

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

RAJIV GANDHI

UTE FOR CONTEMPORARY STUDIES

**Working Paper** 

January 2020



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Published by: Rajiv Gandhi Institute for Contemporary Studies, New Delhi Development and Trade of Medicinal and Aromatic Plants (MAPs): Learnings from Comparative Analysis of MAPs Export of India and China

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Rajiv Gandhi Institute of Contemporary Studies (RGICS)



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### **Abbreviations**

ABS - Access and Benefit Sharing
ADB - Asian Development Bank

ASEAN - The Association of Southeast Asian Nations

ASU - Ayurveda, Siddha, Unani

AYUSH - The Ministry of 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 PlantsC&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 ResearchCSPC - 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

Gol - Government of India

GRAS - Generally Recognized as Safe

GSP - Good Storage Practices

GTP - Global Triangle Partnership Scheme

HGT - Home Grown Technology

ICARThe Indian Council of Agricultural ResearchICDInternational 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

## 1

### **Background Summary**

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 the world 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 projection made by World Health Organization (WHO) states that the global herbal market would grow to \$5 trillion by 2050 from the current market level of \$62 billion (Ekor Martins, 2014).

Alternative medicine disciplines such as Yoga, Acupuncture, Homeopathy, massage, 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 are common and both the systems follow similar philosophies for classification of individuals, materials and diseases.



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 (eg. 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).

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 realisation 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 good agricultural practices, 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 exsitu 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.

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 Undergraduates, PG, and Doctoral courses at par with traditional medical colleges. The professionals passing out from these institutions are also getting similar placements and gradual recognition in the society.

The AYUSH Ministry in Government of India has created an exclusive organization called National Medicinal Plants Board (NMPB) 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 decentralisation 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. It is hoped that these efforts of Government of India and States will soon rejuvenate this sector to catch up with the development in China.

In 2017, 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, according to the China Chamber of Commerce for Import & Export of Medicine & Health Products.

Domestic demand of medicinal plants in India has been estimated as 1,95,000 MT for the year of 2014-15. 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 22% of the total production is sourced through cultivation of medicinal plants (NMPB, 2019). China's domestic demand for TCM is also surging.

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 globe. India exported raw herbs worth USD 330.18 million during 2017–18 with a growth rate of 14.22% over the previous year (MoC&I, 2019). When these figures are compared with China (TCM) India has to make a lot of efforts to catch up the export of TCM in 2017 at \$ 3.6 billion.

The export of value-added extracts of medicinal herbs/herbal products from India during 2017–18 stood at USD 456.12 million recording a growth rate of 12.23% over the year before (MoC&I, 2019). 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).

In 2012, China took the title in the race to export the largest amount of medicine to Africa, with the USA coming in way behind. The trade volume has never gone back since. As of 2018, China remains

the single largest exporter of medicine to the whole of Africa, and the biggest provider of health aid to Africa too. The main reason why Chinese medicine resonates with African countries rests in their availability, and the price the medicine comes at. Providing affordable healthcare remains one of the biggest obstacles to governments in Africa. Health in Africa is an expensive affair, accounting for an average of 20 percent of most government budgets. Yet, even with the amounts given to the health sector, the services and medicine provided are never enough. India needs to explore the African market so as to increase its share in international market for Traditional medicines.

Lack of National/ State policy, rules, regulations and guidelines inhibit compliance to sustainable management practices and lead to depletion of resources. These aspects of management of wild medicinal plants inhibit production of quality products and non-remunerative price to gatherers. These aspects need to be looked into so as to get better appreciation of the contribution of medicinal plant collection and trade.

The trade in medicinal plants is highly secretive. The forest department which manages the natural forest have not shown due importance to these resources and therefore the quality of data on medicinal plants is always under scrutiny. This aspect is not known for Chinese medicinal plants.

The comparative study of TISM and TCM brings out the fact that the efforts of Government of India and State required more aggressive stance in respect of investment on research, education, production, processing and conservation of natural resources. The access to international market also requires more concerted efforts. Some of the above shortcomings and proposed policy interventions have been suggested in the working paper. This working paper is part of a 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). The Paper highlights major initiatives of India and China to promote medicinal plants/herbal products and enhance its trade globally.

# 2

### The Study

The 'Development and Trade of Medicinal and Aromatic Plants (MAPs): Learning from Comparative Analysis of MAPs Export of India and China' study is analytical in nature which warrants collection and analysis of large scale secondary as well as primary data and facts relating to production and trading/export of MAPs in India and China and the factor which contributed towards higher growth TCM in comparison to TISM. 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 representing gatherers, farmers, traders, processing

industry, Government supported MFP Federations of Madhya Pradesh and Chhattisgarh, medicinal plant based research institutes such as National Botanical Research Institute, Lucknow, some international agencies/ organisations such as TRAFFIC, traders in the industry such as The Central Herbal Agro Marketing Federation of India (CHAMF) and Organic India.

The major objectives of the study are as follows-

- 1) To understand the existing efforts for development and trade of MAPs in India and China.
- 2) To assess the current level of production, trade and export of MAPs in both the countries as a result of the various initiative undertaken.
- 3) To assess the benefits and impacts created at various levels from development of MAPs sector and future trends.
- 4) To draw lessons from each-other's experiences and make suitable recommendations to apply interventions for further development of this sector to have respectable share in the international markets.
- 5) Sustainable development of MAP sector so as to enhance the livelihood support of millions of medicinal plant gatherers and farmers who are important stakeholders of this sector.

# <u>3</u>

## 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 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. [1]

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. Among these, about 15,000 species are threatened with extinction from overharvesting and habitat destruction and 20 % of their wild resources have already been nearly exhausted with the ever increasing human population and consequent plant consumption. This threat has been known for decades, but in recent times the fast paced loss of species and habitat destruction worldwide has increased the risk of extinction of medicinal plants, especially in China, India, Kenya, Nepal, Tanzania and Uganda (Chen Shi-Lin et al, 2016). 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.

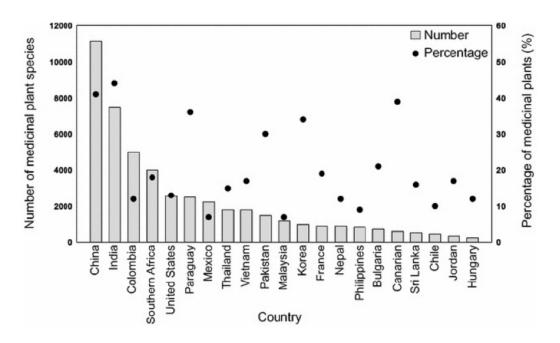


Diagram 1: Number and percentage of medicinal plant species in different countries

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

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.

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.

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.)<sup>[2]</sup>

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)

Domestic demand of medicinal plants in India has been estimated as 1, 95,000 MT for the year of 2014-15. 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 22% of the total production is sourced through cultivation of medicinal plants (NMPB, 2019).

Ayurveda is one of the ancient Indian systems of medicine with widespread acceptance. Further, Ayurveda, Siddha and Unani systems of medicine have more than 90% formulations which are plant based.

Due to increase in demand, overexploitation and indiscriminate collection of plant species, the natural regeneration of species is being threatened. In India the gradual decline of resources is attributed due to heavy demand by ever increasing number of herbal industries and pharmacies. It is also to be noted that as high as 29.5% of total raw material required by industry is plant root which means destruction of plants in the manufacturing of herbal drugs in India (Table:1).

The climate change phenomenon is also reported impacting the natural re-generation in the forests (Prasad, pers. comm., 2019). At the top of this, uncontrolled deforestation for commercial reasons as well as fast urbanization leads to habitat destruction and therefore affects species rarity. There are multiple biological characters which correlate with the extinction risk, such as habitat specificity, distribution range, population size, species diversity, growth rate, and reproductive system. This reduction/ extinction of world flora will not only impact the corresponding market negatively, but will

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	1997
Fruits	10.3	
Seeds	6.6	Bangalore,
Stems	5.5	
Bark	13.5	Source: FRLHT,
Wood	2.8	Soul
Whole Plant	16.5	

also impact the sustainability of the natural environment which impacts climate change resistance for living beings the world over (Chen Shi-Lin et al, 2016). The world is slowly waking up to these impacts which can profoundly influence the future. [3]

In India, climate change is also indirectly affecting the natural re-generation and population viability of medicinal plants in the wild. Due to climate change and consequent crop loss is forcing the gatherers from natural forests to meet their livelihood demands, collect medicinal plants unsustainably. This way the species are not allowed to mature and regenerate.



The increasing awareness and demand for herbal-based drugs by consumers in both developed and developing countries has led to multinational pharmaceutical industries exploring their use on commercial scale. This has put pressure on wild populations of MAPs. In India Prasad and Sharma (2015) in an UNDP and NMPB sponsored project for documenting supply and value-chain analysis of medicinal plants in the states of Madhya Pradesh and Chhattisgarh have reported that 10-90% of 'most collected 15 - 20 species', have declined in the natural forests.

