation has been set up for manufacturing of Ayurvedic and Unani medicines.

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[77] Planning Commission. Twelfth Five Year Plan 2012-17, Planning Commission GOI. Vol. 3. New Delhi: Sage Publications India Pvt. Ltd.; 2013.

[78] Ministry of Health and Family Welfare. Indian Public Health Standards, Revised Guidelines for Sub Center, Directorate General of Health Services. New Delhi: Government of India; 2012.

[79] Samal J. Indian public health standards for Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy facilities: An assessment. Int J Med Public Health 2014;4:331-5

[80] https://pib.gov.in/newsite/PrintRelease.aspx?relid=121432

5.1.2.2. R & D Initiatives for Development of Herbal Medicines

The formulation of medicines under Ayurveda and other system of medicines are given in ancient text books such as Charak and Sushurt Samhitas. CSIR has published Wealth of India, a serial publication which provided foundation for understanding importance of various plants and their derivatives. Unfortunately, the class of Taxonomists gradually declined and as a result fewer publications on the medicinal plant wealth of India published by CSIR around half a century ago continues to be the only authoritative document on the subject. In addition to this, the Vaidya and other traditional healers have been using the traditional practice based knowledge for making herbal medicines for local healthcare. To conduct systematic research and document the knowledge, Government and private sector both took various initiatives in India. Government established set of research councils and institutions to undertake systematic research and promote development of herbal based healthcare under TISM in India and abroad.

Central Council for Research in Ayurvedic Sciences (CCRAS: The council has been established as an autonomous body under Ministry of AYUSH, Govt. of India for coordinating, formulating, developing and promoting research on scientific lines in Ayurveda. The main activity of the Council includes clinical research, drug research, and literary research in Ayurvedic Sciences. The research activities are carried out through its 30 Institutes/Centers/ Units located all over India and also through collaborative studies with various universities, hospitals and institutes. Different clinical projects on the topics like hemorrhoids, Rasayana (Immunomodulation) and osteoarthritis have been successfully completed under CCRAS research program. Intra Mural Research (IMR) projects have been initiated in drug standardization and pharmacological research.

Central Council for Research in Homoeopathy (CCRH): Established as an autonomous body under the Ministry of AYUSH to promote R & D under Homoeopathy. The council undertook various initiatives in recent times such as i) Beneficiaries from Out Patient Department (OPD) Homoeopathy; ii) Clinical Research; iii) Drug validation study on five diseases - dyspepsia, migraine, asthma, acne and haemorrhoids; iv) Drug development; v) Fundamental and basic research; vi) Public health research; vii) Launching of Swasthya Rakshan Program, which provided community health services in 55 villages/ urban areas through 11 Research Institutes (About 3000 camps have been conducted and about 2 lakh people have been benefitted); viii) Epidemics; ix) Prevention of Dengue.

Central Council for Research in Unani Medicine (CCRUM): CCRUM, an autonomous body under the Ministry of AYUSH has taken new initiatives apart from ongoing research activities. These include starting of National Programme for prevention and control of Cancer, Diabetes, Cardiovascular diseases and Stroke (NPCDCS) and Swasthya Rakshan programmes. In the area of research, clinical validation of Unani pharmacopoeial formulations, Multi-centric control trails,

Collaborative studies have also been undertaken with reputed medical colleges, Universities and scientific organizations.

Central Council for Research in Siddha (CCRS): This is also an autonomous body the Ministry of AYUSH which undertook various research programs in recent times such as-

Survey of Traditional Medicinal Plants including aromatic plants & herbs and documenting the same in the form of Herbarium sheets, Museum specimens.

Around 10225 field collections having 8225 herbarium sheets covering 1784 species have been recorded and documented in the form of Herbarium and are being maintained and the same is now under digitization under IMR project of Siddha Medicinal Plants Garden and the work is progressing.

Conservation: Siddha Medicinal Plants Garden conserves the medicinal plants in the form of Model Garden 1/ Model garden II/ Poly greenhouse / Arboretum and in the petaloid pond for aquatics.

5.1.2.3. Development of Drug Formulations and Ensuring Quality Standards:

Legally Ayurvedic medicines can be manufactured under license from the formulae or the natural raw materials of plant, animal, mineral or marine origin mentioned in the authoritative books listed in a schedule of the Drugs & Cosmetics Act, 1940. Different kinds of formulations are manufactured and administered as Ayurvedic drugs. Considering their method of preparation, palatability, bioavailability and therapeutic values formulations are grouped in various dosage forms viz. Avleh, churna, Asava, Bhasma, Ghrita, Taila, Kupipakva, Gutika, Guggulu Modaka, Louha, Pisti, etc. as described in the Ayurvedic Formulary of India published by the Government. In persuasion of standardization of Ayurvedic drugs for the purpose of effective quality control, 265 standardized formulations from classical texts are published in four volumes of the National Ayurvedic Formulary and 645 monographs of quality standards of single drugs and 252 monographs of quality standards of multi-ingredient formulations are published in two parts of Ayurvedic Pharmacopoeia in thirteen volumes. Pharmacopoeial standards of Ayurvedic drugs are developed on the basis of twelve assessment parameters of identity, purity and strength including confirmed identification, chemical constituents and permissible limits of heavy metals, pesticide residue, aflatoxins and microbial load. Similarly, in order to ensure supply of quality Ayurvedic medicines to the health facilities across the country, an Essential Drug List containing more than 250 medicines is published and the states are supported to procure such medicines for free public distribution to patients through dispensaries and other medical centers. The work of development and revision of standards of Ayurveda drugs is done under the supervision of Pharmacopoeia Commission of Indian Medicine & Homoeopathy and with the responsibility of Ayurvedic Pharmacopoeia Committee of interdisciplinary experts. Various scientific laboratories and Pharmacopoeial Laboratory for Indian Medicine (PLIM), which is an appellate laboratory

under the provisions of Drugs & Cosmetics rules, 1945, are engaged in the work of standardization and SOPs of Ayurvedic drugs using sophisticated equipment and analytical tools.

Although, significant achievements have been made by the existing pharmacopoeia set up, a unified pharmacopoeial infrastructure is intended for better coordination and outcomes. For this purpose, development of pharmacopoeial standards is proposed to be augmented through studies conducted by laboratories or institutions accredited by Government. Standard Operating Procedures (SOP) of manufacturing processes of formulation for development of different quality standards i.e. atlas of chromatography, pharmacognosy atlas to facilitate the testing procedures and marker compounds or phytochemical standard material of ASU&H drugs are being appended to the quality standards Parameters like DNA barcoding or fingerprinting of medicinal plant materials are combined within the framework for quality control of Ayurvedic drugs. Drug Control Cell in coordination with in the Ministry of AYUSH looks after regulatory and quality control matters of Ayurvedic drugs under the provisions of Drugs and Cosmetics Act, 1940 and rules there under. Lot of thrust has been given to check manufacturing companies for compliance to Good Manufacturing Practices, prescribed Shelf-life and evidence of safety and effectiveness of drugs.

5.1.2.4. Technology Development:

The Government is also focusing on developing appropriate technologies for development of single and poly-herbal products to make it globally acceptable through the Global Triangle Partnership Scheme (GTP). The GTP Scheme is an important initiative between AYUSH, CSIR and ICMR will work together to bring safe, effective and standardized Ayurvedic products for the identified disease conditions, to develop new Ayurvedic and plant based products effective in the disease conditions of national/global importance.

The sector also requires support for medicinal plant processing and post-harvest management including marketing. In India particularly, the infrastructure needs of drying yards, storage godowns, processing units, quality testing and marketing are to be met.

5.1.2.5. Development of Traditional Knowledge Digital Library:

Development of a database called “Traditional Knowledge Digital Library” (TKDL) that will document as well as establish the prior art to hinder patenting Indian knowledge. TKDL is an initiative to provide the information on traditional knowledge existing in the country, in languages and format understandable by patent examiners at International Patent Office’s {IPO} so as to prevent the grant of wrong patents. A Traditional knowledge digital library (TKDL) with the objective to make all documented information on Ayurveda available to patent examiners so as to prevent grant of patents on non-original inventions and to retrieve about 35,000 formulations of Ayurveda, 30 Ayurveda experts and scientists and five patent examiners have provided the expertise for setting up of the facility is being developed. The Ministry of AYUSH has

been identified as the nodal agency for the documentation and digitalization of indigenous knowledge so as to protect the existing Indian knowledge under the TKDL Programme. The task has been entrusted to National Institute of Science Communication and Information Resources (NISCAIR), a CSIR laboratory. The collaboration in preserving and protecting traditional knowledge related to the Indian systems of healthcare will be strengthened, through the TKDL platform and development of international standardized terminologies [disease-morbidity codes] in Ayurveda, Siddha and Unani (ASU), database on medicinal plants, foods, etc.[81] This innovative step has resulted in the documentation of 100,000 herbal formulations through collating the information from the existing literature in the digital form. This Digital Library has made an impact at an international level after realizing its utility in preventing misappropriation of the rich traditional knowledge and also making it as a precious tool for encouraging advanced research.[82]

5.1.2.6. Pharmaceutical Companies in Ayurvedic Research:

All the major herbal medicine manufacturers such as Dabur, Himalaya, Patanjali, Emami, etc., have developed their own R & D infrastructure. However, Ayurvedic Pharmaceuticals Industries are mainly interested in research in pharmaceutics which is development of drugs. There is shortage of authentic research for the development of new drug. Most of the companies are changing formulation of classical drugs by adding extra ingredients and promoting as novel patented products like many chywanprash brand. One of the reasons they are not investing that authentic Ayurvedic research requires huge capital support and advanced technological equipment which Ayurvedic companies cannot provide.

According to Himanshu Tiwari, Multani Pharmaceuticals, reason for the apathy toward research is that only few Ayurvedic products have commercial appeal. Few products have the commercial potential like Aloe Vera, an Ayurvedic product that is supplied to major pharmaceutical manufacturer in country. Another possible reason could be Ayurvedic medicine do not go through usual route of toxicology studies and clinical trials. This makes the product less appealing for companies that are into exclusively research filed.

Ayurvedic preparations are acceptable in India. Ayurvedic drugs can be validated through reverse pharmacology. It is an interesting and important scientific approach to develop new drug candidates or formulations from already known facts in traditional medicines through sound preclinical and clinical researches.

[81] https://www.dailypioneer.com/2019/india/ayush-min--csir-join-hands-for-herbal-drug-research.html

[82] Medicinal plants conservation and enterprise development; Chandra Prakash Kala; Article in Medicinal Plants - International Journal of Phytomedicines and Related Industries · January 2009

5.1.3. Promotion of Good Manufacturing Practices (GMP)

Government has promulgated GMP regulations for traditional systems of medicines to improve the quality and standard of Ayurvedic, Siddha and Unani drugs in pharmacies. New rules delineating essential infrastructure, manpower and quality control requirements came into force from 2000 and form part of the Drugs and Cosmetics Act, 1940.

In all the traditional system of medicines the quality assurance aspects are considered as an integral part and they need to be exercised to the fullest extent. Following are the initiatives taken by the Government to ensure quality and standards in processing and manufacturing of herbal medicines:

- Gazette Notification GSR 561 (E) Dated: 23rd June, 2000.
- Schedule T' under rule 157 of Drugs and Cosmetics Rule, 1945.
- Applicable to whole of the country with effect from 23rd June, 2000 for New A.S.U. Manufacturing units.
- Units registered prior to 23rd June 2000 are given 2 years' time to comply with Individual Vaidyas/ Siddhas/ Hakims exempted.
- Request for GMP certificate will be made on Plain Paper.
- After proper inspection, GMP certificate will be issued within 3 months. G.M.P. certificate will be given in form EL (under Rule 157 -B) for a period of 3 years.

Licensing of Ayurvedic medicine is also governed under drug and cosmetics act, 1940. All Ayurvedic Patent and Proprietary medicines should contain only the ingredients mentioned in the recommended books as specified in the Act. For all new innovative herbal medicine, the safety and efficacy data are mandatory based on clinical trials. Depending on the nature of herbs and market availability, different requirements exist for submission of clinical trial and safety data which are mandated to be followed.

5.1.4. Intellectual Property Rights (IPR) under TISM

The existing IPR laws and existing frameworks have not been able to protect the bio-piracy by its steps taken both at the national and the international level. The modalities for legislations in IPR are still emerging and evolving. The Legal protection accorded to traditional knowledge in India is through:

India's patent laws with the Amendment Act of 2005 which contains provisions for mandatory disclosure of source and geographical origin of the biological material used in the invention while applying for patents and also allowed the composition of a drug to be patented.

The Indian Biodiversity Act 2002 which follows the Convention for Biological Diversity's guidelines regarding benefit sharing. India has established a central authority "National Biodiversity

Authority" to monitor and control foreign access to Indian biological resources including traditional medicine.

At the international level, the Inter-governmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore under World Intellectual Property Organization (WIPO)[83], is considering various concerns and issues of misappropriation of TK and looking for ways & means and principles for protection of TK.[84]

5.1.5. Processing and Manufacturing of AYUSH Medicines

To meet the increasing demand for herbal based healthcare products in domestic and global markets and also promoting livelihoods of the communities who have been traditionally dependent on forest produce collection, initiatives have been undertaken at several levels for processing and manufacturing of herbal drugs and medicines.

5.1.5.1. Private Licensed Pharmacies under AYUSH System:

Private manufacturers dominate the Indian herbal medicine manufacturing sector. Number of Licensed Drug Manufacturing Units (i.e. Licensed Pharmacies) under AYUSH system are 8954 in 2018 due to drive undertaken to close non GMP compliant units in some states. Of these, 7718 were registered under Ayurveda system and remaining viz. 1236 belong to other systems.

Most of the licensed drug manufacturing units mentioned above are small and medium size and only about 50 companies have revenue of INR 100 crores or more accounting for more than 85 per cent of revenue generated by the sector. Industry estimates reveal that these 50 companies reported revenue of INR 22500 (approximately) for FY 2017-18.

The sector is privatized and there is no official data available on production, sales volume, and employment contribution of this sector. Some of the large product manufacturing companies (with over INR 1000 crores turnover) include Dabur India, Himalaya Herbal Healthcare, Baidyanath Group, Emami Group, Hindustan Unilever Limited and Patanjali Ayurved Limited. Some companies offer both products and services (for example, Jiva Ayurveda, Kairali Ayurvedic Group and Patanjali Ayurved Limited).

5.1.5.2. AYUSH Industrial Cluster Development:

The herbal industry sector is dominated by micro, small and medium enterprises (MSMEs). These account for more than 80% of the enterprises that are located in identifiable geographical clusters across India. In order to exploit the emerging market opportunities, and overcome the constraints of MSMEs due to lack of technology and other resource and facility access, cluster based approach is being highly recognized as an efficient and sustainable strategy for

[83] https://www.wipo.int/portal/en/index.html

[84] https://nistads.res.in/all-html/Indian%20Herbal%20Sector.html

competitiveness augmentation. It is in this context that the scheme for AYUSH clusters' development was introduced during the XI plan. Development and implementation of AYUSH Cluster Scheme has been approved for continuation in the 12th Plan period (2012-17)[85].

The Government sanctioned 10 AYUSH Industry Clusters in Public-Private-Partnership mode at various locations across the country. The total outlay is of INR 100 Crores. Out of these, 3 Clusters, one each at Kerala, Punjab and Rajasthan have been completed so far. The Scheme aims at quality control, standardization and capacity building of the AYUSH enterprises, mostly micro and small, to make them competitive through setting up of common facility centers. An approach like this which leverages the geographical proximity of the MSMEs on 'collaborating while competing' principle is participatory, cost efficient which provides crucial opportunity for customization of interventions.

The Scheme is implemented on a Support from Department of AYUSH and by the way of grant to the Special Purpose Vehicle (SPV), formed by group of entrepreneurs from AYUSH sector. The responsibilities of procurement of raw material lie with the Special Purpose Vehicle (SPV). The assistance under the scheme would be available to units operating in the following sectors; a) located in existing clusters i.e. a group of AYUSH enterprises located in close proximity: (i) Ayurveda (ii) Siddha (iii) Unani (iv) Homeopathy (v) Yoga and naturopathy (b) SPV formed by at least 15 enterprises located in an existing cluster i.e. a group of AYUSH enterprises located in close proximity: shall be eligible for funding under the scheme.

Out of 15 participating units, at least 75% should be manufacturing units having valid GMP certificates for manufacture of AYUSH drugs. The cluster for the purpose of this scheme would be an area covering a radius of 100 km and at least 15 participating enterprises should be located in this cluster.

The Scheme would cover two types of interventions namely, Core intervention and Add on intervention:

- Core Interventions such as those related to setting up of common facilities for testing, certification, standardization, quality control and other capacity building measures.
- Add on Interventions such as those related to marketing/ branding, provision of general infrastructure to support production units etc.

