

## **9. Indian System of Medicines**

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This report refers to the phrase – “Indian System of Medicines” (“ISM”) as including Traditional Medicines, Ayurveda, Unani and Siddha systems of medicine. For convenience, throughout this text we have used the acronym AYUSH to denote Ayurved, Unani and Siddha systems of traditional medicine prevalent in India because of the use of this acronym in common parlance. This section of the paper also looks at the export of medicinal plants from India, because at present the ratio of export of finished products to raw material (i.e. the medicinal plants) is about 40:60<sup>15</sup>. ISM's include many different categories of products and while an attempt has been made at their categorization below, ISM's include everything from over the counter formulations to herbal remedies to prescription drugs.

This report attempts to address several of the problems which inhibit the growth of exports from this sector, such as unsustainable cultivation practices for the ingredients of AYUSH medicines, non-recognition of AYUSH as valid medicinal products, absence of specific AYUSH driven good manufacturing practices, unclear guidelines for gauging quality, specific fears such as biopiracy and inadequate benefit sharing policies in Traditional Medicines, Non Tariff Barriers, inadequate awareness in target markets, etc. While not an exhaustive list these are indicative of the factors that are holding back exports of a sector with good potential.

### **9.1 Background of AYUSH Industries in India**

There has been a great deal of interest in alternate remedies for some time now,<sup>16</sup> as illustrated by measures such as the Work Programme for the European Medicines Agency 2007, which identifies greater co-operation with India - especially in the field of traditional and herbal medicines and remedies.<sup>17</sup> However, alternate remedies are not necessarily the same as AYUSH and there are serious information gaps, which need to be addressed in target markets before AYUSH becomes acceptable as a form of medicine. In India, the AYUSH industry is of no uncertain heritage and can trace its history to the ancient texts which form the basis of this branch of medical knowledge. These texts are listed in Schedule 1 of the Drugs and Cosmetics Act, 1940.

Though the precise figures of recent AYUSH trade are unclear, in 2006 the exports of medicinal plants and plant based products were in the region of Rs.800 Crores. The ratio of raw to finished products was about 60:40. This is a worrying figure for India in light of earlier figures. In 2001-02 the figures for exports were in the range of US\$133.28 million and at that time 70 percent of products were plants or plant products whereas the remaining 30 percent were finished products. At that time i.e. in 2001-02 it was

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<sup>15</sup> Technopak report prepared for APEDA, “Export Promotion of Medicinal and Aromatic Plants”, January, 22, 2007.

<sup>16</sup> World Health Organization, Fact Sheet No. 134, at <http://www.who.int/mediacentre/factsheets/fs134/en/> (revised May 2003).

<sup>17</sup> Work programme for the European Medicines Agency 2007, EMEA/MB/428793/2006/EN/FINAL, as available at [www.emea.eu](http://www.emea.eu).

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envisaged that the ratio of raw materials to finished products ought to be reversed within the next five years. The fact that the ratio remains worryingly weighed in favour of export of raw products suggests that any of the following or a combination of the following broad factors are inhibiting exports of finished products.

- ❖ Issues of technical up gradation of domestic industry.
- ❖ Non-facilitation of export.
- ❖ Issues with market access in importing markets – and this would include issues such as non-tariff measures, non-awareness of target markets, etc.

India's most important competitor in the realm of medicinal plants as well as alternative medicines is China, which is also the largest exporter of such products in the world. The most important markets for export are Hong Kong (which is also a major re-exporter), Germany, Japan, France, Korea, Italy and China.

### **9.2 Categorisation of AYUSH Products**

The precise classification of AYUSH products has been one of the stumbling blocks to the increase in their exports. The classification of the products, determines the regulations to which these products are subjected, in the different export markets. There are possibly two methods of classification. Consultations with prominent members of the industry seem to suggest that one broad division is between the herbal and phyto-chemicals section and the producers of ASU (Ayurveda, Siddha and Unani) products. Members also suggest that the former seems to be set for a very rapid expansion over the next few years, whereas the latter will require innovation from within, as well as favourable regulatory structures through governmental action to achieve high growth levels.