Despite many opportunities and challenges in India, the medicinal plant sector has not been growing to its full potential. In order to fulfil the demand for medicinal plants through sustainable and fair trade, it will be essential to engage all stakeholders including farmers, collectors and traders, as part of a holistic inclusive approach to enable expansion of the herbal sector in India. [4] Although the AYUSH industry represents one of the oldest traditional forms of medicine in India, it has not been able to exploit the opportunities of the emerging market so far.

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.

On the other hand, while China has been systematically up-grading and promoting its TCM market through active and scientific approach since long, which has benefitted the country to a large extent, India is yet to catch up with Chinese share of international market. However India has now taken up many positive steps towards promotion of TISM through Ministry of AYUSH in Government of India. In a holistic approach the Government has initiated re-structuring of medical education giving same emphasis on development of professionals with specialisations in TISM as it has so far been for western system of education and research in medical sciences. The investment in research and development of TISM is also now catching up. Re-structuring of education system is underway to achieving the above goals. The conservation and development of natural resources leading to production of medicinal and aromatic plants in natural eco-system as well as ex-situ cultivation is getting boost through different plans and schemes. These steps are likely to get further boost in future.

The plant diversity in China is increasingly threatened, with an estimated 4000–5000 plant species being threatened or on the verge of extinction, making China, proportionally, one of the highest priorities for global plant biodiversity conservation. According to same paper (Huang, 2011) in the face of the current ecological crisis, it is timely that China has launched China's Strategy for Plant Conservation (CSPC). China has increasingly recognized the importance of plant diversity in efforts to conserve and sustainably use its plant diversity. More than 3000 nature reserves have been established, covering approximately 16% of the land surface of China. These natural reserves play important roles in plant conservation, covering more than 85% of types of terrestrial natural ecosystems, 40% of types of natural wetlands, 20% of native forests and 65% of natural communities of vascular plants. Meanwhile, the flora conserved in botanical gardens is also extensive. A recent survey shows that the 10 largest botanical gardens have living collections of 43,502 taxa, with a total of 24,667 species in ex situ conservation. These provide an important reserve of plant resources for sustainable economic and social development in China. Plant diversity is the basis for bioresources and sustainable utilization (Huang, 2011).

Presently, China has an edge over India in respect of popularising the TCM in the international market. They also enjoy a major share in the international market as compared to India. However, of late, India has also geared up through different policy and legal strategic planning and development initiatives by which it is gradually catching up with China. The drastic changes in approach for conservation, production, and use of medicinal plants for health care not only in rural areas but also bringing it to urban population are being emphasized.

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. It has been systematically up-grading and promoting its TCM market through active and scientific approach since long, which has benefitted the country to a large extent, evident through the extent of market it has gained worldwide recently. India has also slowly woken up to the immense potential this sector has and has taken many positive steps towards its promotion.

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). 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).



# 4

### Policy and Legal Framework for promotion of Traditional Medicine

#### 4.1 Current Legislative and Policy Framework in India

There are several laws and policies with some bearing on the sustainable use and conservation of MAPs in India. Most of these pre-date the government's recent appreciation of the threat to MAPs and ensuing concern about their conservation status.

The most relevant of the older policies and legislation are the National Forest Policy, 1988, the Indian Forest Act (IFA), 1927 and related state legislation, the Forest (Conservation) Act (FCA), 1980, and the Joint Forest Management orders and rules passed in 1990 and promulgated by both GoI and different states. These are the key policies & acts guiding and regulating the use and management of state forests today. The Panchayats (Extension to the Scheduled Areas) Act, 1996 (PESA) is also particularly relevant to community-owned forests and tribal areas as it gives local tribal people certain rights over natural resources.

The Gol's growing concern about the status of medicinal plants is also reflected in more recent policy statements and actions.

The 1999 National Policy and Macro-level Action Strategy on Biodiversity recognizes the national significance of medicinal plants, and states that a key area for action is there in situ conservation<sup>[5]</sup> and ex situ cultivation<sup>[6]</sup>. In 1999, the Planning Commission of India also recognized the importance of the medicinal plants sector, & set up a 'National Task Force on the Conservation, Cultivation, Sustainable Use and Legal Protection of Medicinal Plants'.

In its Tenth Five Year Plan for 2002-2007, the Planning Commission clearly states that "the conservation, preservation, promotion, cultivation, collection and processing of medicinal plants and herbs required to meet growing domestic demand for Indian Systems of Medicine and Homeopathy drugs and the export potential must be ensured". It also states that, "Natural forests rich in medicinal plants should be identified and managed for sustainable supply of crude drugs."

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.

Another relevant law which has a bearing on medicinal plants is the Foreign Trade (Development and Regulations) Act, 1992. This act is designed to help the central government regulate the import and export of goods through Negative List of Imports or a negative List of Exports, as the situation demands. The Ministry of Environment & Forest, Government of India, in 1992 prepared a 'Negative

<sup>[5]</sup> Experiences have amply demonstrated that in a densely populated developing country like India, where a sizeable population are living in close proximity to forests, declaring protected areas will not entirely be sufficient to ensure in situ conservation on the fast eroding biological diversity. The success of any conservation programme vests solely on the efficient management of protected areas. The involvement of local communities in conservation activities has now been increasingly realised. A people nature-oriented approach thus becomes highly imperative. This will help to generate a sense of responsibility among the local people about the values of biodiversity and the need to use it sustainably for their own prosperity and the maintenance of ecosystem resilience.

<sup>[6]</sup> Ex-situ conservation of medicinal plants outside natural habitat by cultivating and maintaining plants in botanic gardens parks, other suitable sites, and through long term preservation of plant propagules in gene banks (seed bank, pollen bank, DNA libraries, etc.) and in plant tissue culture repositories and by cryopreservation).

List' of 56 species of medicinal plants and banned their export. In1998 the list was reduced to 29 species. In 2000, the Negative List was suspended and a list of 114 medicinal species was notified for regulating their wild harvest. Provisions of the Convention of International Trade in Endangered Species of Wild Fauna and Flora (CITIES) are also implemented through this Act. CITES has notified 11 Indian medicinal plant species in its schedules.

Trade in plants and plant portions of species listed in the Wildlife (Protection) Act, 1972 or in Appendix I of CITES is allowed if the produce is obtained from cultivation carried out in accordance with the rules. The exporter must have a Certificate of Legal Possession issued by the jurisdictional Divisional Forest Officer (DFO). For species listed under Schedule VI of the Wildlife (Protection) Act, 1972, the trader needs to comply with provisions under Section 17-A of the Wildlife (Protection) Act, 1972. The provision specifies that there is 'Prohibition of picking, uprooting, etc., of specified plant, where no person shall—

- a. willfully pick, uproot, damage, destroy, acquire or collect any specified plant from any forest land and any area specified, by notification, by the Central Government;
- b. possess, sell, offer for sale, or transfer by way of gift or otherwise, or transport any specified plant, whether alive or dead, or part or derivative thereof: Provided that nothing in this section shall prevent a member of a scheduled tribe, subject to the provisions of Chapter IV, from picking, collecting or possessing in the district he resides any specified plant or part or derivative thereof for his bona fide personal use.<sup>[7]</sup>

The latest legislation that is relevant to medicinal plant resource is the Biological Diversity Act, 2002. This act is part of India's follow up to the Convention on Biological Diversity (CBD). 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. For implementation, the Act provides for a National Biodiversity Authority (NBA) and also provides for the creation of State & local Biodiversity Boards.

In respect of traditional knowledge of plants the major policy statement is articulated in the 2002 policy of the AYUSH department of the Ministry of Health & Family Welfare. This policy make specific mention of the need to promote research on plant drugs, conserve and cultivate medicinal plants and also to revitalize community based local health traditions.

Recently in the Eleventh Five Year Plan for 2007-2012, the Planning Commission emphasised 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

It further stressed that on MAPs inclusion in National Forestry Information System and in National Working Plan Code. 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 for industry and launch of protocols for survey, inventory, and management planning for medicinal and aromatic plants in forests.

The Govt. of India has also approved the Criteria and Indicators(C&I) for Sustainable Management of NTFPs bulk of which is MAPs resources. This is stepping stone for establishing national certification

standards and protocols for improving access to international market and to get green premium price. This is becoming mandatory for sustainable management and development of MAP resources. The National Biodiversity Strategy and Action Plan (NBSAP) 2007, suggests detailed strategies for the conservation and sustainable use of medicinal plants.