The testing laboratory should be as per standard of National Accreditation Board for Testing and Calibration of Laboratories (NABL). Testing facilities such as analytical lab, toxicology centre,

[85] http://ayush.gov.in/sites/default/files/7113825026 Cluster%20scheme%20without%20Track%20Change%20%2021.pdf

process & product validation laboratory, raw material testing, standardization laboratory, etc. which will enable better quality assurance & control are the mandatory component of the project.

Manufacturing facilities of tablets, capsules, syrups, ointments, pills, powders, bhasmas etc., including, packaging and labeling of raw materials and other inputs will be present. This will supplement the members' production capacity in case of need. Product Display Centre, Quality and productivity improvement, Standardization of raw materials and finished products, Development of references and standards, Adoption of new technologies and processes, Application of ERP and other IT tools, Assistance for ISO, WHO GMP, GLP, US FDA, EU GMP, Australian TGA and other standards and compliances, Development of Drug Master File for the purpose of registration with regulatory bodies overseas, studies/ surveys, preparation of DPRs, sensitization/awareness creation/skill development are all facilities which will be integrated under the scheme.

Scope of services include project development, value chain analysis for preparation of DPR, monitoring and implementation including strategy formulation for the sector, need assessment, financial advisory services to the Department and implementing agencies, appraisal of the DPRs, capacity building of SPVs, and assisting them in implementation of projects, project monitoring and periodic reporting.

Add-on interventions will be:

- Common Marketing Brochure for classical formulations
- Common Website
- Joint Participation in National and International Exhibitions
- Business Delegations Abroad
- Brand development and promotion
- Infrastructure to support the production units such as water supply, roads, sewerage, effluent treatment, power supply, boundary wall etc
- AYUSH parks with necessary infrastructure
- Raising of common nursery
- Support for cultivation
- Need based infrastructural support for collection, assortment, grading, etc., along the value chain
- Provision of warehousing/storage godowns

Such cluster based industrial zones can be developed as Special Economic Zones through which product modernization and its access to international market can be achieved. Similar, strategy has been followed by China.

5.1.5.3. Government led Initiative for Promoting Processing of Herbal Medicines:

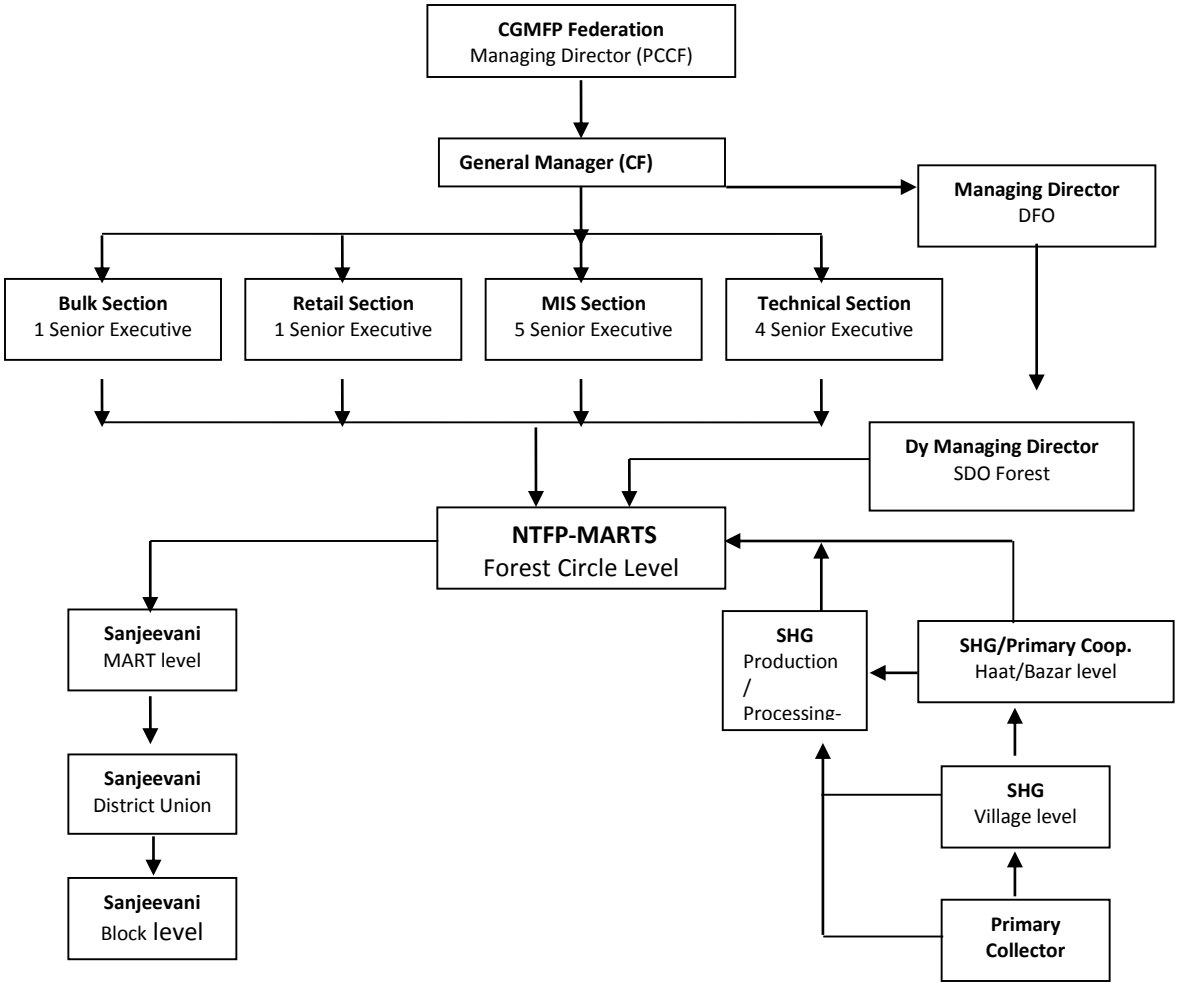
Apart from promotion of participation of private sectors in manufacturing of AYUSH herbal medicines, Government promoted participation of primary gatherers of medicinal plants in processing. Such initiatives have been undertaken by the agencies of central and state governments so as to ensure better income for the primary gatherers.

Case of Decentralized Model of Collection and Manufacturing of Herbal Medicines in Chhattisgarh:

Forests constitute over 44% geographical of Chhattisgarh state in central India. A significantly high percentage of state's population i. e., 76.76% reside in rural areas. The rural communities, especially the tribal who have inhabited the forests for centuries, depend on forests for their livelihood security. Forests provide a range of medicinal plants which are used by the forest dwelling communities for commercial, consumption and health purposes.

Seeing this, the state government issued a new state forest policy in 2002 and declared the State as 'Herbal State' so as to focus on conservation, sustainable collection, processing and marketing of MAPs with an objective to generate additional employment opportunities in the state. Accordingly, CGMFP Federation evolved a comprehensive programme to promote organized production, collection, processing and marketing of these resources through community based institutional set-up and infrastructure building at different levels.

Development of a Network of Enterprises: The Federation evolved a network of community enterprises involving SHGs and cooperatives at various stages of production, collection, processing and marketing of different NTFPs including MAPs. About 74 micro-enterprises have been established for collection and processing involving primary forest produce gatherers. NWFP Mart is established in all the six headquarters of forest circle, where collected & processed minor forest produce are bought at decided rates by Forest Produce societies. For retail selling of these herbal products 30 Sanjeevani retail outlets are established in the headquarters of Divisional Forest offices.



Processing Units for Herbal Medicines: Out of total 74 community based processing units, seven are engaged in processing of herbal medicines. The processing units were provided with required processing facilities, capacity building and capital along with assured buyback arrangement through a network of NWFP-MARTs at pre-decided rates.

Development of Brand for Herbal Products: The mission mode approach with quality production, collection and processing, better packaging, intensive marketing, creating foundation for herbal medicine industry and as a result, a good number of ayurvedic preparations are productized under the brand of 'Chhattisgarh Herbal**'**.

All the products are sold under 'Chhattisgarh Herbals' brand and it was a well-established brand of herbal products being prepared and sold under community led value chain intervention.

Case of Centralized Model of Processing of Herbal Medicines in Madhya Pradesh: Minor Forest Produce Processing and Research Centre (MFP-PARC):

In order to give benefits to forest dwellers, the Madhya Pradesh State Minor Forest Produce (Trading & Development) Cooperative Federation (MP MFP Federation) along with Madhya Pradesh Mandi Board established Minor Forest Produce Processing and Research Centre (MFP-PARC) in Bhopal in 2002-03. It was registered under non-profit making organization and was given the status of an ISO 9001:2008, EMS 14001: 2004 & GMP Certified unit. It is also among the eight pharmacies recognized by Government of India for supply of Ayurvedic drugs to the Ayush Department of different states. The Government of Madhya Pradesh has declared this center as a state pharmacy.

The raw materials are collected through the District MFP Unions, which collects them in a sustainable manner through the collectors of Primary Cooperative Societies spread all over the state. At times, this centre also encourages the procurement of MAP through local farmers/growers. In case of non-fulfillment of requirements, open tenders are invited from private parties/traders. These raw material samples are then subjected to stringent laboratory tests before using them for processing.

MFP-PARC has excellent quality testing & research facilities, advanced equipment support, named as “Vindhya Herbal Quality Testing & Research Laboratory”. It is well equipped for assessing the identity, purity, and strength of medicinal plant raw materials. It has state of the art high precision equipments and other peripherals which have been installed to meet the globally acceptable quality standards. The testing service is also provided to other processors and manufacturers of herbal medicines.

The manufacturing is done under strict vigil of Ayurveda acharyas (qualified and experienced Ayurvedic doctors). Only the desired herbal products which have been duly licensed are undertaken for manufacture by the traditional methodology like use of “Gajput bhatti” using traditional fuel-cow-dung cakes/fuel wood. Over-all traditional methods and age-old proven

practices are followed along with latest methods and techniques in manufacturing of the products. Proper packaging rules are followed.

MFP-PARC processes and markets herbal products including honey under the brand name “Vindhya Herbals”. Several other processing units are also working at Rehti (Sehore), Barman (Narsinghpur), Katni, Panna & Dewas. These units help provide herbal products for the brand. Most of the products under the brand name of “Vindhya Herbals” are organic in nature and are tested in state-of-the-art in-house laboratories.

MFP-PARC produces 65 patented and 188 classical ayurvedic medicines. It acquired licenses and certification for production of herbal drugs.

The MPMFP Federation has established a chain of sale outlets, named "Sanjeevani Ayurveda Kendra”. These outlets sell Vindhya Herbals products and provide consultation of Ayurvedic doctors. There are 27 "Sanjeevani Ayurveda Kendra" outlets in many districts of Madhya Pradesh. Apart from these Kendras, the products are distributed through a well-established distribution channel which also includes distributors, franchise, and online portals like Indiamart.com, Delli Haat etc., spread in several major cities of India.

5.1.6. Issues and other relevant aspects

Herbal drug industry faces several constraints and issues that are impacting its growth. According to a survey of 150 companies conducted by National Institute of Science, Technology and Development Studies (NISTADS), New Delhi and Rajiv Gandhi School of Intellectual Property Law, West Bengal following issues are being faced by Indian herbal drug industry with respect to production, commercialization, and regulation for traditional or herbal drugs:

- Differing regulatory requirements and subsequent delays in application submission and review process.
- In India, the traditional herbal medicines, such as Ayurveda, Siddha, and Unani (ASU), are considered safe because of their long history of use. As such, no safety and efficacy studies are required for marketing approval, as per the Drugs and Cosmetics Act of 1940. In the United States, most of the Indian herbal medicinal products are marketed as dietary supplements under the Dietary Supplement Health and Education Act of 1994. The Act does not require submission of any safety or efficacy data for marketing approval. The manufacturers do not need to register their products with the US Food and Drug Administration (FDA) or get approval before producing or selling dietary supplements. Indian manufacturers prefer to sell their products as dietary supplements without any health claims because doing so does not require any scientific evidence. In European Union (EU), however, the rules and regulations for marketing authorization for traditional medicinal products are much more stringent and detailed information on every aspect is needed to get approval. Therefore, the stringent regulatory requirements in the EU have

made the United States a more favorable export destination than the EU. Different countries have their own standards, which vary from those of India. Compliance with such multiple standards has become a major worry for Indian manufacturers and traders.

- The Limited market in foreign countries is another major hindrance for exporting as revealed from the survey. Scarcity of herbal practitioners, particularly for TISM, in overseas countries has resulted in limited recognition of Indian herbal medicines.
- When the quality of an herbal product is questioned, standardization of raw material emerges as a major issue for the Indian herbal industry. Medicinal plants are easily contaminated during growth, collection, and processing. The survey revealed that more than 50% of companies face problems in collecting and authenticating raw material. Further, 54 companies (36%) consider adulteration of raw materials, which affects quality of the product, to be very common.
- Substitution, adulteration, and heavy metal contamination are the three major problems reported for Indian herbal medicines. Microbial contaminants and mycotoxin (notably aflatoxin) contamination during pre-harvest and post-harvest stages, including storage conditions, are also a major challenge for the manufacturers. Conventional quality control methods often become insufficient because of the complex nature of herbal medicines. To overcome this problem, one or more compounds are selected as markers for identification and quality assessment by the natural products analysts. Several markers help identify herbal drug components. Although developed countries require chemical fingerprinting and marker-based assessment of raw materials and active ingredients for assuring its quality, in India this concept was only recently introduced. The India GMP regulation does not provide any guidelines for marker-based identification. In general, marker-based analysis is a costly process that requires sophisticated and expensive instruments. In India, most manufacturing firms are small and medium enterprises and don't have (or can't afford) such elaborate research facilities in their units. Marker-based studies are further limited because reference standards are not available for all the herbs/plants used in medicinal preparations. Scarcity of third-party laboratories within and outside India for testing ingredients of Indian origin is also a major issue for the manufacturers.
- Another major drawback in the Indian herbal industry is the implementation of the DCA and its regulation.
- SFDA interprets the DCA differently; as a result, the same drug or formulation that is not permitted in one state is allowed to be manufactured in another state. The survey also identified non uniformity in the drug registration timeline across states as a major issue. Development of unified protocols, defined timelines, and specific guidelines defining the meetings with regulators may help remove the anomalies with respect to state licensing authorities and establishing a unified system in the country. Most respondents suggested

the need for scientific advice at the beginning of drug and formulation development, clinical trials, and dossier submission.[86]

Another survey conducted in Uttaranchal state to gather data on the traditional uses of medicinal plant species reveals that the knowledge of traditional Vaidyas has not so far been adequately utilized. Attempts should be made to systematically document all of the formulations prepared by traditional Vaidyas. The high profile formulations may be developed if most of the reputed traditional Vaidyas are organized.[87]

Value Chain Analysis for medicinal plant based products in Uttarakhand also emphasizes that standardization of the production procedures of the medicinal plant industry is eminent for the development of a more systematic, uniform and high quality medicinal and aromatic plant industry in India. The standards of the cultivation, maintenance, harvesting, processing, storage, and packaging function of the medicinal and aromatic plant industry are necessary to develop norms for certification.[88]

The study by CII mentions following issues that need to be addressed:

- Non availability of official source of data on aspects such as size of manufacturing sector, number of private hospitals, clinics, wellness centres and spas, employment generated and human resource requirements, availability and requirement of raw material, trade in Ayurveda services, consumers of Ayurveda and alike.
- Shortage of human resources and skilled professionals
- Products can be classified as Ayurveda products or food supplements. So, companies are registered with Ministry of AYUSH & Food Safety and Standards Authority of India (FSSAI).
- Shortage of quality raw materials
- Variable quality standards of manufacturing units and services
- Most Ayurveda products are not patented as it is traditional knowledge. This makes it difficult to have IP rights on the drugs. There is limited funding for R&D in this area.
- Lack of Product Traceability
- Variation across states in terms of Ayurveda Policy
- Difficulties in registering the product as drug in foreign countries
- Issues in registering poly herbal formulation abroad
- Non-recognition and degree and traditional medical practice[89]

[86] Herbal Drug Regulation and Commercialization: An Indian Industry Perspective; Niharika Sahoo, and Padmavati Manchikanti, The Journal Of Alternative And Complementary Medicine Volume 19, Number 12, 2013, pp. 957–963
[87] Current Status of Medicinal Plants used by Traditional Vaidyas in Uttaranchal State of India; Chandra Prakash Kala; Ethnobotany Research and Applications · December 2005
[88] Tanya Chhabra. Value Chain Analysis for Medicinal Plant based products in India: Case Study of Uttarakhand. Arc Org Inorg Chem Sci 4(1)- 2018. AOICS.MS.ID.000176.
[89] Ayurveda Industry Market Size, Strength and Way Forward, Confederation of Indian Industry, 2018

5.2. Development of TCM in China

5.2.1. Demand Scenario of TCM

TCM has be integral part of healthcare system in China. Right from the beginning, TCM was given equal weightage with respect of western medicines. A large infrastructure has been promoted for education and healthcare around TCM. As a result, demand for TCM is rapidly growing in domestic and international markets. Domestic demand for industry products has increased from $25.8 billion in 2014 to an estimated $43.6 billion in 2019. The export of TCM has reached above 3 billion USD annually. China plans to provide every Chinese citizen access to basic TCM services by 2020, and by 2030 TCM services will cover all areas of medical care. The ambitious "Healthy China 2030" plan estimates that the value of the TCM market may reach 5 trillion RMB by 2030 (US$ 737.9 billion). This would require huge amount of TCM raw materials and medicines to fulfill the growing domestic and global demand of TCM products.