Broadly, AYUSH products may be classified into the following categories<sup>18</sup>.

1. OTC products: This would mean over the counter products, which have a consumer demand potential. (e.g.: imago, etc.)
2. Ethically Promoted Products: These are products, which would be patronized by modern medical practitioners as well as Ayurvedic Physicians and have a prescription demand.
3. ASU Classical Products: These are products that are patronized by traditional practitioners of ASU sciences. (This category, as well as the category referred above is dependent on a structure specializing in the delivery of ASU healthcare. Consequently the export demand for

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<sup>18</sup> As per the ADMA.

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these products would not be as much as the others – simply because most other countries would not have as many certified ASU healthcare professionals).

4. ASU foods: This category includes specific foods as properly called, as dietary and nutritional supplements, organic teas, etc., – i.e. intended for oral consumption.
5. ASU Cosmetics: This would include cosmetic and beauty products, as different from the OTC category and include miscellaneous products such as massage oils, etc., which may have therapeutic qualities in addition to being used for cosmetic application.
6. There will, inevitably, be overlaps between categories 1, 4 and 5 but it is also clear that these are the categories with the greatest export potential. Apart from these finished products, a large number of medicinal plants are also exported by India in the form of raw materials for either re-export (from Hong Kong, Germany, etc.) or for the herbal medical/cosmetic industry in the importing countries.

### **9.3 Regulatory Structures**

The regulatory structure governing ASU products in India is divided between the regulation of the products themselves and the regulation of the institutions which either train the personnel in charge of training doctors in AYUSH, or are concerned with delivery of AYUSH healthcare or in some cases, both.

Chapter IV A of the Drugs and Cosmetics Act, 1940 (the “Act”) governs these products and they are defined in the Act as including all medicines intended for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals and manufactured exclusively in accordance with the formulae described in, the authoritative books of Ayurvedic, Siddha and Unani (Tibb) systems of medicine specified in the First Schedule to the Act.

Legally there may be two kinds of ASU medicine. The first is the kind defined above – i.e. all the classical formulations mentioned in the approved ancient texts and the second is the category of proprietary medicines which are formulations evolved by the manufacturers with such ingredients as are mentioned in the approved classical texts.

Though the Act classifies AYUSH products as medicinal products for regulatory convenience (regulating manufacture on a commercial scale as well as regulating sale through pharmacies against a prescription), many of these products are not only used as medicines, but also as food supplements, or

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health foods, or OTC products. However, the effect of the legislation is that any product which is manufactured for commercial sale without a license as required under the Act is not an AYUSH product. Technical implementation/enforcement related evaluation of AYUSH medicines is done by:

- ❖ Ayurveda, Siddha, Unani Drugs Technical Advisory Board (ASUDTAB – which advises the government on drug related issues)
- ❖ Ayurveda, Siddha, Unani Drugs Consultative Committee (ASUDCC – which advises the government on implementation issues)
- ❖ State licensing authorities who actually look after the testing process of AYUSH drugs to ascertain their purity, safety etc.

But this is only insofar as the manufacture of AYUSH products is concerned. The growth of raw ingredients, etc; is governed by different sets of Good Practice guidelines which are discussed later in this Chapter.

### **9.4 AYUSH Sector – Export Potential**

The segments in AYUSH which have export potential can be summarized as:

- i. Herbal Extracts/ Phyto chemicals
- ii. Ayurvedic Classical/ Generic medicines
- iii. Ayurvedic Prescription and branded medicines
- iv. Ayurvedic Dietary Supplements
- v. Ayurvedic Food Products
- vi. Ayurvedic Cosmetics and Beauty Treatments
- vii. Ayurvedic Panchakarma therapy
- viii. Ayurvedic Practice
- ix. Ayurvedic Educational Courses