Provisions of international trade of wildlife products including MAPs are made by the Ministry of Commerce and established through the EXIM policy. The policy provisions for MAPs is 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. Under the existing policy, the export of 29 plants, portions and their derivatives and extracts obtained from the wild, except formulations, is prohibited.<sup>[8]</sup>

The National Commission for Indian System of Medicine Bill, 2019 has been introduced to provide for a medical education system that improves access to quality and affordable medical education, ensures availability of adequate and high quality medical professionals of Indian System of Medicine in all parts of the country; that promotes equitable and universal healthcare that encourages community health perspective and makes services of such medical professionals accessible to all the citizens; that promotes national health goals; that encourages such medical professionals to adopt latest medical research in their work and to contribute to research; that has an objective periodic and transparent assessment of medical institutions and facilitates maintenance of a medical register of Indian System of Medicine for India and enforces high ethical standards in all aspects of medical services; that is flexible to adapt to the changing needs and has an effective grievance redressal mechanism and for matters connected therewith or incidental thereto. [9]

The following table gives an at a glance overview on the most relevant policies and legislations for the conservation and sustainable use of medicinal plants in India

Table 2: At a glance overview on the most relevant policies and legislations.[10]

S.No.	Title of the Act	Details of the Act
1	The Indian	This legislation was meant primarily to enable the state to
	Forest Act,	acquire ownership over forests and their produce. The focus
	1927	was on controlling and regulating timber trade
2	The Wildlife (Protection) Act, 1972 amended in 1983, 1986, 1991 and 2002	<ul> <li>Meant for protection of wild plants and animals and regulates hunting, trade and collection of specific forest products.</li> <li>Rules of this Act, allows certain tribes to pick, collect or possess specified plants for their bona fide personal use.</li> <li>A licensing system is provided in the revised Act to regulate cultivation and trade of specified plants in a similar pattern</li> </ul>
		as used for trade in fauna.

<sup>[9]</sup> http://164.100.47.5/committee\_web/BillFile/Bill/14/113/l%20of%202019\_2019\_2\_15.pdf

	T	
3	The Forest (Conservation) Act, 1980 amended in 1988	<ul> <li>Addresses mainly issues relating to using forestlands for non-forestry purposes such as industry and mining.</li> <li>The Act requires the state government in question to get approval from the central governmentbeforedenotifyingreserved forests, leasing forestland to private persons or corporations, or clearing land for reforestation</li> </ul>
4	The National Wildlife Action Plan, 1983	<ul> <li>Emphasizes the need for establishing a network of representative protected areas and developing appropriate management systems, which will also consider requirements of local communities outside protected areas.</li> <li>This Action Plan was amended in 2002 to address issues relating to increased commercial use of natural resources, continuous growth in human and livestock populations and changes in consumption patterns</li> </ul>
5	The Environment (Protection) Act, 1986	<ul> <li>Enables the central government to take suitable steps to protect and improve the environment.</li> <li>The Act authorizes the central government to lay down standardsfor controlling emissions and effluent discharges of environmental pollutants, to regulate industrial locations and to prescribe procedures for managing hazardous substances</li> </ul>
6	National Forest Policy 1988	<ul> <li>Articulates the twin objectives of ecological stability and social justice.</li> <li>This policy focuses on symbiotic relationship between tribals and other poor people and forests and goes on to emphasize protection of people's rights.</li> <li>The policy treats local needs as 'first charge' on forest produce.</li> <li>This policy has for the first time created space for the participation of forest dependent local communities in the management of state-owned forestlands.</li> </ul>
7	Joint Forest Management	<ul> <li>Formally launched on June 01, 1990 as a government attempt towards regenerating and sustainably using forests, by a circular from the MoEF to all states and union territories providing guidelines for the 'Involvement of Village Communities and Voluntary Agencies in the Regeneration of Degraded Forests. Initial thrust of JFM was towards timber production</li> <li>The February 2000 Guidelines for JFM thus shifted focus from timber to NTFP. These guidelines also extended JFM to standing or well-stocked forests, and not only to degraded areas as dictated by the previous guidelines.</li> </ul>

8	A National Policy on Indian Systems of Medicine &	<ul> <li>This policy makes a clear mention of conservation of medicinal plants resources as an important aspect of promoting ISM in the country.</li> <li>The policy, besides looking at aspects relating to intellectual</li> </ul>
Homeopathy 2002	property rights and revitalization of local health traditions also addresses issues related to the conservation and sustainable use of medicinal plants.	
9	The Foreign Trade (Development	Help the central government regulate the import and export of goods through Negative List of Imports or a negative List of Exports, as situation demands.
	& Regulations) Act, 1992	In 2000, the Negative List was suspended and a list of 114 species was notified for regulating their wild harvest
10	The Panchayats (Extension to	<ul> <li>Provides a more radical constitutional and legislative mandate for devolution of local self- governance in Schedule V (tribal majority) areas.</li> </ul>
	the Scheduled Areas) Act, 1996 (PESA),	<ul> <li>PESA empowers the Gram Sabha (the body of all adult voters of a self-defined community) to safeguard and preserve the traditions and customs of the people, their cultural identity, community resources and the customary mode of dispute resolution.</li> </ul>
		<ul> <li>This Act is of particular relevance for the states of Chhattisgarh and Arunachal Pradesh, which have many tribal residents.</li> </ul>
11	The Biological Diversity Act,	Part of India's follow up to the Convention on Biological Diversity.
2002	The Act is of particular relevance when addressing issues relating to the intellectual property rights over materials and knowledge relating to biodiversity or its elements.	
	More specifically, it provides for the designation of institutions as repositories of biological resources.	
	•	<ul> <li>For implementation, the Act provides for a National Biodiversity Authority (NBA) and also recommends the creation of State Biodiversity Boards and local biodiversity committees.</li> </ul>
12	Sustainable	Development of C&I for Sustainable Management
	Forest	Development of Standards for Certification
	Management	

#### 4.2 Administrative, Research and Development set-up in India

#### 4.2.1 Ministry of AYUSH, Government of India

The Ministry of AYUSH was formed in the year 2014 to ensure the optimal development and propagation of AYUSH systems of health care. It was renamed Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy (AYUSH), with focused attention for development of Education and Research in Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy

#### 4.2.2 National Medicinal Plants Board (NMPB)

In order to promote medicinal plants sector, Government of India set up National Medicinal Plants Board (NMPB) in the year 2000. Currently the board is working under the Ministry of AYUSH (Ayurveda, Yoga & Naturopathy, Unani, Siddha & Homoeopathy), Government of India. The primary mandate of NMPB is to develop an appropriate mechanism for coordination between various ministries/ departments/ organization and implementation of support policies/programs for overall (conservation, cultivation, trade and export) growth of medicinal plants sector both at the Central / State and International level.

To meet increasing demand for medicinal plants NMBP focuses on in-situ & ex-situ conservation and augmenting local medicinal plants and aromatic species of medical significance. The NMPB also promote research & development, capacity building through trainings, raising awareness through promotional activities like creation of Home/School herbal gardens. NMPB also seek to support programs for quality assurance and standardization through development of Good Agricultural and Collection Practices (GACPs), development of monographs laying down standards of quality, safety and efficacy; development of agro-techniques and credible institution a mechanism for certification of quality of raw drugs, seeds and planting material. Overall, NMPB's main objective is the development of medicinal plants sector through developing a strong coordination between various ministries/ departments/ organization for implementation of policies / programs on medicinal plants.



#### 4.3 Agricultural Universities/ other Traditional Universities

Several Agricultural Universities set-up by the Government is engaged with agro - technology development, including plant introduction and improvement aspects of the identified species, by co-coordinated efforts of various disciplines. It aims to strengthen and complement ICAR supported coordinated/network research project on MAP. Its objectives are to collect & conserve those species whose availability (from wild) is fast dwindling, to conduct basic research on those aspects of the crops which are relevant and concurrently to carry out applied research for overall improvement of the M&AP crops, to develop high quality materials of medicinal and aromatic plants through crop improvement and crop physiological aspects, to introduce and develop the agro technology of new medicinal & aromatic plants which have potential for commercial cultivation, to study the biochemical parameters of different medicinal plants through phyto-chemical analysis, to establish medicinal and aromatic plants garden for information and to provide seed/planting material for needy farmers and to train needy farmers for agro technology of new adopted M&AP crops and value added quality processing materials.