5.2.2. Industrial Development for TCM in China

China has also made systematic efforts for growth of TCM processing and industrial development so that the TCM products not only fulfill the domestic demand but also expand their outreach in global healthcare sector. In 1996, China introduced the concept of "internationalization of TCM" which changed the entire approach and strategies towards development and manufacturing of TCM medicine.[90] To expand the market of TCM, the State Food Drug Administration (SFDA) has continuously deregulated the restrictions on TCM drug sales. The government began to classify prescription and OTC drugs in 1999. To date, 60,000 TCM and ethnic minority medical drugs have been approved, and 2088 pharmaceutical enterprises that have been approved by the Good Manufacturing Practice (GMP) of Medical Products are manufacturing Chinese patent medicines. The dosage forms of TCM medicines have increased from a traditionally limited number of forms such as pills, powders, ointments and pellets into more than 40, including dropping pills, tablets, pods and capsules, indicating marked improvement in the technological level of Chinese medicinal drug production, and initial establishment of a modern Chinese medicine industry based on the production of medicinal materials and industrial production and tied together by commerce.

5.2.2.1. Industrial Development for TCM Manufacturing

The development of the TCM pharmaceutical industry is rapid. China has successfully established a modern Chinese medicine industry based on the production of medicinal materials and industrial production and tied together by commerce. The Government stance is on pushing high-

[90] Internationalization of traditional Chinese medicine: Current international market, internationalization challenges and prospective suggestions; Annie Xianghong Lin, Ging Chan, Yuanjia Hu, Defang Ouyang, Carolina Oi Lam Ung, Luwen Shi and Hao Hu; Chinese Medicine · February 2018

quality, innovative healthcare companies, and the underperforming companies are seriously dealt with risk of being eliminated. This strategy of the Government makes compliance to rules and regulations more efficient. These healthcare system reforms and new regulation continue to drive excellent Chinese market growth.

Chinese companies are responsive to the market and open-minded, having sufficient funds and competitive products, all together making the private medical companies become leading players in the sector. The industry is transforming from the "Made in China" model to "Created in China," with more innovator drugs, in which the private companies are having a leading role. The Pharmaceutical industries were provided incentives for development of industry which are mostly state-owned.

The international global biopharmaceutical industry is constantly looking for collaborative efforts like greater exchanges and cooperation in the industry which signifies a bright future for the sector. International prospects at present are for investment opportunities in China's healthcare sector in research and innovation with international tie-ups, as well as mergers and acquisitions. Consequently, TCM has become a significant component of the Chinese domestic pharmaceutical market.

The game changer for TCM was undoubtedly the discovery of artemisinin, which landed China a Nobel Prize, and is now widely used in anti-malarial drugs throughout the world.[91]

China is not, however, merely relying on a belief system in terms of development of its TCM health infrastructure. It is promoting R&D on the substances used in TCM, such as natural plant materials, to determine their clinical efficacy, as well as to isolate active ingredients and develop methods for creating 'modern' formulated products based on TCM materials. In the Chinese health care system, TCM products are not used in isolation from physician practice. There is a network of TCM hospitals that are visited by large numbers of Chinese patients, where treatments such as acupuncture are administered in addition to supply of TCM products. A number of these hospitals combine Western medical practice and TCM practice in a single facility.

Revenue for the TCM Manufacturing industry is expected to increase at an annualized rate of 10.6% over the five years through 2019. In 2019, industry revenue is expected to total $44.5 billion, up 9.9% from 2018. The industry has an estimated 1,496 enterprises, which employ 191,156 workers with a total payroll of $2.1 billion. Traditional Chinese medicine pills are the main product used in TCM clinics, and are also important components of Chinese patent drugs.

91 http://en.cccmhpie.org.cn/Web/Content.aspx?queryStr=w7x1X10x16x0X10x16o3w8w1u9v1u9u9u9v5z8w7x08q7x15x15o3w8w1u9v1

Domestic demand for industry products has increased from $25.8 billion in 2014 to an estimated $43.6 billion in 2019.

The companies holding the largest market share in the Traditional Chinese Medicine Manufacturing in China industry include Kangmei Pharmaceutical Co. Ltd., Beijing Tong Ren Tang Co. Ltd, Tasly Pharmaceutical Group, Zhengzhou Ruilong Pharmaceutical Co. Ltd. and Jiangsu Kanion Pharmaceutical Co. Ltd.[92]

Development of Integrated Facilities for TCM Manufacturing: A Case of Guangdong- Macao Traditional Chinese Medicine Park (GMTCM)

China has been evolving its regulatory environment, stepped up investments in innovations, research and development, to accelerate its pace of pharmaceutical development both domestic and worldwide. They have fast-paced on investment and capitalized on knowledge from other markets. Similarly in the TCM arena, the Government has made constant encouraging policies and programmes to support its strategy of global outreach.

The **policies and regulations** made by the Government of China are towards promoting the SEZ at GMTCM for TCM development through the following initiatives which supports it.

- Talent Policy
- Taxation
- Industry Support Policy
- Finance Policy
- Customs Clearance Policy
- Headquarters Economy Policy
- Innovative Reforms on Administrative Approval

The GMTCM Park development as a Special Economic Zone (SEZs) are defined as small geographical areas that allow the integration of free-market principles to attract additional foreign investment) aims to create conditions for TCM product modernization and internationalization for the enterprises located inside and outside GMTCM Park. It will play a leading role in expanding the TCM industrial scale through four aspects, which are branding, technology, culture and experience.

The Park is a model of cooperation between the Chinese mainland and Macao. The Park was established by the Macao Special Administrative Region Government and the Guangdong provincial Government in 2011. A total of 162 TCM companies are registered till 2019. The Park has become one of the first 17 National TCM Service Export Bases that promote the inheritance, innovation, and popularity of the treatments. The Park has become a significant sci-tech innovation promoter.

[92] https://www.ibisworld.com/china/market-research-reports/traditional-chinese-medicine-manufacturing-industry/

The industrial park is equipped with a professional enterprise service team to create a full-chain enterprise service system, which provides services such as policy declaration, investment and financing docking, marketing, high-tech cultivation, and entrepreneurship counselling.

Promotional Agenda of the GMTCM Park

- The Park aims to provide integrated infrastructure facilities for Industrial development through facilities for processing to small industries so as to develop world standard TCM

Enterprises that offer business support services, i.e. storage and logistics of Traditional Chinese Medicine, health tourism, F&B, hotels, TCM clinics, and so on are encouraged and are brought together at one forum. Service-oriented enterprises focusing on business and exhibition, investment and financing, management consulting, talent training, application services, in healthcare-related industry, and others are also promoted. This helps offer solutions to assist the overall development of enterprises smoothly and helps easy transition of TCM products to market.

- Integrated Facility Development for R & D, Quality Control and Certification

Within the PARK, integrated facilities have been developed for R & D, clinical trials, third party quality testing which can be used by the internal and external industries at affordable rates to develop quality TCM as per the global norms and standards. It will serve as a platform for pharmaceutical supply chain. It helps extend better collaboration between enterprises, universities and research institutes to advance its industrialization, modernization and globalization.

- Promotion of International Trade of TCM

The centre is being developed keeping in view International Cooperation and Exchange to facilitate export of TCM. Organization of International events such as “2019 Traditional Medicine International Cooperation Forum (Macao, China)” to facilitate international cooperation among Chinese TCM industries and global health industries for promotion of TCM worldwide is being carried out. The Park has collaborated with a large number of official institutions, professional entity associations and enterprises for strategic cooperation, both nationally and internationally. It has attracted pharmaceutical companies, research and development centers, laboratories and medical testing institutions from both domestic and international.

Promotion of Partnership among Chinese and Global Health Industries to form joint venture for collaboration between two health care systems viz. TCM and western model of healthcare is being encouraged. It also conducts TCM training program and international exchanges of experiences.

- It aims to serve as a base for healthcare and wellness and to promote TCM culture with a vision of becoming a cluster in health industry and culture promotion.

Furthermore, it aims to foster exchanges and trade of health related techniques of TCM products, including results transfer, technology and techniques exchanges, trade import and export. It provides third-party quality test service to develop a platform for quality control, provide technical support for product incubation, testing services and pilot test production. It integrates testing, authentication and consultation.

Achievements of the GMTCM Park so far

At present, 11 new Chinese medicine products such as medicines and health food are being developed for 4 companies, and 2 products have been listed for 1 company in Macao. The initiative has resulted in improved quality standards and successful promotion of sales in Mozambique. It has assisted 5 park enterprises to complete nearly 100 million yuan in financing, helped the park enterprises to obtain various government subsidies of more than 26 million yuan, helped 6 enterprises to successfully apply for national high-tech enterprises, and assisted 23 enterprises to obtain new R & D institutions in Guangdong Province, 10 types of qualifications, such as technology-based SMEs; also established three major training activities: “Houpo Business School”, “Houpok Youyou”, and “Houpok Lecture Hall”, with a total of more than 1,500 trainings.

The GMTCM aims to be a one-stop” consulting services at implementation stage of any TCM related project. It offers a full range of services in support of the enterprises creating a positive environment for development and promotion of TCM worldwide.

5.2.3. Improving Quality Standards of TCM Products

China has taken up the strategy of winning over the market by quality especially, the export product is expected to rise in quality as a means of enlarging overseas market by attracting buyers with good quality. The country is focusing on meeting all the parameters to increase quality of TCM based on international medicine standards.

TCM product quality has vastly been improved through several efforts. The Government is promoting good regulatory practices for strategic products, including TCM products, to benefit the global supply of high-quality and affordable health products and technologies. It is also pro-actively engaged in improving implementation and enforcement of health services and food and drug safety laws.

TCM is considered a Category 1 pharmaceutical in the group and is subject to State pharmaceutical standards. The law specifically notes the additional requirements for TCM medications including sourcing, cultivation, ecological environment, collection, handling, processing, and preparation information which are included in the pre-trial testing phase. Only

after final completion, reporting, and examination are the medicines approved for production. Going through these rigorous quality check processes aims to assure the quality of the products and a documented scientific backing for the products are built.

There are new Pharmaceutical Examination and Approval Procedures which China is subjecting to TCM for more rigorous pharmaceutical testing. The State encourages research and development of types of TCM with clinical effects, and practices a classification protection system for types of TCM with reliable quality and certain curative effects. The country brought in significant reform to its pharmaceutical regulatory review and approval processes for innovative medicines, protection of intellectual property, timely predictable and transparent government reimbursement for innovative medicines and accepting overseas clinical trial data.

Since 1996, all exported Chinese traditional medicines and their manufacturing processes were subjected to inspection by SATCM designated organizations. Manufacturers in compliance received a quality registration certificate. This certificate is revocable if the investigative organization finds quality control problems. Moreover, product quality violations are subject to criminal sanction which is more likely to occur than enforcement of fines or other equitable remedies.

All the new herbal drugs must be approved according to the Drug Administration Laws. The China Food and Drug Administration review the quality of all products; and those that don't pass the mark are being strictly eliminated. Therefore the competition for generic products is going to be tougher. This will bring a major quality check on TCM products also. Farms producing raw ingredients must comply with State Drug Administration (SDA)-imposed standards.[93]

Government has also prioritized an increased investment in technological transformation so that the TCM production quality levels reach a historical new height. A big data platform of Chinese medicine, for TCM preparation; and for quality of TCM is being built as another strategy.

By 2020, China plans to make the medicine quality of a large number of bio-pharmaceutical enterprises get in line with international standard and at least 100 pharmaceutical preparation enterprises obtain the authentication of American, European, Japanese countries and also the World Health Organization (WHO).

The Government adopted GAPs and GMPs. The GAP guidelines suggest selection of the correct germplasm with high content of stable active components. The cultivation practices offer Standard Operating Procedures (SOPs) for use of fertilizers, irrigation systems and disease management allied with insects and pest prevention and cure. GAPs also establish standards for noxious and harmful contaminants like heavy metals, pesticide residues and microbes in plants.

[93] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1297513/

All manufactures of TCM are mandated to comply with guidelines laid down by China's State Drug Administration (SDA) and farms producing raw ingredients must comply with SDA-imposed standards. This step was important looking at the standards placed by developed counties in import of Chinese medicine. But there is still scope for improvement in current market scenario where sub-standard medicines still reach the buyers. The Chinese Government is planning strategy to improve this.[94]

The International Organization for Standardization (ISO) standard specifies the minimum quality requirements and testing methods for the herb. In 2014, the ISO released "International Standard for the Use of Sterile Acupuncture for One Time" in Beijing, the first time in the field of TCM all over the world. Similar international standards have been developed for many other products.[95]

5.2.4. Issues and other relevant aspects

TCM's growing market and globalization could not stop people from challenging its efficacy and scientific background. Hot debates on TCM have begun since the 1990s. The topics on TCM system were discussed in some reputable journals, but its efficacy was not explained well. Now China is the only country in the world where both TCM and modern medicine are practiced in health care system. China has significantly increased the financial support for marketing TCM and unveiling TCM mystery with the hope that TCM would be modernized, industrialized and internationalized eventually.

TCM, as one treatment, should be in line with scientific standards: each claim that TCM treats any disease or indication should be supported by randomized clinical trial data. TCM practitioners must receive modern education and understand the concepts of diseases and health. In the field of diseases treatment market, TCM should have some regulatory guidelines like Directive 2004/24/EC; in health improvement market, TCM should be also regulated strictly.[96]

Consumer confidence on alternative systems can be a driving force for fostering the future of these traditional systems. Increase in the consumer confidence is subject to the scientific approaches and evidence based research. Therefore, it's imperative to undertake measures which entice traditional medicine manufacturers for adopting scientific techniques, processes and procedures.

Practitioners of alternative medicines need to adapt a scientific approach for conducting herb drug interaction studies. It will further provide new avenues for conducting research, innovation

[94] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1297513/
[95] https://pdfs.semanticscholar.org/d96b/a6b39e50909036b9e541c8d1dd5665459a31.pdf
[96] Traditional Chinese Medicine (TCM) – Does its contemporary business booming and globalization really reconfirm its medical efficacy & safety?; Juncai Xu, Zhijie Xia; ELSEVIER; July 2019.

and development, ultimately transforming the alternative medicine industries leading to acceptability and consumer confidence.

Recognition of traditional medical systems and bringing them to the mainstream necessitates the need of mass awareness. A strong advocacy for promoting the use of traditional medicines is required to stimulate the policy makers, stake holders and other relevant parties for accepting traditional medicines in mainstream.

Proper use of herbal medicines in the general public and consumers may be promoted. The narrative of traditional medicines, always being safe is misleading. Recognition of Drug interactions. The widespread belief that whole herbs formulations are harmless is not correct. Concurrent use of herbs with modern medicine may mimic, magnify, or oppose the effect of drugs. The apparently harmless garlic can interact with some modern drugs and cause serious interaction like bleeding when taken with low dose aspirin and Warfarin etc.

Incentivising the traditional medicine industry, promoting educational programs related to traditional medicines can have a positive impact on the future of TCM, and other forms of traditional systems.[97]

TCM's entry into the American market requires the approval of the Food and Drug Administration (FDA), which implies large capital (over 100 million USD) and lengthy process (lasting at least 8 years). However, the more complex problem in the entry process is that the risks of American financing support for TCM enterprises implementing internationalization strategy are still neither clear nor strong enough. With the implementation of "Regulations for Botanical Drug Approval" and "Guidance for Industry: Botanical Drug Development", the United States began to consider botanical drug compounds as a therapeutic drugs.

The drop of the two major markets in Hong Kong and Japan is another major reason for the decline in the overall TCM export value and export volume. Japan was once the largest importer of Chinese medicinal materials and mainly involved Chinese medicinal materials and decoction pieces. But after 1990, Japan began to vigorously develop the herbal medicine base and establish the herbal plantations in order to become self-sufficient of medicinal herbs and to reduce import from China, which led to Japan's falling import of volume and value of Chinese medicinal materials. Japan has become the second largest market for TCM exports next to the United States, with an export value of 505 million USD in 2016, a 6.62% increase over the past year. There are more than 200 Japanese Kampo medicine manufacturers in Japan. These domestic enterprises possess advanced equipment and technology to process Chinese medicinal materials and to manufacture quality stable TCM under strict standards. The locally manufactured TCM has

[97] Traditional Chinese Medicine Going Global Opportunities for Belt and Road Countries; Muhammad Ovais, Ali T Khalil, Sohail A. Jan, Muhammad Ayaz, Ikram Ullah, Waseem Shinwari, and Zabta K. Shinwari; Proceedings of the Pakistan Academy of Sciences · October 2019

occupied a considerable share of the markets of Chinese patent medicines and health care products.

In South Korea, the drop in the sales of TCM manufactured in China was multifactorial: the issues with the packaging design and promotion strategy of TCM discouraging the use and masking the true value of TCM in health; and concerns over the content of heavy metals and pesticide residues exceeding the national standards which are a lot more stringent compared to standards alike in many developed countries. In addition, many developed countries have set up high green trade barriers and technical trade barriers for TCM entering their countries, hindering the process of internationalization of TCM.

Another factor discouraging the internationalization of TCM is the high policy thresholds. In certain countries such as Russia, Vietnam and Australia, TCM is sold as a pharmaceutical drug. In many other countries and regions, however, TCM are approved for sales as health care product, active pharmaceutical ingredient (API), or dietary supplement. On 1st May 2011, the European Union's 2004/24/EC EU Directive on traditional herbal medicine (namely the EU botanical drug approval and continuity clause) came into force. This directive provides a simplified registration procedure for traditional herbal medicines, and gives a 7-year transition period of the traditional herbal medicine sold in the EU market before 2004. However, after 7 years, all unregistered traditional herbal medicines will be removed from the EU market.

On the other hand, each TCM consisting of multiple compounds is a complex chemical system. Its characteristics of synergistic reaction of multi-components, multi channels and multi-targets are difficult to be elucidated by the study model of "single component and single target" in modern medicine. The uncertainties in the effective substance basis and the mechanism of TCM further make it difficult to formulate a scientific and effective system for evaluating the efficacy and safety of TCM. International communities always find it hard to recognize and adopt the quality standards and the standards of production management of TCM. As a result, Chinese patent medicines lose their competitiveness the international market.

China has set up a quality inspection technology system focusing on chemical marker detection. This method has gradually developed into quality analysis mode of quantitative analysis, chromatographic fingerprint, and discriminant analysis from the initial sensory experience. However, the research pattern of the quality control of TCM is still relying on the analysis method research. This ignores the quality control during the production process; paying attention to the chemical markers detection and ignoring the biomarkers; and emphasizing the drug quality analysis and evaluation and ignoring the study on the medicines regulation system. The scientific and reliable quality assurance system complying with the characteristics of TCM are yet to be fully constructed.

Many countries have added test items of microbes, preservatives, pesticide residues, heavy metals and aflatoxin for traditional medicines and herbal health foods, and formulated their national standards presenting significant cross-country variations. Although China has strengthened the quality control in microorganisms, pesticide residues, heavy metals and arsenic salts, there is still a large gap between Chinese and international standards.

The low level of dosage form is one of the important factors that restrict TCM internationalization. The modernization level of the TCM formulation is relatively backward. The advanced dosage form for TCM such as sustained release, controlled-release and targeted preparations are still in the research stage. Majority of small and medium-sized TCM enterprises still use the traditional excipients, which makes it difficult for the TCM formulation to meet the international standard requirements. The basic research on TCM formulation is backward, especially the researches on pharmacokinetics, stability, dose–response relationships, etc. are relatively scarce.

Along with the gradual expansion of the international market of natural medicines, some developed countries have implemented trade protectionism in order to protect the interests of the domestic pharmaceutical companies and related medical services. These technical barriers to trade, such as technical standard barriers, technical regulation barriers, patent technology barriers, green barriers, etc., which makes Chinese products fail to enter or forced to withdraw from the target market due to short comings in technology, environmental protection, and other areas mandated by the policy and regulations.

The intellectual property of TCM is also the weak link of the internationalization of TCM. There are multiple issues related to the patents of TCM: low international patent application, low effective patents, numerous invalid patents, low patent quality and fast growth of application volume not transformed into a rapid growth of market share etc.

There are also many problems in the technology transfer of TCM, including lacking of original innovation, lacking of basic research, serious shortage of R&D investment, dislocation of R&D subjects, imperfect market transformation and industrialization mechanism, and weak service links.[98]

One fundamental challenge in conducting valid RCTs in TCM is the batch-to-batch variation of the active constituents contained in the herbal formulation used. Product-to-product variation arising from different manufacturers, brands, or formulation further hinders the fair comparison of the findings among similar studies. Such inconsistencies may result in lack of reproducibility between clinical trials and even challenge the validity of generalizing the findings of clinical trials

[98] Internationalization of traditional Chinese medicine: Current international market, internationalization challenges and prospective suggestions; Annie Xianghong Lin, Ging Chan, Yuanjia Hu, Defang Ouyang, Carolina Oi Lam Ung, Luwen Shi and Hao Hu; Chinese Medicine · February 2018

to routine use. However this is something that can potentially be overcome by technological advancement. Newly developed analytical tools and techniques have made it possible to profile the constituents of herbs, for example, by using high-pressure liquid chromatography to establish a chemical fingerprint of the herb, where the profiles of different batches can be compared to ensure no significant variability. Precise reporting of such information by clinical trials has to be implemented to assure validity of TCM trials. In parallel, legislation to define the required standard of proprietary products will eventually be required for acceptance of the clinical trial findings and efficacy of TCM products by the Western medicine practitioners.

Another challenge is the difficulty in creating an appropriate placebo for multiple-herb herbal decoctions, which compromises the effectiveness of blinding. While it is feasible to create placebos for capsules, pills, and tablets, it is technically challenging to create an indistinguishable placebo for a multiple-herb formulation in the form of decoction. Besides herbal medicine, designing appropriate placebo for acupuncture trials is yet another challenge, though researchers have come up with various control measures such as non-acupuncture inert controls, placebo acupuncture, sham acupuncture, real acupuncture with a decoy treatment, waiting list controls, standard care controls, and adjunctive care comparisons.

Incorporating TCM principles in an RCT poses another challenge as it appears that the standardized treatment approach required by RCTs is in discordance with the individualized treatment approach inherent in TCM practice. [99]

[99] Developing Traditional Chinese Medicine in the Era of Evidence-Based Medicine: Current Evidences and Challenges; Foon Yin Fung and Yeh Ching Linn, Hindawi Publishing Corporation Evidence-Based Complementary and Alternative Medicine Volume 2015, Article ID 425037 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4407626/

Chapter 6

Trade and Export Promotion of Medicinal Plants

6.1. Trade and Export of Medicinal Plants in India

The world herbal trade is currently at USD 120 billion annually. India has a very low share in the global export of herbs and herbal products due to many reasons. The total demand of herbal raw drugs is expected to grow to 6,50,000 MT by the year 2020 in India. In view of the increasing demand of wellness products, the export value of the herbal raw drugs has the potential to maintain the current rate of growth of about 20% per annum. India has taken up several steps to promote trade and export of MAPs in order to meet the growing domestic and global demand for herbal or alternative medicines.

6.1.1. Trade and Supply Channels of MAPs

A clear business channel is not followed in the medicinal plant trade in India. Overtime, various trade and marketing channels evolved and with development of technology and interventions from different players including Government, new trading and marketing channels are taking shape.

***Trading through Open Market**:*

The trading of MAPs by the private traders has been in existence for a long time and their supremacy continued. The trade channel of non-nationalized NTFPs including MAPs is through open market and Government mandi (APMC). The open trade of medicinal plants has been in vogue for time immemorial in the country. Over period of time, a vast network of variety of traders i. e., petty traders, small traders, big traders, wholesalers, commission agents, etc has evolved and spread from small villages to city centers for trading purposes. (Gautam et al, 2010)

In general, the poor forest produce gatherers sell medicinal plant products to petty traders after doing some primary processing due to lack of holding capacity and storage facilities at the local level. These traders are located in cluster of 4-5 villages wherein they operate. In collection seasons, the traders regularly visit the villages for buying products in exchange of some goods. The traders also buy the produces in the weekly haats (markets). No specific parameter is used to evaluate the quality and decide the purchase rates of medicinal plant products. It is mostly decided through evaluating the quality on the basis of their long experiences of trade. (Gautam et al, 2010)

After procurement of sufficient quantity of medicinal plant products, the traders sell the same to small and big traders in towns and districts headquarters. The big traders, many of them have storage facilities, stock and supply these products to advance it to agents or industries directly in bulk. In many cases, the small traders also sell their medicinal products directly to industries or commission agents depending on the location and access to the industry, connectivity, and the desire to earn more profits. In addition, trade of medicinal plants at local level is also done through government agriculture produce 'mandis', wherein the small traders sell the produce to big traders or commission agents. Sometimes, agents of industries also visit these markets to buy directly through traders of Mandi (Gautam et al, 2010). The top 10 herbal mandies are situated in Amritsar, Bengaluru, Chennai, Dehradun, Delhi, Jaipur, Kolkata, Lucknow, Mumbai and Neemuch.

Table Conventional Herbal Raw Drug Mandies of India are as follows:

S. No.	Name of Mandi	Number of Traders in the Mandi (Approx.)	Number of Major Entities Traded
1.	Khari Baoli, Delhi	250	300
2.	Majith Mandi, Amritsar (Punjab)	35	70
3.	Tanakpur (Uttarakhand)	14	35
4.	Ramnagar (Uttarakhand)	12	28
5.	Sharanpur (Uttar Pradesh)	08	38
6.	Kanpur (Uttar Pradesh)	21	35
7.	Lucknow (Uttar Pradesh)	23	72
8.	Kannauj (Uttar Pradesh)	09	31
9.	Banaras (Uttar Pradesh)	06	29
10.	Jagdalpur (Chhattisgarh)	06	23
11.	Dhamtri (Chhattisgarh)	18	20
12.	Kankar (Chhattisgarh)	04	09
13.	Katni (Chhattisgarh)	05	10
14.	Raipur (Chhattisgarh)	21	06
15.	Jabalpur (Madhya Pradesh)	03	08
16.	Indore (Madhya Pradesh)	10	12
17.	Betul (Madhya Pradesh)	02	07
18.	Bhopal (Madhya Pradesh)	11	13
19.	Chhindwara (Madhya Pradesh)	01	12
20.	Mumbai (Maharashtra)	250	78
21.	Chandrapur (Maharashtra)	01	02
22.	Nagpur (Maharashtra)	07	35
23.	Amravati (Maharashtra)	02	07
24.	Koraput (Odisha)	09	20
25.	Cuttak (Odisha)	03	49
26.	Patna (Bihar)	04	29
27.	Ranchi (Jharkhand)	02	11
28.	Kolkata (West Bengal)	54	31

29.	Chennai (Tamil Nadu)	40	175
30.	Virudhnagar (Tamil Nadu)	15	93
31.	Dindukkal (Tamil Nadu)	06	39
32.	Jammu (Jammu & Kashmir)	37	48
33.	Srinagar (Jammu & Kashmir)	14	12
34.	Jaipur (Rajasthan)	39	11

Source: Goraya, G. S. (2017), NMPB

Trading of MAPs through open market is dominant channel and about 90% of total trade of MAPs takes place through this channels which is highly unorganized. Hence, this requires adequate market system development and regulation so as to ensure supply of quality raw material and ensure remunerative income to the primary forest produce gatherers.

Procurement of MFPs on Minimum Support Price (MSP)

The tribal communities live in and around forest areas have been dependent on forests for meeting their various needs. NTFPs are major source of cash income for the forest dwelling communities particularly in lean periods. They collect various NTFPs including MAPs and sell in local markets. In order to check exploitation of tribal communities Government initiated MSP for MFP schemes in 2013-14 for procurement of NTFPs gathered by the tribal communities on minimum support price. The schemes started with procurement of 10 MFPs which gradually covered 40 MFPs including MAPs. TRIFED is designated as nodal agency for implementation of the scheme at central level which carry out the procurement activities with the support of state agencies. The scheme has provided alternative option to the primary forest produce gatherers to sell their produce at minimum assured price and also influenced the market price offered by the traders.

Cultivator to Processor Trading under Contract Farming Arrangement

Under the contract farming arrangement, the farmer grow medicinal plants as per the requirement of herbal industry. The quantity and price are already decided in the beginning. On harvesting, the farmers directly supply the raw material to the concerned industry as a pre-decided rates.

The trend of contract farming is increasing in India however, there remained complaints from both sides – cultivators and processors. The market of MAPs is dynamic. In case of higher market price during harvesting season, the cultivators tend to sell the produce in open market and when the market price are low than the price decided in the initial contract, the processors tend to buy from market. There needs a proper mechanism and regulatory agency which can facilitate and mediate in case of conflict of interest and breaching of contract by any of the parties so that cultivation of MAPs can be promoted in large scale in the country to meet growing industrial demand.

Trading through Farmers' Collective: A Case of Central Herbal Agro Marketing Federation of India (CHAMF)

Finding appropriate market is always difficult for the farmers who want to engage in cultivation of MAPs in India as the market system for MAPs is not well organized. To address the issue, some progressive farmers in central India tool lead and formed a federation namely The Central Herbal Agro Marketing Federation of India (CHAMF) in 2002 which now have become a national level organization of organic MAPs producer farmers and is also recognized by Agricultural Ministry, Govt. of India.

Dr. Rajaram Tripathi, a cultivator and processor of medicinal herbs in Bastar region of Chhattisgarh, took lead to form the federation. He told that that 'marketing' is a major challenge for the MAP producers in India. Therefore a plan is chalked out with the specific strategy of pooling the entire production of its members which can be then sold collectively to any bulk buyer or industry through CHAMF. The federation has about 22,000 MAP farmers spread across 19 States. CHAMF also supports the farmers in cultivation, technology, processing and marketing. The federation also enters into purchase agreements with the buyers and then advises its members to plan the production accordingly, which then guarantees the cultivators an assured buy-back option. Organic farming is practiced for all kinds of production highlighting its advantage over other products in the market, which helps negotiate better prices.

The federation has a comprehensive product portfolio where a large number of medicinal species are cultivated among which there are many endangered and rare species also. Guggul, sarpgandha, safed musli, vacha, ashoka indica mentioned in Red Data Book are some species which are on verge of extinction, and being cultivated through MDHP efforts.

One of the crops the federation focuses on extensively is Stevia cultivation, resulting in farmers in Chhattisgarh (where most production process takes place) seeing their incomes double. As many as 400 farmers linked with CHAMF are cultivating the product on around 700 acres of land spread across the three insurgency-hit districts of Kondagaon, Sukma and Bastar in Bastar Division through community farming. The product is being exported to European countries. This approach of the federation has been appreciated and many external parties from the state and outside are interested to take lessons from the company in cultivation of Stevia.

Many multinational companies and India's big business houses are entering this business. The Tata Group is in discussion with CHAMF to procure herbs such as white musli and stevia and market it under a new brand of herbal products. Many companies from outside India are also interested for joint ventures with the federation to source herbal products. The efforts made through the federation have helped cultivators tap the vast market of herbs & medicinal plants and guarantee wider scope in the future.

6.1.2. Initiatives for Trade and Export Promotion

The various ministries and associate agencies of government at Central and State level have taken up several measures and initiatives to promote trade and export of AYUSH products and integrate them into domestic and global mainstream healthcare systems.

Initiatives to bring the Herbal Industry at the Forefront:

a) Scheme on Home Grown Technology (HGT) of Technology Information Forecast and Assessment Council (TIFAC) promotes Indian capabilities for the development of novel products and processes in different areas including the pharma sector – herbal sector also.
b) New Millennium Indian Technology Leadership Initiative (NMITLI) is launched by CSIR to attain a global leadership position in a "team India Spirit for Indian industry by synergizing the best competencies of publicly funded R&D institutions, academia and private industry.
c) 'Niryat Bandhu Scheme' has been galvanised and repositioned to achieve the objectives of 'Skill India' and trade promotion/awareness.

Initiatives for Quality Improvement:

a) Collaboration with NitiAayog and Invest India, in a Scheme for Integrated Health Research (SIHR) has been finalized with an outlay of ₹490 crore. The Central Research Councils of Ayurveda, Unani and Siddha are validating classical formulations for various conditions, through generating evidence on its clinical safety and efficacy.
b) The Indian Council of Medical Research (ICMR) research and experimentation, sufficient clinical data is being gathered for a number of Ayurvedic components. The Ayurvedic Pharmacopoeia of India gives monographs for 258 different Ayurvedic drugs. Indian Drug Manufacturers Association has published Indian Herbal Pharmacopoeia (2002) with 52 monographs on widely used medicinal plants growing in India where scientific data have been incorporated.[100]
c) Novel efforts like AyuGenomics (diagnostic typologies and a genetic basis) are taken up aiming to understand Ayurvedic concept of nature from pharmcogenomics perspective to provide a base for human classification, diagnostics and customized medicine. Projects like AyuSoft, a vision of converting classical Ayurvedic texts into comprehensive, authentic, intelligent and interactive knowledge repositories with complex analytical

[100]https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1297513/

tools for deriving radical ayurvedic solutions for health & treatment advice as a decision support system are appreciable.[101]

a) New analytical approaches like Herboprint, a scientific tool for standardization of traditional medicines are used to develop tools for activity-based standardization of botanicals. It works through interpretation of the fingerprint having molecules at different retention times and their retention time and their UV spectrum properties along with polarity is providing information about the chemical and therapeutic clinical properties of the material under analysis. (Patwardhan,2012)The Ministry of AYUSH through its Quality Certification programme like AYUSH mark and Premium mark is also assisting industry in setting up of quality standards.
b) The NMPB has launched a "Voluntary Certification Scheme for Medicinal Plants Produce (VCSMPP)" in 2017 in order to encourage the Good Agricultural Practices (GAPs) and Good Field Collection Practices (GFCPs) in medicinal plants. The VCSMPP will enhance the availability of the certified quality medicinal plants raw material in the country and also boost their export and increase India's share in the global export of herbs.