Some well-known educational institutes of Agriculture and Ayurveda in India are:

- Anand Agricultural University
- · Rajiv Gandhi University of Health Sciences, Bangalore
- Gujarat Ayurved University, Jamnagar
- · Rishikul Government PG Ayurvedic College & Hospital, Haridwar
- · National Institute of Ayurved, Jaipur
- Bharati Vidyapeeth, Pune

#### 4.4 Councils

**ICAR:** The Indian Council of Agricultural Research (ICAR) is an autonomous organisation under the Department of Agricultural Research and Education (DARE), Ministry of Agriculture and Farmers Welfare, Government of India. It was established in 1929. The Council is the apex body for co-ordinating, guiding and managing research and education in agriculture including horticulture, fisheries and animal sciences in the entire country. With 101 ICAR institutes and 71 agricultural universities spread across the country this is one of the largest national agricultural systems in the world. The ICAR undergoes pioneering research and promotes medicinal plants sector.<sup>[11]</sup>

**ICMR:** The Indian Council of Medical Research (ICMR), New Delhi, the apex body in India for the formulation, coordination and promotion of biomedical research, is one of the oldest medical research bodies in the world. The ICMR is funded by the Government of India through the Department of Health Research, Ministry of Health & Family Welfare. The Council's research priorities coincide with the National health priorities such as control and management of communicable diseases, fertility control, maternal and child health, control of nutritional disorders, developing alternative strategies for health care delivery, containment within safety limits of environmental and occupational health problems; research on major non-communicable diseases like cancer, cardiovascular diseases, blindness, diabetes and other metabolic and hematological disorders; mental health research and drug research (including medicinal plants and traditional remedies). All these efforts are undertaken with a view to reduce the total burden of disease and to promote health and well-being of the population. Some recent activities are as follows:

- Published Monographs on Quality Standards on Indian Medicinal Plants
- Published Phyto-chemical Reference Standards of selected Indian Medicinal Plants [12]

CIMAP: Central Institute of Medicinal and Aromatic Plants (CIMAP) is a research institute of Council of Scientific and Industrial Research (CSIR) with its headquarter in Lucknow. It is engaged in the field of science and business of medicinal and aromatic plants. CIMAP has four research centers situated in Bangalore, Hyderabad, Pantnagar and Purara (near Bageshwar, Uttarakhand). CIMAP is committed to provide global standards for plant based research, processes and products using green technology mode while generating an ambience of team spirit, development of research and technology, expertise and human resource and modernization of infrastructure to ensure sustained clientele from agriculture, society and industry.[13]

ICFRE: The Indian Council of Forestry Research and Education, with its Headquarters at Dehradun is an apex body in the national forestry research system that promotes and undertakes need based forestry research extension. The Council has a pan India presence with its 9 Regional Research Institutes and 5 Centers in different bio-geographical regions of the country. Each Institute has a history of its own and under the umbrella of ICFRE are directing and managing research, extension and education in forestry sector in the states under their jurisdiction.[14]

#### 4.5 **State Forest Research Institutes**

- There are several forest research institutes in India. Forest Research Institution Dehradun is regarded as one of the oldest in the respective field in India and is managed by the Indian Council of Forestry Research and Education (ICFRE).
- The forest research institutes in India are broadly classified into three categories which are - Institutes under India's Ministry of Environment and Forests, Institutes under the Indian Council of Forestry Research and Education and Institutes Under state governments. There are various forest research projects and courses such as Environment Management, Forestry Management, Wood Science Technology, and others offered by forest research institutions in India.

# 5

### Policy level Initiatives for Promotion of TCM in China

China has been keen in developing their indigenous medicine system under the advance healthcare system of the country. In 2018, the trade value of plant extracts in the country reached a new record high to 3.094 billion dollars, a year-on-year increase of 18.26%; among them, export value and import value amounted to 2.368 billion dollars and 726 million dollars respectively, up by 17.79% and 19.8% separately than the last year; and the surplus reached 1.641 billion dollars, grew 16.92% year on year. China has multi-pronged approach and strategies for development of TCM and promoting its export worldwide. Some significant steps undertaken are-

#### 5.1 Administrative Set-up of TCM

The Administrative Department of Public Health under the State Council is responsible for the supervision and control of the protection of TCM in the country. Within the Department, the State Administration of Traditional Chinese Medicine (SATCM) is solely dedicated to TCM. This organization, in conjunction with several regional and municipal governments, has encouraged more than 170 pieces of TCM legislations till date. (Schroeder Teresa, 2002)

The State Drug Administration works in conjunction with the various national and regional TCM laws to create national legislation. It regulates the development, production and sale of pharmaceutical including TCM drugs. (Schroeder Teresa, 2002)

By 1986, the State Council set up independent administration of TCM. In China, all provinces, autonomous regions, and municipalities which are directly under the Central Government have established their respective TCM administrations, so at the regional and local level an organizational basis for TCM has been developed. Furthermore, municipalities and local governments have made direct monetary investments in the modernization of TCM. A vast network from national to local level was established to systematically facilitate development of TCM and its usage in healthcare through participation of multiple institutions and stakeholders.<sup>[15]</sup>



#### 5.2 TCM: Legal Framework

Since 1978, the Communist Party of China (CPC) gave emphasis on implementing the Party's Policies regarding TCM and promoting TCM Practitioners. It provided support in areas of human resources, finance, and supplies, rigorously promoting the development of TCM.

A major fillip was given to TCM by the Government in the Chinese tenth Five Year Plan (2001-2005) where stiffer regulations and increased educational opportunities received further attention when the industrialization of high-tech TCM development was made a key task.

TCM was prioritized again since the CPC's 18th National Congress in 2012, wherein 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 CPC's 18th National Congress and the Fifth Plenary Session of the 18th CPC Central Committee both 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.

Another important strategy was, The Development Plan for Traditional Chinese Medicine-Related Health Services (2015-2020) by The General Office of the State Council. The key tasks included 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 under the plan were 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.

In 2016 the CPC Central Committee and the State Council issued the Outline of the Healthy China 2030 Plan, a guide to improving the health of the Chinese people in the next 15 years. It is an important medium for implementing the country's commitment to the UN 2030 Agenda for Sustainable Development. One of its major objectives, under optimizing health care services is giving priority to let TCM play its unique role. The plan focuses at integrating healthcare delivery system moving from an extensive development mode based on scale to an intensive one focusing on quality and efficiency. The emphasis is on prevention and control of health care ailments and services.

The State Council also issued the Outline of the Strategic Plan on the Development of Traditional Chinese Medicine (2016-2030), which made TCM development a national strategy, with systemic plans for TCM development in the new era. 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. [16]

Of late, China has made a number of laws and regulations which have been implemented for protection of TCM wild medicinal resources. A number of national and local nature reserves have

been established; research has been conducted on the protection of rare and endangered Chinese medicinal resources; and artificial production or wild tending is being carried out for few scarce and endangered resources.[17]

Another crucial law to protect TCM was The Law on Traditional Chinese Medicine, 2017, highlighting the following:

- 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. 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.
- The state will support TCM research and development and protect TCM intellectual property.
- 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 and banning the use of toxic pesticides.
- Expansion of International exchanges and cooperation on TCM.
- 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.[18]

At the regional level and local level also, TCM is being promoted by the Government. TCM has been incorporated into the national economic and social development plans by the local governments, and 28 provinces have started formulating local TCM regulations. North China's Hebei province has completed and enacted the regulation. TCM management systems in provincial regions have been enhanced, with TCM administrations established in the provinces of Gansu, Zhejiang and Jiangxi. Fiscal investment in TCM has increased remarkably in the provinces of Jilin, Zhejiang and Fujian. [19]

#### 5.3 Major Reforms by Government through Policy Interventions and support for TCM Promotion

The Chinese government has taken numerous step to promote, standardize, and development of

the TCM. These steps have helped TCM to grow nationally and internationally. Few key steps taken by the government of China are as follows:

#### 5.4 Up-holding the Cultural Heritage

The Chinese people have a deep understanding and acceptance of TCM and its philosophy through their culture which makes them understand it better. Looking at the huge population in China and to meet the their demand for healthcare, the country aspires to expand the supply of TCM services, improve community-level TCM health management, advance the integral development of TCM with community service, care of the elderly, promote TCM tourism, and spread knowledge of TCM to advocate healthy ways of life and work.

### 5.5 Equal footing to both Traditional and Western Systems of Medicine

China has also re-emphasized on giving equal importance to both its traditional Chinese and Western systems of medicine in order to reach its health goals. This will be in terms of ideological understanding, legal status, academic development, and practical applications.

The Government encourages exchanges between TCM and Western medicine, and creates opportunities for Western medical practitioners to learn from their TCM counterparts. TCM colleges and universities offer Western medicine courses to have a combination of skilled doctors having specialized knowledge of both. The General hospitals and community-level medical care organizations have been encouraged to set up TCM departments.



### 5.6 Up-holding Innovations through Research and Technology in TCM

The dual evaluation of TCM system vis-à-vis modern medicine system is based on rigorous evidences expected to provide significant assistance in clinical research. An established system is put in place in order to take forward the theories and clinical experiences of well-known TCM experts. Efforts have also been put to rediscover and categorize ancient TCM classics and folk medical experience and practices and properly document the same. A number of technological innovations are put in place to encourage TCM progress. Systematic research on the fundamental theories, clinical diagnosis and treatment, and therapeutic evaluation of TCM is encouraged and rigorously done. Interdisciplinary efforts have been organized in joint research with international collaborations on the treatment and control of major difficult and complicated diseases and major infectious diseases, as well as on the prevention and treatment of common diseases, frequently occurring diseases, and chronic diseases using TCM.

Clinical research institutes have been built as part of the clinical research system for preventing and treating infectious diseases and chronic non-infectious diseases. Recent research has focused on the creation of synthetic materials as substitutes for traditional ingredients extracted from endangered species, improved TCM production and increasing Chinese visibility in the TCM arena.

By the year 2015, 16 seed and seedling bases for Chinese medicinal plants and 2 germplasm banks have been established. These transformations and applications of research results will support clinical effectiveness for better quality of Chinese medicine and in turn will encourage sound development of the TCM pharmaceutical industry.

The state sponsored TCM research and development mostly occurs within state institutions, most notably the Beijing University of Chinese Medicine.

#### **5.7 Infrastructure Development for TCM Promotion**

An urban TCM medical care network is being established for both urban and rural areas. They mainly comprise of hospitals for TCM (including ethnic minority medicine and integrated Chinese and Western medicine), TCM clinics and general hospitals, TCM clinical departments and community health centers, TCM departments of township-level health centers, and village health clinics, which provides basic TCM healthcare services.

Statistics collected at the end of 2015 show that there were 3,966 TCM hospitals across the country, including 253 hospitals of ethnic minority medicine and 446 hospitals of integrated Chinese and Western medicine. There were 452,000 practitioners and assistant practitioners of TCM (including practitioners of ethnic minority medicine and integrated Chinese and Western medicine). There were 42,528 TCM clinics, including 550 for ethnic minority medicine and 7,706 for integrated medicine; there were 910 million visits that year to TCM medical and health service units across the country and 26,915,000 in-patients treated.

#### 5.8 Preventive Healthcare Promoted through TCM

TCM, being an alternative medicine, its role in disease prevention is crucial. This health care service was highlighted through bringing up preventive healthcare departments at higher ranked TCM hospitals as well as providing such medical care services at community-level medical institutions,

maternal and child health centers and rehabilitation centers. TCM has played an important role in the prevention and treatment of major epidemics and medical relief in public emergencies and natural disasters in the country.

#### 5.9 Emphasis on TCM Training

With an ever-increasing availability of TCM institutions, health care services and hospitals, it is essential that the TCM practitioners should get sufficiently trained. Domestic users of both Western and traditional medicine will benefit from the increased training and uniform certification of medical professionals. Focus is also put on giving practical education. Domestic users of both Western and traditional medicine are expected to benefit from uniform certification of medical professionals.

All TCM education encourages practicable TCM by working in rural areas, supplemented by continuing education and further specialization. The Ninth People's Congress adopted the Law on Licensed Doctors of the People's Republic of China since 1998. This regulation covers both doctors, and assistant doctors. The law requires uniform examinations for all doctors and assistant doctors formulated by the administrative department for public health under the State Council. Furthermore, as growing numbers of international students study in China; the regulations assure the international community that doctors trained in China are competent.

#### 5.10 TCM Pharmaceutical Industry

TCM is generally subject to State Pharmaceutical Standards. 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.

The dosage forms of TCM medicines have 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.

The Regulations on Protection of TCMs protect 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 may result in fines, removal of the certificate of authority, confiscation of fraudulent products, and criminal sanctions. This strict punishment structure indicates a desire to strongly discourage any violation.

The provinces such as Hebei, Guizhou, Yunnan, Sichuan, Shaanxi and Shanxi have designated traditional medicine as a pillar industry in China for local level production. The planting of Chinese medicinal herbs has become an important addition to the rural industrial structure which has many benefits such as improving the environment along with farmers' incomes.

#### 5.11 TCM Quality

National regulation of TCM accelerated in 1992 with the Regulations on Protection of TCMs, which came into effect since the year, 1993. 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.

Since 1996, all exported Chinese traditional medicines and their manufacturing processes have been subjected to inspection by SATCM designated organizations. Manufacturers in compliance are eligible to receive a quality registration certificate. This certificate is revocable by the investigative organization if caught with quality control problems. Most importantly, the product quality violations are subjected to criminal sanctions in the country. As a general rule, TCM drug manufacturers, distributors, and wholesalers have to provide the same standards as other Chinese drug manufacturers.

The Outline of the Medium- and Long-term Development Plan for the Standardization of Traditional Chinese Medicine (2011-2020) plan has been issued and implemented, putting in place initially a system of TCM standards which amount to 649, showing an average annual growth of 29 percent. 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 have been set up in Guangdong, Shanghai, Gansu and other provinces.

#### 5.12 Internet Regulation

Chinese Government restricts the sales channels of Chinese TCM suppliers. On January 1, 2000, the Ministry of Health outlawed online diagnosis and treatment services. The State Drug Administration and the Ministry of Health collaborate to ensure both domestic and international purchase of TCM medicines via the Internet. Specifically the legislation was passed in the year 2000 and 2001 to regulate online advertising and sales of Chinese medicines. 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 has 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 traders of online pharmaceutical information.

#### 5.13 Promotion of Ethnic Minority Medicine

China has taken several steps to promote its ethnic medicine. Ethnic medicine is incorporated into poverty alleviation programs its role in improving China's public health services is recognized by the Government. The ethnic groups affected by extreme poverty have rich knowledge of valuable herbs and useful medical practices. China's TCM Law, in effect since July 2017, states that ethnic medicine is an important part of TCM and requires local governments to provide support. More than 40 ethnic drugs were added to the reimbursement list for the national medical insurance program in 2017, an increase of 95 percent year-on-year. About 43 Chinese colleges have also launched education programs on ethnic medicine, with over 13,000 students enrolled by the year 2016. [20]

Steady progress has also been witnessed in standardization of ethnic minority medicine. For example, Uyghur medicine has taken the lead, with the publishing of 14 guidelines for disease diagnosis and treatment, and curative effect evaluation. In the Tibetan autonomous region, the first local technical committee for standardization of Tibetan medicine has been established to uphold its unique knowledge.<sup>[21]</sup>

# <u>6</u>

#### Modes of Production in the MAP Sector

#### 6.1 Modes of Production in Medicinal Plants Sector- India

In India, most of the medicinal herbs are collected through wild harvesting (70-80% of the total demand of industry) many of which are also harvested through destructive means. To meet the demand for medicinal plants, cultivation and ex-situ conservation practices (medicinal plant gardens, nurseries, home-gardens, school nurseries, private nurseries etc) are followed. 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 being 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. The availability of medicinal plant seedling of indigenous varieties along with commercial ones and existing seed banks are not sufficient.

In-situ conservation deals with the on-site conservation of the wild genetic resources/genetic diversity in natural habitat. This is done through the conservation of forest areas preserve through Protected Areas like National Parks, Wildlife sanctuaries and Biosphere reserve.

Promotions of in-situ conservation of Medicinal Plants are one of the priority areas for Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy (AYUSH), Government of India due to its dependence on medicinal plant. The department undergoes surveys, inventorisation and documentation of important medicinal plants in their natural habitat.

In-situ conservation of endangered medicinal plants in their natural habitats by establishment of Medicinal Plants Conservation and Development Area's (MPCDA's) is taken up. It also provides strength / up-gradation of already existing MPCDA's by means of survey inventory, documentation, protection and main streaming in habitat management approaches (NMPB, 2019).<sup>[22]</sup>

Direct involvement of the industries for procurement of raw materials is slowly becoming a rising trend; recently, major industries like Dabur, Baidyanath, Himalaya Ayurveda have been taking steps towards Contract Farming and procurement of raw material directly from the cultivators.

Contract farming is defined as a system for the production and supply of agriculture and horticulture products under forward contract between suppliers and farmers. Farmers are required to plant the contractors crop on his land and to harvest and deliver to the contractor a quantum of produce based upon anticipated yield and contracted acreage. Contract farming can lead to improvement in income reducing some of the risk farmer's face from production and price fluctuations. From the point of view of purchasers, contract farming provides greater control over volume and quality consistency; to a certain extent (Choudhary et al, 2012). 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. For example, one of the big names in the Indian herbal industry, 'Himalaya Ayurveda' 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. Sami Labs has over 4000 acre of land under medicinal plant cultivation (Choudhary et al, 2012).

By 2015, Himalaya aimed to source 70% of its raw materials through cultivation. Besides paying a one-time fee of Rs7.5 lakh to Gram Mooligai, which supplies 60% of its raw stock, Himalaya will 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).

Reiterating its commitment to contract farming for medicinal plants, the company acquired more than 8000 hectares 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. Sami Labs 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 (Choudhary et al, 2012).

—Ageing populations in Europe or the USare moving towards herbal products for Several Indian and multinational companies have already began such initiative in India and have demonstrated repeated success. From the point of view of farmers, contract farming can provide access to markets, credit, technology and input that they would otherwise be excluded. Moreover, contract farming can lead to improvement in income reducing some of the risk farmers, face from production and price fluctuations. From the point of view of purchasers, contract farming provides greater control over volume and quality consistency; to a certain extent, it can also lower certain transaction and production costs that purchasers face. [23]

#### **6.1.1 Processing and Value Addition Practices**

The supply chain tends to be long. Information flow along the chain is linear, with no direct contacts between collectors / cultivators and final consumers. There is limited scope for first level semi-processing at village level.

Medicinal Plants are processed in two stages:

- a. Semi-processing; and
- b. Conversion into formulations.