Initiatives for Herbal Healthcare Promotion:

a) Good Manufacturing Practices (GMP) have been notified under 'Schedule T' of the Drugs & Cosmetics Rules, 1945 and testing for heavy metals, viz. mercury, arsenic, lead and cadmium, in all purely herbal Ayurvedic drugs is made mandatory for export purposes. The requirement of proof for effectiveness of licensing on the patent or proprietary ASU medicine for the enactment of Drugs & Cosmetics Rule 158 B since August 2010 has necessitated the development of present guidelines of GCP. These guidelines have been prepared by a comprehensive consultative process and are fine-tuned to the best interest of Ayurveda.
b) The Government has promulgated GMP regulations for traditional systems of medicines to improve the quality and standard of Ayurvedic, Siddha and Unani drugs in pharmacies. New rules delineating essential infrastructure, manpower and quality control requirements came into force from 2000 and form part of the Drugs and Cosmetics Act, 1940. Licensing of Ayurvedic medicine is also governed under drug and cosmetics act, 1940. All Ayurvedic Patent and Proprietary medicines should contain only the ingredients mentioned in the recommended books as specified in the Act. For all new innovative herbal medicine, the safety and efficacy data are mandatory based on clinical trials. Depending on the nature of herbs and market availability, different requirements exist for submission of clinical trial and safety data which are mandated to be followed.[102]

[101] https://www.currentscience.ac.in/Volumes/102/10/1406.pdf
[102] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1297513/

c) Standard Operating Procedures (SOP) of manufacturing processes of formulation for development of different quality standards are being added. Parameters like DNA barcoding or fingerprinting of medicinal plant materials are combined within the framework for quality control of Ayurvedic drugs.
d) National Panel on Bhasmas for identification of thrust areas of R&D in the area of Bhasmas and Kushtas has been developed.
e) Novel efforts like AyuGenomics (diagnostic typologies and a genetic basis) are taken up aiming to understand Ayurvedic concept of nature from pharmcogenomics perspective to provide a base for human classification, diagnostics and customized medicine.
f) The Governments at Centre and in States have now taken up the issue of educational re-structuring to promote popularisation of TISM in the international markets. Now the Government is investing in creating AYUSH medical colleges and dispensaries (Ayurvedic, Homeopathy and others) with Under-graduates, PG, and Doctoral courses at par with medical colleges. The professionals passing out from these institutions are also getting similar placements and gradual recognition in the society.

Special Initiatives for Export Promotion of AYUSH:

a) For promotion of AYUSH systems across the globe, Ministry of AYUSH has signed Country to Country MoUs with 18 countries for cooperation in field of Traditional Medicine and Homeopathy, 19 MoUs for undertaking Collaborative Research/ Academic collaboration and 13 MoUs for setting up AYUSH Academic Chairs in foreign Universities. 31 AYUSH Information Cell have been set up in 28 countries to disseminate authentic information about AYUSH systems.[103]

i. Collaboration is explored with international agencies like FAO, World Bank, Asian Development Bank (ADB), UNDP, TRAFFIC, GEF, etc. for mainstreaming of medicinal plant development strategies. There are international agreements and protocols to deal with all of these issues, which are constantly evolving and the country is placing its interest in them.
ii. International Cooperation Scheme of AYUSH Ministry provides financial assistance to the exporters for the participation in Trade Fairs, organizing International Business Meets & Conferences and product registration reimbursements.
iii. Under Market Access Initiative (MAI) Scheme of the Department of Commerce, the EPCs / Trade Bodies are provided financial assistance for participation and organizing Trade Fairs, Buyer Seller Meets (BSMs), Reverse Buyer Seller Meets (RBSMs), Research & Product Development, Market Studies, etc.

[103] https://pib.gov.in/Pressreleaseshare.aspx?PRID=1579476

iv. Merchandise Exports from India Scheme (MEIS) provides incentives to the exporting community for specified goods so as to offset infrastructural inefficiencies and the associated costs of exporting products, giving special emphasis to those which are of India's export interest and have the capability to generate employment and enhance India's competitiveness in the world market.

v. The Department of Commerce has set up Export Promotion Councils (EPCs) for promoting exports of various product groups / sectors. The export promotion of several Herbal Products has been assigned to Pharmaceuticals Export Promotion Council (PHARMEXCIL), and Shellac & Forest Products Export Promotion Council (SHEFEXIL), headquartered at Hyderabad and Kolkata respectively.[104] These EPCs facilitate the exporting community and undertake various promotional measures for promotion of export of their products.[105]

vi. The Ministry of AYUSH is exploring bilateral and international collaboration in the field of medicinal plants with other countries. MOUs for bilateral Collaboration in the field of medicinal plants have been developed for National Medicinal Plant Board (NMPB) which could be appropriately fine-tuned for country specific needs.[106]

vii. For international cooperation the NMPB, under its Central Sector Scheme has several responsibilities such as collaborating with relevant agencies at the international level, setting up information centers on medicinal plants in Indian Missions abroad, providing financial assistance for acquiring international certification, subsidizing specific market promoting activities like product registrations, GRAS (Generally Recognized as Safe) affirmation, international certifications, positive listing of Indian botanicals in the importing countries, resolving issues of botanical ingredients which have been illogically banned by some international regulatory bodies, commissioning studies on international regulations in the medicinal plants sector.[107]

viii. Strengthening of AYUSH Delivery Systems is in process which includes assistance to accredited AYUSH Centres, Central Drug Controller for AYUSH, and development of common facilities for AYUSH Industry Clusters and promotion of international cooperation.

ix. The present Government's policy regarding Ayurveda and other Indian systems of medicine is aligned with the Traditional Medicine Strategy 2014-2023 of WHO, which has been adopted in the World Health Assembly for implementation by 192 member countries of WHO, the strategy seeks to help health care leaders to develop solution that

[104] http://dx.doi.org/10.1155/2015/218901

[105] https://pib.gov.in/PressReleasePage.aspx?PRID=1558955

[106] https://nmpb.nic.in/sites/default/files/Read%20More%20under%20International%20cooperation%20Tab_0.pdf

[107] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1297513/

contribute to a broader vision of improved health and patient autonomy. This collaboration has the potential to take the country forward in the area of TISM to a large extent.

6.1.3. Status of Export of AYUSH Products

As per a published report of National Medicinal Plant Board (NMPB), 2017 out of 6500 medicinal plant species traditionally used by Indian communities, only 1622 botanicals corresponding to 1178 plant species are found to be in all India trade. Of these 42% are herbs, 27% trees and 31% are shrubs & climbers. Only 242 species witness high volume trade (>100 MT) annually (Goraya & Ved, (2017).

It is noted that the export of herbs and value-added extracts of medicinal herbs are gradually increasing over the years. India exported USD 330.18 million worth of herbs during 2017-18 with a growth rate of 14.22% over the previous year.[108] Also, the export of value-added extracts of medicinal herbs / herbal products during 2017-18 stood at USD 456.12 million recording a growth rate of 12.23% over the previous year.[109]

The Indian government's resolve to triple the industry size to $ 9 billion by 2022 is a good measure in the right direction.[110] The AYUSH Ministry has recently seen a rise of 15 per cent in budgetary allocation for the sector. The current efforts put in by the government have already resulted in a 15-20 % growth in patient in-flow to AYUSH sectors. An outlay of Rs 1,939.76 crore has been earmarked for the AYUSH sector in the current financial year, an increase of 14.59% over the revised estimates of Rs 1,692.77 crore of the last fiscal. The government allocated Rs 40 crore for the All India Institute of Ayurveda, New Delhi, for financial year 2019-2020, while Rs 50 crore was earmarked for the National Institute of Homoeopathy in Kolkata.[111]

Table 11: Export of Herbs and Herbal Products for last three years and the current year in value (USD Million)

Commodity	*2015-16*	*2016-17*	*2017-18*	*April – November, 2019 (Provisional)*
Plant and Plant Portion (Herbs)	*274.14*	*289.07*	*330.18*	*205.45*

[108] http://pib.nic.in/newsite/PrintRelease.aspx?relid=187278

[109] https://pib.gov.in/Pressreleaseshare.aspx?PRID=1558955

[110]https://www.businesstoday.in/current/economy-politics/why-pm-narendra-modi-s-love-for-AYUSH-may-help-indian-ayurveda/story/288110.html

[111] https://economictimes.indiatimes.com/news/economy/policy/budget-2019-in-fillip-to-traditional-medicine-ayush-ministry-gets-rs-1939-76-crore/articleshow/70094965.cms?from=mdr

AYUSH and Herbal Products	*364.00*	*401.68*	*456.12*	*290.96*

(Source: Government of India, Ministry of Commerce and Industry)

Table 12: Export of MAPs from India (Rs. in Crore)

Year	***AYUSH Items***		***All Items***		***%age share of AYUSH Items***
	Export	***Growth Over previous Year (%)***	***Export***	***Growth Over Previous Year (%)***	
1995-1996	*627.48*	*-*	*-*	*-*	*-*
1996-1997	*884.65*	*41.00*	*118817.97*	*-*	*0.74*
1997-1998	*1107.75*	*25.00*	*129277.70*	*9.00*	*0.86*
1998-1999	*1276.28*	*15.00*	*139753.16*	*8.00*	*0.91*
1999-2000	*1324.73*	*4.00*	*159561.78*	*14.00*	*0.83*
2000-2001	*1364.13*	*3.00*	*203571.01*	*28.00*	*0.67*
2001-2002	*1278.68*	*-6.00*	*209017.97*	*3.00*	*0.61*
2002-2003	*1864.88*	*46.00*	*255137.28*	*22.00*	*0.73*
2003-2004	*1227.06*	*-34.00*	*293366.75*	*15.00*	*0.42*
2004-2005	*1657.69*	*35.00*	*375339.53*	*28.00*	*0.44*
2005-2006	*1939.96*	*17.00*	*456417.86*	*22.00*	*0.43*
2006-2007	*2186.96*	*13.00*	*571779.29*	*25.00*	*0.38*
2007-2008	*2275.64*	*4.00*	*655863.52*	*15.00*	*0.35*
2008-2009	*3036.35*	*33.00*	*840755.06*	*28.00*	*0.36*
2009-2010	*2887.01*	*-5.00*	*845533.64*	*1.00*	*0.34*
2010-2011	*3341.90*	*16.00*	*1142921.92*	*35.00*	*0.29*
2011-2012	*19069.39*	*471.00*	*1465959.40*	*28.00*	*1.30*
2012-2013	*24741.22*	*30.00*	*1634318.84*	*11.00*	*1.51*
2013-2014	*15717.23*	*-36.00*	*1905011.09*	*17.00*	*0.83*
2014-2015	*13620.57*	*-13.00*	*1896348.42*	*-0.50*	*0.72*
2015-2016	*10523.52*	*-23.00*	*1716378.05*	*-9.50*	*0.61*
2016-2017	*7823.65*	*-26.00*	*1849428.76*	*7.80*	*0.42*

(Source: Ministry of Health & Family Welfare, Govt. of India. (ON1695) & Past Issues)

6.1.4. Issues in Export and Trade Practices of MAP sector

There are several reasons for which India is unable to compete in the international market in propagating and promoting its indigenous system of medicine. Official export from India is only a very small percentage compared to the trade and consumption figures. Again, since many Ayurveda medicines are reported to contain heavy metal contents they are not officially exported from India. Again, if not imported under legal conditions, it is very difficult to actually come at

the right fact and figures regarding its current usage and domestic demand position in India. The authorities in India should act on these discrepancies in order to bring back faith of potential users.

At the domestic level there are several issues which need upfront action. Several laws are outdated and the reasons to follow it do not hold true anymore, but remain unchanged. There is a complex regulatory mechanism for trade in wild collected/cultivated MAPs which varies from State to State. Since the same law differs from state to state, the trade of certain MAPs species in one state might be prohibited while it might be open for trade in its neighboring state. The reason for which it was prohibited at the state in the first place or for that matter, the reason for having not put restriction on trade in the other state might not exist anymore, but the laws are still being followed unchanged. The provision of issuance of clearances and certificates exist at every level from cultivation to legal procurement and then for transit of the legally collected product. There is a need to develop more uniform laws and update the provisions on a regular basis based on continues studies.

There is a lack of co-ordination between the Central Government and the State Government. This is because medicinal plant exports are a state subject while the role of the States in exports still remains un-defined. Consultation of the Centre with the respective State Governments is required for preparation of a guidebook clearly defining the role of the state in exports. The State Governments need to come forward and need to assist the exports from their respective states pro-actively.

On the basis of the survey results, specific management and monitoring plans for all protected areas and threatened plant species need to be developed and strictly enforced. Monitoring of threatened species needs to include not only in situ activities, but also the development of a more effective warning system for illegal trade and further control measures for the export of rare, threatened plant species, such as wild orchids, and rare medicinal plants. Current supervision and management of trade in natural resources that are legally protected is lacking. It is also important that such measures are balanced in controlling trade, while still allowing scientific exchange and progress.

Each State government has been vested with the power to create their own rules to regulate the transit of forest produce including MAPs. Transit rules also provide authority to State governments to prohibit the collection and trade of forest produce obtained from a species considered to be of conservation concern in that particular State. This is in addition to the federal regulations which are applicable across the country. For example, in Himachal Pradesh, the trade of T. wallichiana is prohibited while it is allowed in Uttarakhand. Similarly, the trade of Saussurea costus is prohibited in Jammu & Kashmir where the species is found in the wild while

it is permitted in Himachal Pradesh.[112] Madhya Pradesh does not enforce the necessity of transit pass during transport of medicinal plants. This facility was intended to benefit the poor gatherers but it has in-fact benefitted the traders most. Therefore the regulatory framework of the states and the centre should be clear and made simpler.

For an ideal production –supply chain, the resource and product development should be linked to market preferences. In India, this is not the case for medicinal plant trade. For sustainable forestry the role of marketing to create effective linkage amongst growers, resource managers, processors and the end users is vital, and this is in demand, when we see the current international market.

At the community level, poorly designed price mechanism, based on local area/ previous year's sales price results in very low remuneration to the people in gathering and cultivation. This system results in de-incentivizing the local communities in engaging in cultivation and trade of medicinal plants. The market channels are un-organized leading to monopoly of few individuals and industries which control and dictate the market. Again, strict GAP provisions should be enforced upon the industries and facilitated by the Government to be followed strictly through clear guidelines and incentive-disincentive mechanism. Another major area of concern is the absence of certification of products (especially certification of source of produce, since this is the prescribed demand of the international community) or agreed standards to guide the quality and price linkages. The institutional efforts are confined up to cultivation at the local level and propagation but are totally absent for marketing.

All the policies / legislations made whether at central or the state level have orientation to conservation, propagation, cultivation and institutionalization etc. Not a single policy discusses about post harvesting, logistics, infrastructure and marketing aspects. Processing units should be encouraged to operate at the community site level and have tie-ups with the industrial houses directly which offers to buy the produce. Therefore the backward linkages need to be strengthened in the sector. There should be need gap analysis of infrastructure (roads, packing houses, storage structures, processing units, testing labs etc.), and plans to provide solutions accordingly. Infrastructure and logistic concerns such as congestion at ports, connectivity from production area to ports has to be reduced, which is a major concern of the exporting industrial houses. The infrastructure arena also has scope for better technology in packaging which should be looked into. Also introduction of technology in loading/unloading/packaging is the need of the hour. The process of documentation and procedures to be followed for exports are complicated and time-taking which should be simplified. Since the transportation cost of perishables from

[112] http://nbaindia.org/uploaded/Biodiversityindia/Legal/3.%20Indian%20forest%20act.pdf

landlocked states is very high, a provision to include interstate movement in the Tax Assessment can be considered with suitable ceilings such as minimum distance/quantity/ value/ commodity.

Efficient transportation system needs to be established in a phased manner along with developing the dedicated corridors for it. Green channel should be created at key ports (volume/value to be considered) to boost the export of perishables. There should be dedicated containers for perishable MAP products at the ports to facilitate exports. MoC can collaborate with Ministry of Railways to have a provision for refrigerated vans linked with superfast trains from land-locked states to key export terminals.