The semi-processing for commercial purposes is in infancy with very little efforts being made to develop the practice through microenterprise development. The technology used has to be updated. The GMP is difficult to be followed by mostly small and medium enterprises which are engaged with processing and manufacturing of the products. There is lack of appropriate scientific know-how on sustainable harvesting practices among the collectors making it difficult to follow the GAP practices at the cultivation level. There are multiple stakeholders but the absence of linkages amongst them further adds to the problems. At the same time the internal and external monitoring information system by the Government at the state level is inadequate.

#### 6.1.2 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. In India, more than 90% of the species used in trade continue to be sourced from the wild of which about 2/3rdare harvested by destructive means. 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 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. 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. [24]

#### Objectives

- Support cultivation of medicinal plants which is the key to integrity, quality, efficacy and safety of the AYUSH systems of medicines by integrating medicinal plants in the farming systems, offer an option of crop diversification and enhance incomes of farmers.
- 2. Cultivation following the 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 AYUSH products.

- 3. 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.
- 4. Implement and support certification mechanism for quality standards, Good AgriculturePractices(GAP),GoodCollectionPractices(GCP),andGoodStoragePractices(GSP).
- 5. Promote partnership, convergence and synergy among stake holders involved in R&D, processing and marketing in the public as well as private sector at national, regional, state and sub state level.

### Strategies

- To adopt an end- to-end approach covering production, post harvest management, processing and marketing. This will be achieved by promoting cultivation of medicinal plants in identified clusters within selected districts of states having potential for medicinal plants cultivation and to promote such cultivation following Good Agricultural and Collection Practices (GACPs) through synergistic linkage with production and supply of quality planting material, processing, quality testing, certification, warehousing and marketing for meeting the demands of the AYUSH industry and for exports of value added items.
- 2. To promote medicinal plants as a crop alternative to the farmers and through increased coverage of medicinal plants and with linkages for processing, marketing and testing, offer remunerative prices to the growers/farmers. This will also reduce pressure on forests on account of wild collection.
- 3. To adopt communication through print and electronic media as a strong component of its strategy to promote integration of medicinal plants farming in the agriculture/horticulture systems with emphasis on quality and standardization through appropriate pre and post harvest linkages.
- 4. To promote and support collective efforts at cultivation and processing in clusters through Self Help Groups, growers cooperatives/associations, producer companies and such other organizations with strong linkages to manufacturers/traders and R&D institutions.

(Source: National AYUSH Mission, Operational Guidelines, Medicinal Plants, Department of AYUSH, Government of India, 2019)

## 6.2 Modes of Production in Medicinal Plants Sector- China

China has a long way to go before it is successful in sustainable sourcing the raw material essential for the large scale TCM requirements of the future looking at the current demands. There are 11,146 medicinal plants species, belonging to 383 families, and 2,313 genera. The herbal geographical distribution covers different longitude, latitude, and altitude in China. Different ecological habitat



causes different genuine medicinal materials. Nowadays there were 100,000 traditional Chinese medicine prescriptions and these prescriptions used 700 Chinese herbal species. Currently a total of 80% of TCM is collected from continuous wild collection which has no scientific basis. The natural reserves in forests cannot meet the ever increasing demand. The wild herbal resources are also reducing every year. In China, there were 1,800–2,100 of 11,146 species of medicinal plants that have been endangered and 20% of all commonly used herbs were facing shortage. Lack of regulation and scientific planning in wild herbal collection can be said to be the major reasons behind such shortages. The species most in 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)

Other than wild harvesting of medicinal plants, the other techniques are cultivation and natural fostering methods used as production modes to meet the demand. Artificial breeding is another method which is being carried out for production, though it is on a small scale presently. (Li Xiwen et al, 2015)

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.<sup>[25]</sup>

Cultivation can be implemented in a large scale and is an efficient method to rapidly provide sufficient raw material. Natural fostering, also named as wild nursery or semi-imitational cultivation, can combine economic benefit and diversity protection and solves the problem between subsistence and biodiversity conservation effectively. Therefore in China, this method is given priority in order to create a balance between use and recovery of medicinal wild species in nature. But at the same time it involves a long-time process and yields low output, therefore taken up alone, it is not a

sufficient method to meet the demands. Therefore, together, wild collection, natural fostering, and cultivation are the methods taken up in China. Factors such as natural reserves, usage amount, and biological characteristics of medicinal plant species, land availability determine the mode that is chosen. Artificial breeding is another method which is being carried out for production, though it is on a small scale presently. (Li Xiwen et al, 2015)

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.

# 6.2.1 Good Agriculture Practice (GAP)

In order to meet international standards and improve production, Good Agriculture Practice (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. Good Agricultural Practice 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. [26]

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.

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. [27]

- 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 10th five year plan.
- 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 bring medicinal material production onto the to 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.<sup>[28]</sup>

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.

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.

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.

# 7

# **Export Promotion Initiatives for TISM and TCM**

# 7.1 Export Promotion of MAPs: Initiatives in India

As far as export promotion of TISM in India is concerned, 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 Kolkata. <sup>[29]</sup> These EPCs facilitate the exporting community and undertake various promotional measures for promotion of export of their products. <sup>[30]</sup>

Table 3: 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
AYUSH and Herbal Products	364.00	401.68	456.12	290.96

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

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. The International Cooperation Scheme of AYUSH Ministry provides financial assistance to the exporters for the participation in Trade Fairs, organising International Business Meets & Conferences and product registration reimbursements.

Table 4: Export of MAPs from India

	AYUSH Items		All Items		
Year	<b>Export</b> (Rs. in Crore)	Growth Over Previous Year (%age)	<b>Export</b> (Rs. in Crore)	Growth Over Previous Year (%age)	%age Share of AYUSH Items
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.

# 7.1.1 Developing International Collaborations

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. The traditional knowledge based on genetic resources needs to be brought under international best practices on TK & GRs like Access and Benefit Sharing (ABS), Prior Informed Consent (PIC), etc., therefore efforts are being made to bring these changes. 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.



The Ministry of AYUSH is exploring bilateral and international collaboration of National Medicinal Plant Board (NMPB)in the field of medicinal plants with other countries. NMPB is 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, 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.<sup>[31]</sup>

# 7.1.2 Quality Production of Herbs and Herbal Products

The NMPB has launched a "Voluntary Certification Scheme for Medicinal Plants Produce (VCSMPP)" in 2017 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. [32]

A very recent development which has potential to bring major changes is the collaboration with Niti Aayog and Invest India, in a Scheme for Integrated Health Research (SIHR) which has been finalised with an outlay of ₹490 crore. The Central Research Councils of Ayurveda, Unani and Siddha is validating classical formulations for various conditions, through generating evidence on its clinical safety and efficacy. Initiatives like these can help tap the untapped potential of integration of AYUSH systems with modern medicine. [33]

The Government has taken up many Initiatives for Processing and Industrial Development. 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. (Patwardhan, 2005)

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. The Ministry has also entered into MoUs with few countries for promotion of traditional medicine which will help exports in the long run.<sup>[35]</sup>

# 7.1.3 Research & Development and Product Innovation

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

<sup>[31]</sup> https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1297513/

<sup>[32]</sup> https://pib.gov.in/newsite/PrintRelease.aspx?relid=187278

<sup>[33]</sup> https://www.thehindubusinessline.com/economy/ayush-proposes-to-bring-19-procedures-under-ayushman-bharat/article29498989.ece [34] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1297513/

<sup>[34]</sup> https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1297513/[35] https://pib.gov.in/PressReleaselframePage.aspx?PRID=1558955

of national/global importance.

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. 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. [36]

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.<sup>[37]</sup>

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. National Panel on Bhasmas for identification of thrust areas of R&D in the area of Bhasmas and Kushtas has been developed and national level facilities needs to be set up for the purpose.<sup>[38]</sup>

An IND application (The United States Food and Drug Administration's Investigational New Drug program is the means by which a pharmaceutical company obtains permission to start human clinical trials and to ship an experimental drug across state lines, usually to clinical investigators, before a marketing application for the drug has been approved) of Lupin Ltd. is in process and a US patent has been granted for development of herbal-based anti-psoriatic composition. Indian Institute of Integrated Medicine, Jammu has commercialized Boswelliaserrata gum resin as NSAID (Non-Steroidal Anti-Inflammatory Drug).<sup>[39]</sup>

# 7.1.4 Knowledge and Skill exchange between TISM and Modern Health Practices

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. [40]

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 tools for deriving radical ayurvedic solutions for health & treatment advice as a decision support system are appreciable.<sup>[41]</sup>

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)

<sup>[36]</sup> http://medind.nic.in/haa/t07/i1/haat07i1p14.pdf

<sup>[37]</sup> http://medind.nic.in/haa/t07/i1/haat07i1p14.pdf [38] https://dst.gov.in/sites/default/files/annual-report-2013-14\_0.pdf

<sup>[39]</sup> Annual Report, 2013-14, Department of Science and Technology, Ministry of Science and Technology, Government of India

<sup>[40]</sup> https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1297513/ [41] https://www.currentscience.ac.in/Volumes/102/10/1406.pdf

# 7.1.5 The Traditional Medicine Strategy 2014-2023 of WHO

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 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.