For the exporting house, procurement of transit pass from the DFO office is a herculean task. Sometimes it takes weeks and by the time the pass is obtained, most of the produce would perish. This aspect should be critically considered.

The subsidy given by the Government of India is laudable, but timely allocation of funds for subsidy is a major concern for the farmers. With regard to schemes affecting the working capital cycle of the exporters as the exporters consider TAS (subsidy) while determining the final selling price, should be released within 2-3 months post application. Timely allocation of funds by central government will smoothen up the process. The MoC is the concerned authority that should take up the matter in order to smoothen the process.

General lack of awareness on the existing schemes and policies related to exports is a major gap which should be bridged through government efforts. There is a serious communication gap between the efforts put in by the government and building the farmers and traders timely knowledge on those efforts and opportunities. Government efforts with these issues at the ground level should be brought forward. There should be emphasis on dissemination of information wherein more stakeholders know about each other's activities. The policies should be made such that it is as practical as possible, instead on just being mere actions on paper. State Medicinal Plant Boards should facilitate to prepare the guidebook for easy dissemination of GAP through the State concerned departments.

Registration of farmers for traceability especially for key products high in demand is important. The importing nations are becoming stricter with regard to production norms/ traceability at farm levels and stress on organic / sustainably sourced products. Promotion of organic products which is the future of the AYUSH sector in the international market is necessary.

Unregulated chemicals usage at the farm level, unscientific harvest and post-harvest management affects the quality and shelf life of the produce negatively. Government should disseminate region-wise and commodity specific guideline of practices. It is also necessary to build farmer awareness which is critical to regulate chemical usage on the farms. The concerned State Government Department shall collaborate with Ministry of Agriculture/ICAR to allow

Agriculture Research Universities to prepare commodity and region specific cultivation guideline manuals. Also it should evaluate the progress regularly in farm activities (including optimum input usage, right harvesting time, scientific harvesting practices, post-harvest handling at farm level, etc.).

6.2. Trade and Export of Medicinal Plants in China

China has adopted a multi-pronged and systematic approach towards TCM product development, improvement and expansion of its market as well as a positive approach towards export promotion and internalization. The Chinese government has undergone planning, coordination and co-operation in the sector which has an important role in its impetus to promote it especially in the last 2 decades. Special Economic Zones have come up at several strategic locations in order to improve export potential of TCM in the country.

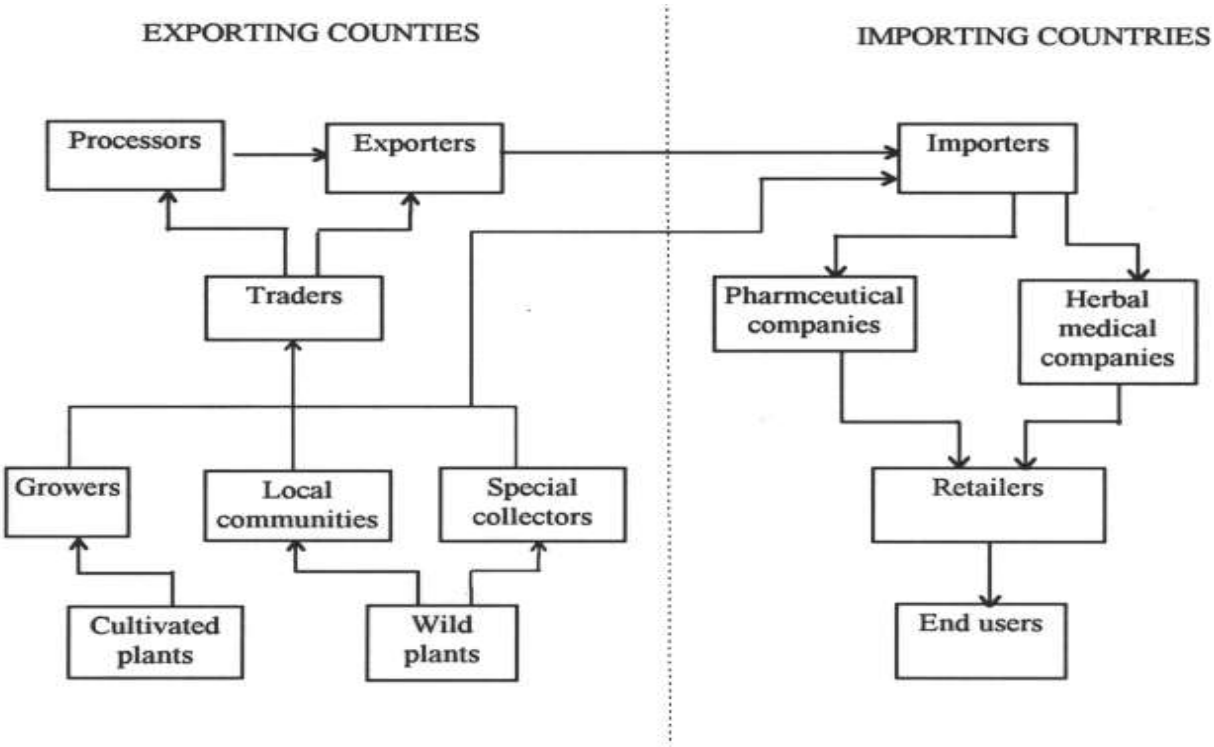
Its policies and programmes are geared up towards supporting and incentivizing export promotional activities among the TCM industries. Industry support policy, promotional finance policy, innovative reforms on administrative set-ups are taken up proactively by the government.

With improvement in its world trade and market situation, China has also strategically planned the development and promotion of TCM. The total output value of the TCM pharmaceutical industry accounts for around 30 percent of the total generated by the country's pharmaceutical industry, and therefore is a big player as a new source of growth in China's economy.

6.2.1. Trade Channels and Market System for TCM

About 80% raw material for TCM has also come from wild sources and therefore, the traditional channel of trading viz. collector/producer – traders – processors/exporters is in vogue in China also. However, in recent times China has made systematic efforts for market system development for trading and export of TCM raw and processed products.

Trading Routes of Crude Drugs



Integrated Market System Development for Trade and Export of TCM

China has taken several steps to upgrade and develop market system development for trading of TCM across the country.

Market infrastructure development for TCM trading: The trading and export markets have been developed in the Provinces wherein natural production and cultivation of TCM raw herbs and other materials take place. Modern market infrastructures have been developed for trading of raw herbs and processed products in the markets. The all the value chain players viz. primary producers/collectors, traders, processors, exporters have been given the facility for office space and shop to carry out their business activities.

Primary Processing Facility Development: The facility for primary processing of raw material such as cleaning, grading, sorting, packaging, etc., are developed in the market premises which is used by the collectors/cultivators for primary processing of their produce at a nominal cost before selling in the market.

Development of Storage Facility for Traders and Processors: Within the same market premises, storage facilities have been developed keeping in the requirement of different value chain players and provided them on lease.

Transport and Export Facility: Transport and export facility are also linked with the market system so that the traders, processors and exporters can transport the TCM products both raw and finished products.

Box 4: Case of Market System Development for TCM Trade and Export

The Chengdu HeHuaChi Chinese Herbal Medicine Market at Chengdu in Situahan Province is one of the biggest medicine herb markets of all China. It works as a major center for import-export herbal businesses of China to the whole country and internationally[113].

Sichuan is the country's biggest province in cultivation of herbs used in traditional medicine and production of more than 5,000 kinds of traditional medicine. Seventy percent of them are traded in Chengdu[114]. Pharmacies, Laboratories, Private clinics, TCM Hospitals, Researchers, and a bunch of other businesses come to the Chengdu TCM Market to buy all kind of medical products and herbs.

TCM Market at Bozhou located in East China's Anhui Province has spread in 75 acre. The TCM market in Bozhou is said to be one of the most wide-ranging and active specialized markets for Chinese medicinal materials, with the market's annual sales standing at 30 billion yuan ($4.73 billion) in 2017[115].

Digitization and Integration of Technology to leverage benefits in TCM Market Trading:

The recent integration of technology with the internet is a huge advantage being leveraged by the country. Digitalization is rapid and being used positively for the growth in the sector. For example, the 111 Inc, China's largest online pharmacy and healthcare service provider started trading its American Depositary Shares on the Nasdaq stock market.

For Market Diversification of TCM, one of the key strategies is Internet regulation. Chinese authorities are actually encouraging medicinal websites which are professional sites and correlated with legal pharmaceutical companies. These steps will help the country establish its capability and willing to produce quality medical products. China has already understood the importance of reliable online medical resources, and therefore is engaging in strict enforcement of these strategic goals.

[113] https://www.tcmchinatravel.com/study/chengdu-chinese-herb-medicine-market-china/
[114] https://www.chinadaily.com.cn/cndy/2011-04/21/content_12365717.htm
[115] http://www.globaltimes.cn/content/1091852.shtml

Box 5: E-commerce under TCM Trade

Initiative of Alibaba for Online Sale of TCM Products

The E-commerce giant Alibaba Health Information Technology Ltd., attempts to enter the rigidly-regulated pharmaceuticals market through purchase of a drugstore chain, Wuqiannian Medicine Co. Ltd., for US$ 2.5 million which sells OTC medicines and liquid tonic made of traditional Chinese medicines, according to the company's website. It has a five-year license granted by the China Food and Drug Administration (CFDA) in 2015 that allows it to sell drugs online.

6.2.2. Trade and Export Promotion Initiatives

China has introduced the concept of "internationalization of TCM" since 1996 to remove the barriers in exports which comprised of two major aspects: (1) it is important to expand the volume of import and export in order to push forward the "going abroad" of TCM, to promote the sustainable development of its international trade and to foster the TCM market share across the countries; (2) the legal status of TCM in overseas countries has to be appropriately established to ensure reasonable market entry and to enable sustainable development of TCM under the protection of the local laws and regulations.[116]

The government of China continuously puts in efforts to strengthen bilateral and multilateral trade negotiations with other countries, negotiate specific technical trade barriers set up by different countries, and create channels for Chinese medicine exports. The government formulates relevant policies and regulations and formulates standards that meet the international market requirements for Chinese medicines along with its corresponding supervision mechanisms. The government has formulated special laws and regulations on production and sales of traditional Chinese medicine, establish and improve the quality control system for traditional Chinese medicines, establish a supervision and security system, and strictly supervise and control the production and export of traditional Chinese medicines.

Strategy taken up by the Chinese Government for Export Promotion:

a) Winning by quality: Export product is expected to rise in quality as a means of enlarging overseas market by attracting buyers with good quality. Another way is through building a big data platform of Chinese medicine (big data platform of TCM preparation; big data platform on the quality of TCM).

b) Market diversification: Target countries and regions do not have to confine to U.S., Japan and Europe but explore new international markets such as Russia, Asian countries and developing countries at large.

[116] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5807832/

c) Reinvigorating trade by science and technology in which the exports will balance between traditional vs. high value added and preferably higher technology content or tech-intensive export encouragement.

d) The strategy of going global in which the Chinese investment goes abroad.

e) Product innovation of TCM (study the TCM by using the methods and means of western medicine; innovate the basic theory of TCM; develop TCM health product)

Systematic Regulations on Protection of TCMs:

For trade promotion of TCM, the country has its focus on deepening reforms. Reforms were brought in the pharmaceutical regulatory review and approval processes for priority areas such as innovative medicines, protections of intellectual property, timely predictable and transparent government reimbursement for innovative medicines and accepting overseas clinical trial data.

The country also plans to strengthen trade by science and technology in which the exports will balance between traditional vs. high value added and preferably higher technology content or tech-intensive export encouragement.

Legislations for TCM Development:

TCM is generally subject to State Pharmaceutical Standards. National regulation of TCM accelerated in 1992 with the Regulations on Protection of TCMs, which came into effect since the year, 1993. The purchase and the export of wild medicinal materials, was put under the provincial governments. These Regulations are formulated for the purposes of improving the quality of types of TCM, protecting the legitimate rights and interests of TCM producing enterprises, and promoting the development of TCM.

The country has revised several laws for examination and approval procedures of drugs produced in China. Under these new laws, all manufacturers, producers and wholesalers must be licensed by local and national agencies, all drug institutions are subject to investigation, and violation of the laws results in large fines and loss of license. These regulations set out distinct steps for application, clinical testing and approvals.

Assurance of TCM safety is also difficult. China has set up a quality inspection technology system focusing on chemical marker detection in order to fare batter in terms of quality indications in the international market.

Several regulations were introduced for regulation on Protection of TCM. It streamlined the protection of all TCM products prepared or produced in China with minimal filing hassle and extended periods of protection, including secrecy. Violation of the Regulation on Protection of

TCM resulted in fines, removal of the certificate of authority, confiscation of fraudulent products, and criminal sanctions.

The State Drug Administration works in combination with these national and regional TCM laws to create national legislation regulating the development, production and sale of pharmaceuticals, specifically including TCM drugs. Although the laws do specify a few areas where TCM drug regulation differs from conventional drug regulation, as a general rule, TCM drug manufacturers, distributors, and wholesalers have to provide the same standards as other Chinese drug manufacturers, which is a major step towards putting the TCM drugs at par with other more acceptable forms of modern medicines manufactured in China.

The Outline of the Medium- and Long-term Development Plan for the Standardization of Traditional Chinese Medicine (2011-2020) plan has put in place initially a system of TCM standards where five national technical committees of standardization have been established for Chinese medicine, acupuncture and moxibustion, TCM drugs, integrated Chinese and Western medicine, and seeds and seedlings of Chinese medicinal plants respectively. Local standardization technical committees of TCM and pharmaceuticals were set up in Guangdong, Shanghai, Gansu and other provinces.

There are strict conditions under which the drug manufacturing enterprise has to operate. The country revised several laws for examination and approval procedures of drugs produced in China. Under these new laws, all manufacturers, producers and wholesalers must be licensed by local and national agencies, all drug institutions are subject to investigation, and violation of the laws resulting in large fines and loss of license. These regulations set out distinct steps for application, clinical testing and approvals. There are compliances to be followed by each province regarding medicinal plants. Specific tasks are allotted to specific authority to be followed; this ensures clear dissemination of information and its compliance.

TCM are an important part of ongoing government policy development, both in terms of medicinal products and in terms of hospital/physician practice. In the Chinese health care system, TCM products are not used in isolation from physician practice. There is a network of TCM hospitals that are visited by large numbers of Chinese patients, where treatments such as acupuncture are administered in addition to supply of TCM products. A number of these hospitals combine Western medical practice and TCM practice in a single facility. Much international collaboration has been made to develop facilities in these private hospitals.

Since 1996, all exported TCM and their manufacturing processes have been subjected to inspection by SATCM designated organizations. TCM Exports brings together the SATCM, Ministry of Foreign Trade and Economic Cooperation, and the State Administration of Import and Export Commodity Inspection to issue yearly statements of exportable TCM and TCM producers

collaboratively. The collaborative efforts and support of different kinds of organizations ensures that the regulation is more likely to be followed than other regulations originating from a single department, council, or ministry.

Quality standards of TCM has been raised to meet export regulations:

Export product is expected to rise in quality as a means of enlarging overseas market by attracting buyers with its authenticity and effectiveness in terms of addressing the health related issues of people. A big data platform of Chinese medicine (TCM preparation, quality control and traceability of TCM) is built as another strategy to make the information available to all. The quality data platform of TCM includes the quality standards of Chinese medicinal materials, decoction pieces, and Chinese patent medicine. For example, the DNA barcode 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. 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 standardized gene identification era.[117]

For promoting TCM Pharmaceutical industry, the Government stance is on pushing high-quality, innovative healthcare companies, and the underperforming companies are seriously dealt with risk of being eliminated. This strategy of the Government makes compliance to rules and regulations more efficient. The Government has taken up green development mode for TCM industrial chain, and various efforts are being put in for the development of non-pharmacological therapies. The social capitals, such as people-to-people network, links and collaborations are encouragingly being supported to develop TCM. The private investors are encouraged to establish TCM healthcare institutions, resulting in a large number of such institutions flourishing in China at present.[118]

The Government is promoting good regulatory practices for strategic products, including TCM products, to benefit the global supply of high-quality and affordable health products and technologies. It is also pro-actively engaged in improving implementation and enforcement of health services and food and drug safety laws. The manufacturers have to strictly comply with all regulations regarding quality standards. Manufacturers in compliance are eligible to receive a

[117] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5807832/
[118] https://www.tomorrowscompany.com/wp-content/uploads/2016/05/Tomorrow_s_Capital_Markets_Final_vfl.pdf

quality registration certificate. This certificate is revocable by the investigative organization if caught with quality control problems.

The Government adopted Good Agricultural Practices (GAPs) and Good Manufacturing Practices (GMPs). About 2,088 pharmaceutical enterprises were approved by the Good Manufacturing Practice (GMP) of Medical Products in manufacturing Chinese patent medicines. There are strict conditions under which the drug manufacturing enterprise has to operate.[119] China is actively promoting the integration of TCM and other traditional medicine with modern technology, so as to explore a new model of healthcare to improve the well-being of all people of the world.[120]

Most importantly, the product quality violations are subjected to criminal sanctions in the country. Enforcement of criminal sanctions is more likely than enforcement of fines or other equitable remedies in China; this makes it obligatory for the rules to be followed. As a general rule, TCM drug manufacturers, distributors, and wholesalers have to provide the same standards as other Chinese drug manufacturers.[121]

All the new herbal drugs must be approved according to the Drug Administration Laws. The China Food and Drug Administration review the quality of all products; and those that don't pass the mark are being strictly eliminated.[122] Only after final completion, reporting, and examination, the medicines approved for production and processing. Going through these rigorous quality check processes aims to assure the quality of the products and a documented scientific backing for the products are built. [123]

Government has also prioritized an increased investment in technological transformation so that the TCM production quality levels reach a historical new height. A big data platform of Chinese medicine, for TCM preparation; and for quality of TCM is being built as another strategy.

Through rigorous R&D, product innovation of TCM (studies the TCM by using the methods and means of western medicine; innovate the basic theory of TCM; develop TCM health product). These steps further augment the quality of TCM.

Legal Provisions for Regulations of Trade and Exports of TCM to ensure Compliances:

- Article 15 states that in the market of country fairs only the sale of medicinal plant materials is permitted, with certain exceptions.

[119] https://www.chinadaily.com.cn/china/2016-12/06/content_27583181.htm
[120] https://www.scio.gov.cn

[121] https://www.who.int/phi/publications/2081China020517.pdf
[122] https://www.fda.gov/consumers/consumer-updates/it-really-fda-approved
[123] https://www.who.int/phi/publications/2081China020517.pdf

- Article 29 states "The Ministry of Public Health has the authority to restrict or prohibit the exportation of medicinal plant materials and patent herbal medicines if they are in short supply in the domestic market".

- Article 31 states "The sale of medicinal plant materials newly discovered or introduced from abroad is not allowed unless it is approved by the health bureau of the province, autonomous region or municipality".

- Documentation for Applications for New Drugs Based on Article 21 of the Drug Administration Law, "the clinical trial or clinical verification of a new drug should be sanctioned by the Ministry of Public Health or the health bureau of the province, autonomous region or municipality".

Product Development and Market Strategy:

The government has developed preferential policies to let the market play a key role in allocating resources. It strives to create a market environment characterized by equal participation and fair play, so as to maximize the potential and vitality of TCM.

The government has initiated a market access system for TCM practitioners, TCM medical institutions and TCM medicines. The government has developed preferential policies to let the market play a key role in allocating resources.

With regard to their legal status, herbal medicines in China are normally considered as medicinal products with special requirements for marketing, for example a backup of quality dossier, safety and efficacy evaluation, and special labeling. The law specifically takes care of the additional requirements for TCM medications including sourcing, cultivation, ecological environment, collection, handling, processing, and preparation information included in the pretrial testing phase. Only after final completion, reporting, and examination are the medicines approved for production. For this new Pharmaceutical Examination and Approval Procedure have been put together.

New drugs have to be examined and approved according to the Drug Administration Law. After approval, a New Drug certificate is granted an approval number. The factory is then permitted to put the WHO/TRM/98.1 page 28 product on the market. Modern scientific and technical knowledge is used in appraising the therapeutic effects and the quality of the modified traditional medicines, and contributes administratively to the exploitation of TCM.

The dosage forms of TCM medicines were increased from limited ones such as pills, powders, ointments and pellets into more than 40 types that include dropping pills, tablets, pods and

capsules, showcasing the high grade improvement in the technological practices of Chinese medicinal drug production.

A registration management system was established for TCM pharmaceutical medicines under the guidance of TCM theories and pharmacology. By the year 2015, around, 60,000 TCM and ethnic minority medical drugs were approved. There are compliances to be followed by each province regarding medicinal plants. Specific tasks are allotted to specific authority to be followed; this ensures clear dissemination of information and its compliance.

Promotion of Collaboration with MNCs for TCM Product Development and Marketing:

China is the world's second-largest economy, and it has the third-largest share of world trade. The country has the fastest-growing healthcare market of all large emerging economies. Due to the country's size and growth potential, the healthcare market has become attractive to foreign investors.

China has opened up its medical industry to foreign investment. Multinational pharmaceutical companies have large-scale deployment of R&D centres in China. Since June 2008, the Academy of Military Medical Sciences and Phytopharm, a British company in plant medicine, signed a cooperation agreement on "NJS" (a new type of Chinese medicine) with "patent licensing", marking the first time that a Chinese patent for innovation in traditional Chinese medicine went abroad. This is also the first time that China has authorized the use of IP of Chinese medicine by international companies.[124]

Strict Regulatory Mechanism for Quality Control:

The Chinese government followed strict conditions before the TCM products reaches international market and ensures that proper investigation and certification is completed for all products exported. Chinese Government restricted the sales channels of Chinese TCM suppliers. Appropriate legislation was passed in the year 2000 and 2001 to regulate online advertising and sales of Chinese medicines. On January 1, 2000, the Ministry of Health outlawed online diagnosis and treatment services. The State Drug Administration and the Ministry of Health collaborated to ensure safety in both domestic and international purchase of TCM medicines via the Internet. The websites claiming to give medical information must receive approval from appropriate medical and health authorities and display the seal of approval on the home page. The Ministry of Health also designated special task force to regularly inspect health and medicine websites for violations. The State Drug Administration is responsible to screen and regulate providers and

[124] https://link.springer.com/chapter/10.1007/978-981-13-8102-7_10

traders of online pharmaceutical information and the Government of China whole-heartedly supports these efforts.

The industry is transforming from the "Made in China" model to "Created in China," with more innovator drugs, in which the private companies are having a leading role.[125] In China, the TCM systems are being evaluated vis-à-vis modern medicine system. The evaluation is based on rigorous evidence which would provide significant assistance in clinical research. Over a period of time, TCM is creating a large body of scientific evidence to support safety, pharmacology and clinical efficacy (Patwardhan, 2005).

Showcasing TCM in the Global Arena:

China is keen on promoting its traditional form of medicine overseas, and has taken up several steps towards ensuring it. These initiatives help showcase the importance the government gives to its indigenous form of medicine system. It also facilitates internationalisation of TCM, through creation of more avenues to showcase the effectiveness and impact of this form of medicine.

Some of these steps taken by the government are as follows:

- The Chinese government has signed 86 TCM cooperation agreements with other countries and international organizations, and has supported the building of 10 TCM centers overseas.
- To promote the orderly development of TCM around the globe and ensure its safe, efficient and targeted application, China has facilitated the founding of the ISO/TC249 TCM in the ISO. With its secretariat in Shanghai, it has now issued a series of ISO standards on TCM.
- While seeking its own development, within its capacity China has persisted in providing aid and assistance to other developing countries, where it can be useful for the people. To date, China has sent medical teams to over 70 countries in Asia, Africa, and Latin America, with TCM professionals in almost every team, accounting for 10 percent of the total number of staff. TCM centers are being built in African countries, and specialized TCM stations have opened in Kuwait, Algeria, Tunisia, Morocco, Malta, and Namibia.
- The Chinese government has sponsored 10 TCM centers overseas. In recent years, China has strengthened work in the prevention and control of AIDS and malaria in developing countries, and in African countries in particular, sending a total of 400 TCM specialists to more than 40 countries including Tanzania, Comoros, and Indonesia.[126]
- The China government is establishing overseas TCM hospitals modeled on those operating in China. There is a modern TCM prescription dispensing facility, complete with

[125] http://www.xinhuanet.com/english/2018-12/17/c_137680388.htm
[126] http://www.chinadaily.com.cn/kindle/2016-12/07/content_27601954.htm

computerization and barcoding of package products, and product-tracking IT systems. The TCM product formulation facility is similar to a traditional Western pharmaceutical formulation facility, albeit with somewhat different characteristics.[127]

Collaboration with WHO:

China actively collaborated with World Health Organization (WHO) to promote TCM at international level. WHO incorporated TCM into the 11th revision of the International Classification of Diseases (ICD-11) which was a milestone for TCM's internationalization. This step helped promote international exchange and cooperation in the supervision and management of traditional medicine and was an effort to ensure that it is safe and effective.

The National Health and Family Planning Commission (NHFPC) of China and WHO jointly developed China-WHO Country Cooperation Strategy: 2016-20. Under this initiative, WHO is supporting China Food and Drug Administration (CFDA), NHFPC and other ministries in strengthening the national regulatory system for regulation of health services, food safety, and health products and technologies, including TCM products, to better protect population health (CHINA-WHO Country Cooperation Strategy 2016–2020).[128]

The Chinese government works hosted the first WHO Congress on Traditional Medicine in Beijing in 2008, and played an important role in drafting the Beijing Declaration. In accordance with initiatives of the Chinese government, the 62nd and 67th World Health Assemblies passed two resolutions on traditional medicine, and urged its member states to implement the WHO's Traditional Medicine Strategy 2014-2023.

Usage of Belt and Road Initiative (BRI) for TCM Promotion Overseas:

The Belt and Road Initiative (BRI) is a long term strategy in China to boost the region's economic development. The BRI aims to enhance trade, infrastructure and connectivity through building networks of railways, highways, bridges, airports, ports, oils and gas pipelines and fiber optics. Its aim is to link China to Asia and Europe consisting of two important strategies: (1) the Silk Road Economic Belt – the land route connecting China with Central Asia, Eastern and Western Europe; and (2) the 21st Century Maritime Silk Road – the sea route connecting China to South East Asia, Africa and Central Asia.

[127] https://www.who.int/phi/publications/2081China020517.pdf

[128] http://www.wpro.who.int/china/160321_ccs_eng.pdf

The BRI involves over 60 countries and provides an opportunity for the global north to connect with the global south through an economic security platform. China has built a group of TCM centers in countries and regions along routes of the Belt and Road.

The plan sets out its development goals: By 2020, the new pattern of all-round cooperation in the "Belt and Road" initiative of TCM will basically take shape. Based on neighboring countries and key countries, 30 overseas centers for Chinese medicine will be established in cooperation with countries along the route. Twenty TCM international standards have been promulgated, 100 kinds of TCM products have been registered and 50 TCM external communication and cooperation demonstration bases have been built.

More countries along the route recognize the legal status of TCM, and Chinese TCM cooperates with them to achieve greater scope, higher level, and deeper levels of openness, exchanges, and integration (Wang Wannan; Liu Yongsong et al, Analysis on the Barriers and Countermeasures of Chinese Medicine Enterprises for Countries along the Belt and Road, Advances in Economics, Business and Management Research, volume 58, 2018)

6.2.4. Status of Export of TCM

Currently, regarding TCM the main focus is to take it global. TCM has already been spread to 183 countries and regions around the world. In 2018, China was the largest exporter of Chinese medicine products and the total GDP of Chinese herbal medicine sector was 261 billion USD, with an annual increase by 21.0% of which the GDP of raw material production was approximately 80.0 billion USD. It sold nearly 224 thousand tonnes of TCM to foreign countries in the same year, with ginseng, Chinese wolf-berry and cinnamon contributing to major sales. Extracts, used as ingredients to make cosmetics and food supplements, took the largest portion of TCM exports. Most of the herbal medicines were exported to Asian nations and regions, which took up more than 85 percent of the total sales chart. Hong Kong, Japan, US and EU are among the major export destinations of TCM. Japan became China's largest TCM export market in the year 2018.

TCM medicines have gradually entered the international system of medicines, and some of them have been registered in Russia, Cuba, Vietnam, Singapore, United Arab Emirates, and other nations. Some 30 countries and regions have opened a couple of hundred TCM schools to train native TCM workers. The World Federation of Acupuncture-Moxibustion Societies, headquartered in China, has 194 member organizations from 53 countries and regions, and the World Federation of Chinese Medicine Societies has 251 member organizations from 67 countries and regions.[129]

[129] http://www.china.org.cn/government/whitepaper/2016-12/06/content_39858330.htm

Traditional Chinese Medicine has become an important area of health and trade cooperation between China and the Association of South East Asian Nations (ASEAN), European Union (EU), Africa, and Central and Eastern Europe and a key component for people-to-people exchange between China and the rest of the world. Hong Kong, Japan, USA and EU are major export destinations of TCMs. While EU showed major growth (49.15 percent) in TCM herbs/plant extracts; Hong Kong, Japan and USA were export markets for Chinese Patent Medicines (54 percent). Trade in Chinese medicinal products has consistently maintained a rapid growth.

Table 13: China's Export Structure of Chinese Medicine, 2013-2017 (Unit: 0.1 Billion US Dollars, %)

Year	Chinese patent medicine		Plant extracts		Chinese herbal medicines and decoction pieces		Health products		Total export amount
	Export amount	Proportion	Export amount	Proportion	Export amount	Proportion	Export amount	Proportion	
2013	2.7	8.6	14.1	44.9	12.1	38.54	2.5	7.96	31.4
2014	2.5	6.96	17.77	49.47	12.95	36.05	2.7	7.52	35.92
2015	2.62	6.95	21.63	57.37	10.58	28.06	2.82	7.48	37.65
2016	2.25	6.57	19.27	56.25	10.25	29.91	2.49	7.27	34.26
2017	2.5	6.87	20.1	55.22	11.4	31.32	2.4	6.59	36.4
2018	2.7	8.6	14.1	44.9	12.1	38.54	2.5	7.96	31.4

Source: Wang W; Liu Y et al; 2018, Analysis on the Barriers and Countermeasures of Chinese Medicine Enterprises for Countries along the Belt and Road, Advances in Economics, Business and Management Research, volume 58

Table 14: Export Status of Chinese Traditional Medicine Corporation in January-November 2017 (Unit: 10,000 US Dollars, %)

No.	Country	Number of exports	Number of exports compared to the same period	Export amount	The export amount is the same as the previous year	The proportion of export amount
1	Vietnam	12062054	241.57	10021.59	394.4	38.35
2	Malaysia	7719560	-3.62	4167.68	-5.29	15.95
3	India	10941572	184.25	2097.37	160.45	8.03
4	Thailand	3182811	17.26	1951.5	44.63	7.47
5	Singapore	2669359	-10.5	1882.84	-9.6	7.2
6	Bangladesh	5230787	-20.38	903.57	-24.25	3.46
7	Saudi Arabia	4865678	21.29	873.26	16.58	3.34

8	Pakistan	4811003	33.34	815.76	28.66	3.12
9	United Arab Emirates	3501082	25.36	618.6	23.85	2.37
10	Iran	3141700	25.13	527.66	-36.56	2.02
11	Indonesia	617503	-24.15	316.02	-25.1	1.21
12	Iraq	1397076	273.05	234.55	235.04	0.9
13	Poland	606913	72.9	227.37	22.83	0.87
14	Egypt	1344956	73.15	224.99	57.62	0.86
15	Turkey	894220	126.26	153.68	1.47	0.59
16	Czech	177664	-44.69	129.59	-48.02	0.5
17	Kuwait	564637	0.49	123.64	-8.93	0.47
18	Israel	488460	15.98	119.69	1.09	0.46
19	Jordan	692745	-10.52	116.74	-17.53	0.45

Source: Wang W; Liu Y et al; 2018, Analysis on the Barriers and Countermeasures of Chinese Medicine Enterprises for Countries along the Belt and Road, Advances in Economics, Business and Management Research, volume 58

China has taken up the exports of TCM very strategically; focusing on countries where the requirement and acceptance of traditional medicine is more lucrative. For example, China exports the largest amount of medicine to Africa. The trade volume has never gone back in case of this particular country. As of 2018, China remains the single largest exporter of medicine to the whole of Africa, and the biggest provider of health aid too. The main reason why Chinese medicine resonates with African countries rests in their availability, and the price the medicine comes at.

The boost from the countries along the Belt and Road Initiative is also a major factor in stimulating demands. Especially for small companies, engaging in international trade has been made easier through this initiative. The initiative is expected to play a significant role to boost trade and development practices related to TCM.[130]

Table 15: Number of Chinese Traditional Medicine Exports to Countries along the "Belt and Road" from January to November' 2017 (Unit: 10,000 US Dollars, %)

S. No.	Area	Export amount	The export amount is the same as the previous year	The proportion of export amount	Number of export companies
Total	China	76069.78	12.05	100	1672
1	Guangxi	10974.67	330.77	14.43	46
2	Guangdong	9866.77	-0.2	12.97	178
3	Anhui	9344.62	24.07	12.28	65
4	Jiangxi	5716.22	-21.45	7.51	56
5	Yunnan	5273.13	4.21	6.93	46

[130] http://iththailand.net/upload/BRI_and_health_and_beyond_-_conf_doc.pdf

6	Sichuan	4314.02	17.45	5.67	51
7	Jiangsu	3670.57	-7.37	4.82	138
8	Hunan	3285.76	-4.07	4.32	78
9	Zhejiang	3275.76	8.54	4.31	223
10	Hebei	3270.07	3.05	4.3	43
11	Shandong	3058.05	-8.54	4.02	143
12	Fujian	2891.36	3.53	3.8	51
13	Beijing	1898.76	26.55	2.5	48
14	Shanghai	1456.91	-30.15	1.91	116
15	Shanxi	1304.07	59.96	1.71	115

Source: Wang W; Liu Y et al; 2018, Analysis on the Barriers and Countermeasures of Chinese Medicine Enterprises for Countries along the Belt and Road, Advances in Economics, Business and Management Research, volume 58

The ties have been successful, the TCM herbal medicines and other related products exported to Belt and Road countries have improved by 54% between 2016 and 2017, to a total of US$295 million.