The strategy has two key goals:

- a) To support Member States in harnessing the potential contribution of Traditional and Complementary Medicine (T&CM) to health, wellness and people centered health care
- b) To promote the safe and effective use of T&CM through the regulation of products, practice and practitioners

It has three strategic objectives to achieve its goals:

- a) Building the knowledge base and formulating nation's policies
- b) Strengthening safety, quality and effectiveness through regulation
- c) Promoting universal health systems

It calls for cooperation on promoting the quality, safety and effectiveness of service provision in traditional and complementary medicine between WHO and Ministry of AYUSH (2016-2020).

- 1. The area of collaboration
  - a) Development of Benchmark for practice in Ayurveda, Unani and Panchakarma
  - b) Development of Basic (essential) terms for T&CM
  - c) Support on establishment of a WHO database for global T&CM practitioners
  - d) Support the establishment of a network of international regulatory cooperation for T&CM practice<sup>[42]</sup>

Instead of taking up many promotional activities for TISM, India is still not prepared for its internationalisation.

# 7.2 Export Promotion of MAPs: Initiatives in China

China introduced the concept of "internationalization of TCM" in 1996, the efforts for which has contributed to bring forth TCM to the forefront in the world health market today. The plan 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.<sup>[43]</sup>

For internationalization of TCM, Chinese Government has adopted a systematic and strategic approach for its export promotion.

## 7.2.1 Winning over the market by quality

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.



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. 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).<sup>[44]</sup>

A number of laws and regulations have been enacted and implemented on strengthening the protection of TCM wild medicinal resources; and artificial production or wild tending have been carried out for certain scarce and endangered resources. The Government is promoting good regulatory practices to ensure supply of high-quality and affordable health products and technologies. The law specifically notes 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.<sup>[45]</sup>

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, 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. Farms producing raw ingredients must comply with State Drug Administration (SDA)-imposed standards.<sup>[46]</sup>

At processing level, 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.[47] 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.[48]

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.

## 7.2.2 Research & Development to Expand TCM Globally

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. [49] The private investors are encouraged to establish TCM healthcare institutions, resulting in a large number of such institutions flourishing in China at present.[50]

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. [51]

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). The country's ambitious plan is by the year 2020, every Chinese citizen will have access to basic TCM services, and by 2030 TCM services will cover all areas of medical care.[52]

### 7.2.3 Plans on 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, Africa, Asian countries and other developing countries at large.

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. The State Drug Administration and the Ministry of Health together restrict both domestic and international purchase of TCM medicine through the Internet to discourage the ability of TCM to reach international market without proper investigation and certification. Legislation is passed on regulating online advertising and sales of Chinese medicine. Websites providing medical information must receive approval from the appropriate medical and health authorities and display the seal of approval on the home page. The Ministry of Health also agreed to designate a special task

<sup>[47]</sup> https://www.fda.gov/consumers/consumer-updates/it-really-fda-approved [48] https://www.who.int/phi/publications/2081China020517.pdf

<sup>[49]</sup> http://www.chinadaily.com.cn/kindle/2016-12/07/content\_27601954.htm

<sup>[50]</sup> https://www.tomorrowscompany.com/wp-content/uploads/2016/05/Tomorrow s Capital Markets Final vfl.pdf

<sup>[51]</sup> http://www.xinhuanet.com/english/2018-12/17/c\_137680388.htm [52] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1297513/

force to periodically inspect all medicine websites for violations. The State Drug Administration independently screens and regulates crud drug providers and traders of online pharmaceutical information. In the year 2000, the Ministry of Health in China has outlawed online diagnosis and treatment services.<sup>[53]</sup>

For Trading and Market System Development, from December 2001 with China becoming member of the WTO, it has reaped top benefits from trade and investment openness and export-led growth. 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. China is therefore in a better position than India to increase investment and develop the TCM sector with its constant endeavour of promoting TCM based healthcare system.

The prospective export of China's TCM model is part of the "one belt, one road" programme. 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 fibre optics. It aims 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. (Lain Sarah, 2018) The TCM and other related products exported to BRI partner countries have increased by 54% between 2016 and 2017, to a total of US\$295 million.<sup>[55]</sup>

For international exchanges and cooperation in TCM for promoting its globalization, 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. [56] TCM has become an important area of health and trade cooperation between China and the ASEAN, Africa, and Central and Eastern Europe, a key component in people-to-people exchanges between China and the rest of the world and between Eastern and Western cultures, and an important vehicle for China and other countries to work together in promoting world peace, improving the well-being of humanity, and developing a community of shared future. [57]

<sup>[54]</sup> https://www.iisd.org/sites/default/files/publications/elements\_sustainable\_trade\_china.pdf

<sup>[55]</sup> https://centralasiaprogram.org/wp-content/uploads/2017/12/OBOR\_Book\_.pdf [56] http://www.china.org.cn/government/whitepaper/2016-12/06/content\_39858330.htm

<sup>[57]</sup> https://www.scio.gov.cn

# <u>8</u>

# **Conclusion and Recommendation**

In India the efforts put in to conserve medicinal plants are many, but lack a systematic approach. The lack of strategy by the Government as well as no defined policy for the conservation of medicinal plants is leading to many issues in the sector. The Government has taken up a number of steps, but a lot still needs to be achieved in the sector.

There are no set laws/ control mechanisms on the exploitation of medicinal plants from outside protected areas. Most species are banned for export not for their medicinal value but because they have endangered status. A national level policy on these issues is required if all such conservation issues needs to be addressed. The policy must be formulated considering the various user groups of medicinal plants since there is a much larger population of non-commercial users, as opposed to commercial users. Laws should cover both these groups extensively.

The policy framework should give increased emphasis to improve cultivation efforts in the area of medicinal plants. This is of utmost importance considering the long term and constant availability of medicinal plants according to its vast demand and the immediate needs of user groups. The policy initiatives should look at improving the means to raise financial resources and incentives for encouraging conservation actions. The legal and regulatory mechanisms related to medicinal plants and essential infrastructure should be put in place accordingly. In order to facilitate implementation, the policy should review existing institutions working in the field, encourage their strengthening and building new institutions where necessary.

The ethnic communities have traditional knowledge and know how to harvest plants while the species could maintain its population at natural or near natural levels. This traditional knowledge needs to be highlighted and conserved in India through efforts put in the right direction. Also these communities cultivate selected medicinal plants only for their personal uses. They have varied ideas on ideal growth conditions for these species. A lot of these understanding have to be developed with the help of proper documentation of this ethno-botanical knowledge from the communities and provide them incentives to keep this tradition alive. The medicinal plant species which have highest commercial value for the communities are sold considerably lower than the market price since they are in the raw form. There should be value addition to medicinal plants through simple techniques such as drying, cleaning, crushing, powdering, grading and packaging which can fetch a better price for the products. A better price for the raw material will also help increase the incentive of the local communities for preservation and protection of the medicinal plant species. Many small scale level efforts are put in this direction by exporters and traders, who are reaping multi-fold benefits through the strategy and well as contributing in increasing the livelihood options of the local communities. The Government of India should take up this work seriously and set-up establishments in large scale for large scale outputs.

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.

# **Need for Legal and Policy Regulation**

The Indian Forest Act applies only to material brought from the forest. The Forest (Conservation) Act, 1980, and the Wildlife (Protection) Act, 1972, facilitate only the in situ conservation of medicinal plants. Outside protected areas the Wildlife (Protection) Act, 1972, provides a regulatory mechanism of six endangered plant species under its Schedule VI. Out of these only one is of medicinal value. The export import policy of India looks at the export as well as import of plants and plant parts on the basis of the Convention of International Trade in Endangered Species of Wild Fauna and Flora (CITES), Appendix 1, which essentially lists the same six species of plants that are under schedule VI of WLPA.<sup>[58]</sup>

Though, the Forest (Conservation) Act, 1980 and the Wildlife (Protection) Act, 1972, give medicinal plants some amount of protection, but a lot of them grow away from the protected areas domain and since there is no consolidated strategy for medicinal plants, a lot of them disappear before even being acknowledged. In the protected areas also, the lack of a focussed conservation strategy is causing reduction in many MAP species. Most medicinal plants used by the Indian pharmaceutical industry are still collected from the wild and most of it uses the roots, bark, wood, stem and in some areas the whole plant which leads to destructive harvesting leading to loss of genetic stocks and diversity of medicinal plants.

While 335 plant species in the country are classified as threatened on FRLHT's Red Data list (2019), India's Wildlife (Protection) Act provides protection only to five species and one genus of plants, through their listing under Schedule VI. With increasing pressures on a variety of wild medicinal plant resources, there is a definite need to expand protection to other widely traded wild species as well. The Policy available for the promotion and safeguard of the TISM sector is clearly inadequate. Policy-level changes and updates are also required but before that a comprehensive and systematic attempt should be made towards documentation of the most traded species of MAPs. Proper up-graded infrastructure and mechanisms are required in the enforcement of the laws related interventions. To have a good regulatory regime is essential in order to reduce delays in exports and commercialization of the products.