6.3. Discussion and Analysis

India exported USD 330.18 million worth of herbs and USD 456.12 million worth of value-added extracts of medicinal herbs / herbal products during 2017-18. When these figures are compared with China (TCM) the export of TCM in 2017 was $ 3.6 billion, which is far better than the export position in India. India is the 2nd largest exporter of herbal medicines, but only after China, both the countries together are producing over 70 percent of the herbal medicines demand across the globe.

When we compare the healthcare spending per capita in China which is around 6% of its GDP with that in India it is only 1.4% of the GDP.[131] China is therefore in a better position than India to increase investment and develop the TCM sector with its constant endeavors.

China has exponentially improved its TCM exports in the recent past. Maintaining the quality of raw materials as well as finished products, and having appropriate technology for processing and appropriate packaging is all important steps towards improving the export potential of the products. The packaging of Chinese traditional Chinese medicine export products and labels are being done under prescribed regulations. The product descriptions are standardized.

Product standard innovation of TCM, building big data platform of Chinese medicine (big data platform of TCM preparation; big data platform on the quality of TCM) are the steps being taken up by the country.

[131]https://www.iisd.org/sites/default/files/publications/elements_sustainable_trade_china.pdf

Quality control is directly related to the safety and effectiveness of TCM and is critical to improve exports. China has set up a quality inspection technology system focusing on chemical marker detection. This method has gradually developed into quality analysis mode of quantitative analysis, chromatographic fingerprint, and discriminate analysis from the initial sensory experience.

China has strengthened the quality control in microorganisms, pesticide residues, heavy metals and arsenic salts, there is still a large gap between Chinese and international standards. A systematic and transparent preparation of large data information platform of TCM preparation is key to comprehensive mining of the vast amounts of information on TCM and its preparation field, professional processing of data—drawing of scientific knowledge map, tracing patent data, digging and analyzing of clinical trial data and marketed drug data, drawing the navigational chart of TCM and its preparation in the era of big data. The establishment of the platform will effectively integrate all aspects of TCM research and development, serve the needs of multiple demand groups including enterprises, government regulators, academic research institutions, and so on, and greatly shorten the development time of new varieties of Chinese medicine and its preparation.

India lags behind in filing patents. Having the Intellectual Property Rights (IPR) in place is a necessary step which China is doing, and India should follow suit.

As part of a new health drive, Chinese authorities are stepping up research into TCM and are encouraging scientists to look for its next magic cure. It is encouraging originality in TCM and explores the market value of existing research. Chinese researchers publish 3,000 scientific papers every year, which deepen research into the different herbs, substances, and working mechanics of TCM. Researchers are trying to enhance TCM precision and steps are being taken to converge it with western medicine. Evidence-based medicine is a widely-used approach in medical practice that is intended to optimize decision-making in treating individual patients by emphasizing the use of evidence from well-designed and well conducted research. Under this approach, clinical evidence serves as the main basis for evaluating effectiveness and safety of treatment. The country is taking up a systematic approach towards these ends.

The DNA barcode 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. This barcode species identification system has established a “genetic identity card” for TCM. □e 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 standardized gene identification era.[132]

Establishing an internationally recognized standard is also key for the industrialization of TCM. An international standard for TCM will legitimatize the use of the medicine all over the world. China is improving its own national standards. National survey of TCM herbs are carried out across the country soon. TCM researchers have also stepped up the studying of ancient recipes.

The game changer for TCM was undoubtedly the discovery of artemisinin, an active compound of sweet wormwood, which landed China a Nobel Prize, and is now widely used in anti-malarial drugs throughout the world. More such technological discoveries are encouraged through relevant mechanisms.

[132] https://www.researchgate.net/publication/323082723_Internationalization_of_traditional_Chinese_medicine_Current_international_market_internationalization_challenges_and_prospective_suggestions

Chapter 7

Conclusion and Recommendations

7.1. Conclusion

Plant resources have been the backbone of all medicinal formulations in western as well as traditional systems of healthcare. The traditional systems claim to be pioneer in treating all types of ailments without any side-effects. The western system of medicines despite being of universal application have been branded to have side-effects. Even in western system of medicines the plants as well as synthetic materials have been used. As against this, the traditional system wholly relies on flora, fauna and minerals and therefore, on positive side it has access by all but in case of western medicines this is expensive and many a times not within the reach of poor and deprived classes.

Among the two traditional system, the TISM and TCM have recorded history of use of traditional knowledge with local flora and fauna for treatment of all types of diseases. This report has very exhaustively scanned the available literature on ancient and modern development of traditional system of medicines. In both these systems there have been development to popularise them and ensure that it should soon have application and popularity outside the respective countries.

India and China have had pride for their traditional healthcare practices based on use of medicinal plants. There are historical evidences about the use of medicinal plants and other natural products (e g. soil) which were extensively used as first-aid as well as for other diseases. These types of treatments were very popular among all class of society till the advent of allopathic or western system of medicine.

Traditional system of medicine related to use of herbal plants are part of traditional eastern systems of Medicine known as Ayurveda, Yoga, Unani, Siddha and Homeopathy (AYUSH) in India. Similarly, the traditional Chinese system was popular as Traditional Chinese Medicine (TCM). Since time immemorial these traditional systems have been practiced for preventive and curative healthcare in both countries. However in the present scenario China appears ahead of India in respect of their popularity and international market access as compared to India. This happened due to aggressive state policy China pursued to mainstream TCM as an important and equivalent part of an integrated system of medicine. Further the Chinese introduced another strategy of treating TCM at par with western system of medicines (allopathy) in medical education with TCM equivalent to western system of medicine. Somehow, India has not carried out this kind of educational re-structuring which therefore puts normal medical education degrees more alluring and attractive than Ayurveda, Yoga, Unani, Siddha and Homeopathy (AYUSH).

With the establishment of National Bio-diversity Authority and their counterparts State Bio-diversity Boards in almost all state of the country have formulated rules to regulate the conservation, use and benefit sharing mechanisms. The only lacunae appears to be in respect of field level compliances of sustainable management practices.

The ideal conservation strategy for any species is one of in situ conservation. For this India follows the protected area management regime. The Government through the Forest Department and the Medicinal Plant Boards have established a network of many medicinal plants conservation areas across the country. However, proper regulation on the harvest of the medicinal plants is unavailable.

It is also important to look at the ex-situ conservation of medicinal plants through increasing the number of medical plant gardens and gene banks in the country. Presently, the efforts are limited to the Government and are not sufficient. The availability of plants and planting material to the various user groups can be ensured through establishment of more herbal nurseries. For cultivation of medicinal plants, the availability of planting material is low and there is lack of standardised agronomic practices and therefore very few species are under commercial plantation at present.

Chinese introduced an integrated approach of strengthening pre-production, production and post production practices which resulted in to all-round growth in creating a robust production and processing system in place. At production stage, promotion by domestication and cultivation of herbal medicines through natural fostering model involving small and marginal farmers has been a very successful and a model for emulation. Promotion of Good Agriculture Practices (GAPs) through involvement of multiple stakeholders including industries has been tried. Strict compliance with GAPs and investment on research with linkage of production with industry has been a successful model. At post production stage, this involves aggressive marketing aiming at export of TCM through certification, branding, using overseas Chinese Diaspora and the Belt and Road Initiative (BRIs).

In India on the other hand, AYUSH is treated as an alternative and comparatively in-expensive form of medicinal system known to have curative properties or delayed action. Indian System of Medicines is treated as a poor man's medicine. Allopathic medicine have been considered to be expensive and beyond the reach of rural population. The availability of herbal material in rural hinterland has been considered as a natural choice for large population of India. The realization that a large number of allopathic medicines use herbal raw material is still not incorporated in the planning and development of herbal sector in India. The resource richness and the traditional knowledge have gradually been used and incorporated in the manufacture of quality allopathic drugs. However the pace of change is still slow and therefore requires more motivation of the stakeholders and aggressive policy intervention in this regard.

Lack of application of GAPs, absence of control over quality production of medicines, low investments on research and development in AYUSH sector, lack of treatment of AYUSH system at par with western system particularly in respect of research and education are major bottleneck in the development. Further, lack of value chain linkages of producers with manufacturers of herbal medicines and absence of a proper marketing strategy have also contributed to poor growth in AYUSH sector in India.

Poor growth and development of the sector in India is also attributed to lack of appreciation by herbal industry that cultivated medicinal plants are as efficient and effective as medicinal plants sourced from wild areas (natural forest). These misconceptions have done great harm to the ex-situ cultivation practices. Further, excessive and un-sustainable collections from natural forests are contributing to fast decline of bio-diversity in these forests. With Good Cultivation Practices the two types of raw material should be treated with equal preference rather than ignoring one at the cost of other.

In India the primary source of raw material is natural forests which meets over 80% industries total requirements. The balance about 20% is accounted for ex-situ cultivation and imports. The short supply of raw material is sometimes being met by substitution or unfortunately by adulteration. The two classical cases of adulteration are use of leaves of *Terminalia arjuna* instead of its bark. The other case is about lack of Ashoka barks which is being substituted by other similar trees. There some more examples on which the NMPB is taking appropriate and due action. Once, the standardization of use of raw material is in place probably these kinds of mal-practices will be checked. The AYUSH Ministry has engaged the state medicinal plants boards, research institutes and grass-root level voluntary organizations to come up with adoptable strategy for wild resource conservation. The protected areas have been offering natural conservation eco-systems with complete ban on extraction. The MPCDAs have also been established across India. All of them may not be in desirable state of conservation but they have given an indication that this could be another form of conservation strategy. The overall emphasis of conservation has been very encouraging.

Cultivation of medicinal plants was extensively promoted by NMPB in 2002 when it supported a large number of projects for domestication of most used medicinal plants. This initiative has a bag of good and not so good experience in their quest to minimize the dependence of industries on wild resources. Contract farming has also been promoted to ensure captive source to meet the increasing demands of industries. However, only a few progressive industries have taken advantage of this initiative. Large number of industries continue to source their requirements from wild collection. This has unduly stressed the wild eco-system resulting into decline of bio-diversity. According to studies (UNDP-NMPB, 2015), the loss of bio-diversity is to the extent of 10 to 90% has been attributed to this unsustainable extraction and use practices. The industry is

using the helplessness of gatherers to extract even destructively resources unmindful of their consequences of resource viability. If this state of affairs continues, many wild areas may be devoid of medicinal plants.

The challenges identified for internationalization of AYUSH includes unclear therapeutic material basis and mechanism, difficulty of quality control, low preparation level, registration/policy barriers, and shortage of intellectual property.

Inadequacy of advanced equipments and technology for processing AYUSH products is a disadvantage especially to manufacture quality products under strict standards. Packaging, design and promotion as well as marketing strategy of AYUSH is in most cases not up to the standards; there are also concerns over the content of heavy metals and pesticide residues exceeding the national standards.

Similar to India, China also sources about 80% of its requirement of raw material for TCM from wild. They also faced the problem of decline of natural resources and therefore started promoting cultivation in a very systematic manner. Their best model has been the Natural Fostering System which encompasses farm and farmers – industry and research institutes. Under this scheme they identify the natural habitat of most required medicinal plants. The industry requiring such material is encouraged to place their units (manufacturing or semi-processing) at such locations. The relevant institutions (R & D) are also identified and associated to extend required technical know-how. This way the industry can have quality raw material without any difficulty. In India, industries are often complaining of non-availability of quality raw material should be encouraged such kind of partnership.

China has done commendable work in promoting processing by linking multi-national bio-pharmaceuticals with local TCM industries. The establishment of SEZ type facilities have further strengthened the TCM as it has not only provided common facilities for R & D for small industries but also facilitated the promotion of small and medium industries to process the herbal products and export them. The tie-up with MNCs have further improved their access to international markets. MNCs are also benefitted by Chinese collaboration due to cheap labour available in China.

China has revamped their medical education system. China treats TCM at par with western system of medicine. They have incorporated the TCM knowledge based education as a necessary part of medical education. The dispensaries and hospitals are equipped to treat patients using both – TCM as well as western medicines. In India, the similar efforts have been initiated but they need to be further strengthened and pursued. India still considers the western system of medicine superior than TISM. This has not done justice with AYUSH.

Both India and China have been making efforts for export promotion of traditional medicines however, the export of TCM was about 3.6 billion USD in 2017 while export of AYUSH products was 345 million USD. China has made vigorous efforts in popularizing TCM globally. India is also trying to increase its outreach but the progress has been far less then China. Another mark difference is the way the two countries export the traditional medicines. While TCM is exporting bulk of their products as medicines or derivatives. In India the export is mostly in the form of food supplements and extracts which undervalues country's export.

7.2. Recommendations

Having captured the key points of TISM and TCM development and their universalization, the following recommendations are being offered here.

7.2.1. India has also actively taken pro-active stance by formulating policies and programmes to popularize the TISM from village to cities. It has been recognized as an important form of healthcare based on our past knowledge. However, the development faces difficulty in the field compliance of various legal provisions. As a result, substitution and adulteration continues unabated. This has to be firmly regulated.

7.2.2. The policy regulations are focussed on conservation and management of MAPs but it is not adequately addressing the issues of production of raw material as per the need of industries. It is highly recommended that contract farming practiced in India should take appropriate learning from natural fostering model of China with appropriate modification. The contract farming model has often been breached by both farmer and industries in case of market price fluctuation. This needs to be protected and facilitated so that both parties abide by the contract. The NMPB or its associate bodies at state level could play role of facilitator for smooth functioning of contract farming. This could be achieved through frequent buyer (industry)-seller (farmer) meet.

7.2.3. The education system is very slowly recognizing the TISM at par with western medical education. Policy shift and change of mind-set of proponents of western medicine system is urgently required for universalization of TISM. The existing barrier and undue preferences in-favour of western medicine should soon be balanced.

7.2.4. The current emphasis on conservation of wild sourced material has not been effective. This needs stricter field compliance so that the germ-plasm is not lost.

7.2.5. Certification of process and products have been in place. However, due to prohibitive cost the growers, gatherers and industry are reluctant to take certification route. QCI and NMPB have entered into an agreement for voluntary certification. People centric participatory group certification needs to be promoted to make it cost effective and which could be acceptable in the international markets.

7.2.6. GFCP, GAP and GMP are well known in India but its field compliance is still lacking in majority of the cases. These have to be facilitated by NMPB.

7.2.7. Clinical trials have been recommended for making the entry of drugs into international markets. However, very little has been done in this respect. This aspect should be examined by AYUSH because this aspect is reported to be very expensive small and medium sized herbal drug manufacturers who are large in number in India.

7.2.8. The Cluster of Herbal Drug Manufacturers was launched by AYUSH in 8 states out of which only three have made some progress. Considering their necessity it is recommended that the concept of cluster or SEZ type facility need to be created.

7.2.9. The TISM is not getting their due recognition because they are sold as supplements rather than medicines. For example, it is sold as dietary supplement in the United States of America. Thus, no overseas doctor prescribes these TISM as medicines. As a result the TISM could not find place in the mainstream healthcare system outside India. This needs to be resolved by AYUSH.

7.2.10. India needs to take initiatives for supporting the neighboring countries in framing regulations for use of AYUSH. In addition to this, AYUSH education also needs to be promoted through partnership with other educational institutions.

7.2.11. There is dearth of herbal practitioners which has resulted in limited recognition in western world. There is a need for adequate support for intensive promotion of Indian herbal medicines in foreign countries through exhibitions and trade fairs. Promotion of AYUSH education in foreign countries is also needed, along with providing support to nourish and strengthen the profession in other countries. Major collaborations in research programmes to promote innovation and technology transfer, exchange of scholars, funding researches, and providing technical support to universities is the need of the hour.

7.2.12. The country has 15 agro-climatic zones harbouring different MAPs. These are brought to established Mandis wherever they are available or there are local markets or weekly markets. In other places, the middlemen or *kochias* (petty traders) collect the herbal material directly from gatherers. In these market mechanisms the gatherers as well as cultivators become victim of nexus existing or developed among traders. This prevents the gatherers and growers realize better price for their produce. The traders underpay on the grounds of quality of raw material and many gatherers and growers do not have their own or community level facilities for primary processing. Like China, India should also develop such marketing complexes in bulk production areas. This will help the producer, trader, industry and exporters. The country has recognized a number of Mandis but they should also be developed as markets for import and export of MAPs in the lines of TCM markets developed by China.

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