Insufficient regulatory guidelines, particularly for good manufacturing practices; non-implementation of good agricultural and collection practices; and lack of proper implementation of the Drugs and Cosmetics Act of 1940 are considered major drawbacks for the Indian herbal industry. Standardization and quality control of raw materials and herbal formulations is the major challenge for Indian herbal drug manufacturing firms. There are delays in application submission and review processes which is an area of concern the manufacturing industry. No safety and efficacy studies are required for marketing approval, as per the Drugs and Cosmetics Act of 1940 (DCA), which again puts a question on the quality and efficiency of the products manufactured. [59] (Sahoo, 2013)

In India, The State Food and Drug Administration (SFDA) regulates manufacturing and marketing approvals. There are drawbacks in proper implementation of the Drugs and Cosmetics Act, 1940. The SFDA interprets the Act differently; as a result, the same drug or formulation that is not permitted in one state is allowed to be manufactured in another state. Also there is non-uniformity in the drug registration timeline across states. Development of unified protocols, standard timelines, and guidelines will help establish a unified system in the country.

# **Need for Export Promotion**

With regard to export promotion, the country faces differing regulatory requirements at the country where the product is imported. Herbal medicines are permitted only if they could successfully pass through a full regimen, which requires safety and efficacy data. The applicant needs to submit specifications for herbal substances/herbal preparations along with quality, specifications, and documentation for each ingredient, vitamin/ mineral separately. This is an expensive process for most Indian herbal medicine manufacturers. Due to strict quality standards, the market is limited for the sector in foreign countries. Again sustainable sourcing and emphasis on organic raw materials is another area where India has to bring changes and up-grade its standards in order to meet the demand from importing countries globally. Different countries have their own standards, which vary from those of India. (Sahoo , 2013)

When one looks at the pharmacopeia standards put up by different countries, it reveals variation in plant-specific parameters and quality standards, such as permissible limits for heavy metals, pesticides, and microbial contamination. There are country-specific standards and regional guidelines that have evolved in each country. Compliance with multiple standards has become a major worry for Indian manufacturing industry as well as traders.

The TISM faces limited market in foreign countries. 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.

There is dearth of herbal practitioners which has resulted in limited recognition. 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. An Indo–US Centre for Research on Indian Systems of Medicine (CRISM) has been set up in the National Center for Natural Products Research, University of Mississippi. The mission of CRISM is to facilitate scientific validation and dissemination of information on ASU medicines through collaborative research. The establishment of such centers will help improve scientific acceptance of TISM.<sup>[60]</sup> (SkofLenart,S. Kreft, 2010)

# **Need for Standardization and Improvement in Quality of Raw Materials**

As per the Department of AYUSH, nearly 600 medicinal plant products, 52 minerals, and 50 animal products are commonly used in traditional Ayurvedic preparations. Medicinal plants can easily

be contaminated during the process of growth, collection, and processing. Most manufacturing companies face problems in collecting and authenticating raw material. And many manufacturing companies prefer adulteration of raw materials, which affects quality of the product. [61]

Substitution, adulteration, and heavy metal contamination are the three major issues. The storage condition also plays an important role, at which stage, microbial contaminants or mycotoxin contamination may occur. Conventional quality control methods become insufficient because of the complex nature of herbal medicines. The developed countries require chemical fingerprinting and marker-based assessment of raw materials and active ingredients for assuring its quality; but in India this concept is only recently introduced. The Indian GMP regulation does not provide any guidelines for marker-based identification. Many manufacturing companies do not perform these chemical marker-based studies for their formulations. Marker-based analysis is a costly process that requires sophisticated and expensive instruments. Most manufacturing firms are small and medium enterprises and don't have elaborate research facilities at their units. Most manufacturers follow the traditional methods for standardizing raw materials and formulations. Marker-based studies are also limited because reference standards are not available for all the herbs/plants used in medicinal preparations. These standards should be documented and developed. There is also need for third-party laboratories within and outside India for testing ingredients of Indian origin.

There is a need for development of extensive guidelines on quality control aspects. There are quidelines for preclinical safety evaluation of ASU and other traditional medicines, but there is requirement for standardization of herbal preparation and marker-based identification of active components. Development of reference standards for marker-based evidences is needed to produce safe and effective herbal medicines.

Evidence-based studies is essential for establishing the safety and efficacy of herbal products in the domestic and export market, therefore scientific and technological advancement through clinical evidence based studies is essential. Initiatives have been taken to address these issues by the Department of AYUSH. Schemes have been implemented to promote development of standardized herbal formulations. One such example is the New Millennium Indian Technology Leadership Initiative by the Council for Scientific and Industrial Research. Under this scheme, for the first time in India an Investigational New Drug application has been filed for an oral herbal formulation developed by extensive studies comprising finger printing, activity-quided fractionation, efficacy studies, toxicology, safety pharmacology, pharmacokinetics, and toxico-kinetics for the treatment of psoriasis.[62]

There is a need to follow good agricultural and collection practices (GACP) and good storage in order to meet the quality standards. In the year 2009, the NMPB developed India-specific guidelines on good agriculture practices and good field collection practices in line with GACP developed by the World Health Organization, but most manufacturers and raw material traders are still not aware of these guidelines. Many companies also find them impractical due to lack of knowledge and the associated operational cost. It is essential that the GMP standards should be strictly promoted and followed by the manufacturing companies, which has been made compulsory since 2006. But non-compliance is easy for Indian manufacturing companies so far. Regulations should be stricter in such cases and compliance should be mandatory, lack of which should lead to serious legal punishments.[63]

A greater emphasis on the documentation practices is required in the sector. There is also the need for establishment of government-certified raw-material supply centers in every state enabling the manufacturers to have access to authentic raw materials. In India, most traditional medicinal

products are available as over the counter (OTC) drugs.

Since most manufacturers are small and medium scale industries, Government support is required in many aspect of production. Supply of standardized raw material is the most common need of such units, Building awareness and education about the GACPs is important. Organic farming should be promoted so that good-quality material can be produced. Initiative must be taken for cultivating some of the herbs predominantly used for herbal medicines. Subsidies and financial assistance should be provided to small and medium companies in time, without the hassles of much paperwork. Capacity building and knowledge sharing is also essential. Awareness on the facilities made available by the Government should be promoted.

There should be uniformity in herbal drug registration process and submission requirements. Pharmacopoeia harmonization and recognition of Indian monographs in other countries can be helpful for registration of drugs across countries.

More focus should be given on scientific and technological advancement in the field of herbal medicine. India must develop scientific cultivation, postharvest technology, processing, manufacturing, research and extension, patenting, and marketing strategy for medicinal plants and products.

India should endeavor to popularize medicinal plant cultivation on scientific basis taking a parallel from China's Fostering method. In this method, China has identified the native occurrence zone of a particular group of medicinal plants. These groups of medicinal plants are popularized for adoption by prospective farmers. The individuals using these plants are then encouraged to tie-up with farmers. This helps industry to get genuine and assured supply and the farmers get remunerative price. This type of arrangement has been tried by NMPB and State Medicinal Plant Boards but with much less success. This needs to be looked into by Government of India with better compliance of formulated policy as this would help in sustainable conservation of wild bio-diversity and apply the principals of their sustainable harvesting and use practices.

Once the material supply line has been scientifically organized, the other area of intervention could be to have strict compliance of Good Manufacturing Practices. Severe penal action leading to closure of defaulting industries will have to be resorted.

India might be behind China with regard to development and promotion of its Traditional System of Medicine, but is slowly and steadily taking proactive steps in the right direction. The TISM needs to be popularized aggressively. At present it is left to individual manufacturing of herbal drugs. Ministry of Commerce and Industry needs to have a dedicated wing to promote marketing of the TISM in the International market. The Government AYUSH Ministry should fix target of accessing 10%, 20%, 25%, 50% of international market in identified timeframe of the certified quality of raw material and drugs are available confirming to Indian Standards, there is no reason why India should lag behind China. Domestic market in India is also very large. In order to take advantage of the domestic requirements, drastic measures in the area of TISM education, research, development and extension will have to be taken up on a priority basis. Chinese experience may have to be studied and with due modification relevant to Indian socio-economic and socio-political environment, may be adopted for good.

A long-term strategy encompassing all issues regarding TISM and an all encompassing law which considers all the existing efforts and suggests ways to conserve and sustainably harvest medicinal plants is the need of the hour.

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#### Need for research on validation of data quoted in this report

While compiling this Working Paper the team has encountered significant variation in figures / data on different aspects. Although each set of data has been supported by referred publications there is a need to carry out intensive research on the aspect of quality of data. It is suggested that a small sub-project may be given separately for data validation. This will go a long way in bringing more transparent and true to the fact situation for intervention by the concerned authorities. Team.



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