Each one of the above potential for export requires a unique and focused strategy in promotion. A cursory study of the potential for each of the above segments would indicate great potential for each of the same. Some of the oft repeated factors which indicate good potential are as under:

- ❖ World market for Natural Products US \$ 62 billion and having double digit growth.
- ❖ Market for Dietary supplements growing in both USA and EU markets.
- ❖ More than 70% of population in developed countries have tried and regularly depend on Natural products for health care solutions
- ❖ Chinese medicinal products and practice have found good acceptance in majority countries of the world

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- ❖ India possesses the distinction of being called the Botanical Garden of the world with more than 40,000 species and 16 eco climatic zones.
- ❖ YOGA as a science has been well accepted and is gaining firm footing in health care segments in most developed countries.
- ❖ Wellness and Wellbeing centres/ Spa's are a growing fancy in western countries.
- ❖ There is a definite interest in Ayurvedic courses in curriculum of major US Universities. Diploma courses have been instituted in colleges in the United Kingdom.
- ❖ There are more than 200 Ayurvedic Physicians from India who are regularly visiting developed countries and imparting educational lectures and health care advice.

### **9.5 Sustainable Growth of Medicinal Plants and Herbs**

Outreach and acceptability of AYUSH systems is critically dependent on a sustained availability of quality plant base raw material. More than 90% of the species used in trade continue to be sourced from the forests. With the upsurge in the demand of herbal products globally, there is increasing pressure of unsustainable collection and over exploitation of medicinal plants bio-diversity from forests leading to shortages of ingredients for AYUSH products, besides a number of plants facing a threat of extinction. While studies seem to show that importers prefer medicinal plants, which are collected from the wild and organically grown (because of the fears of heavy metals and pesticides in the cultivated varieties), it is also a fact that wild collection is not sustainable as a form of supply of raw materials.

In fact, the European Herb Growers Association (EUROPAM) has evolved a set of Good Agricultural Practices (GAP) applicable to the growth of medicinal plants<sup>19</sup>. However, it is necessary that India specific GAPs are prepared by National Medicinal Plant Board (NMPB) at the earliest. It is understood that the preparation of GAPs has some how got stuck in turf issues within the government. There should be no doubt about the domain jurisdiction of NMPB on the subject and the sooner the matter is addressed the better it would be for the sector.

Domestication and cultivation of medicinal plants, therefore, is the key to meeting the raw material needs of the industry besides offering opportunities for higher levels of incomes, crop diversification and growth of exports. According to a recent study, 960 medicinal plants are in trade of which 178 species are consumed in excess of 100 MT per year. More than 90% of the consumption of the domestic industry comes from forests with less than 40 species being cultivated to any significant degree even though agro-techniques of more than 100 species have been developed. The primary reason is the absence of adequate knowledge about the cultivation practices among the farmers and above all, absence of proper markets.

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<sup>19</sup> Available at [www.europam.net/GAP.htm](http://www.europam.net/GAP.htm). Last visited on 8 October, 2007.

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The global trade requires products of standardized phyto-chemical composition free from heavy metals, and other toxic impurities and certified to be organic or Good Agricultural Practices (GAP) compliant. This is possible only through cultivation route where chain of custody regime is easier to maintain.

Indian share of the world herbal trade is less than 1%. Even here, the export of herbal products is largely in the form of raw herbs with 2/3<sup>rd</sup> of the export basket comprising raw herbs. This needs to change considering the US \$ 62 billion herbal market.

Government of India has recently launched a central sector scheme in mission mode. The mission is expected to address aspects relating to conservation of medicinal plants, their cultivation and harvesting, and marketing with a view to sustain supplies of good quality medicinal plants for AYUSH industry and at the same time promote medicinal plant cultivation as an alternative option to agriculture. The Mission seeks to develop medicinal plants sector through production of raw material of quality and standardized constituents for use by the AYUSH/ Herbal industry and thereby enhance the quality and acceptability of AYUSH systems of medicine and promote export of value added items for an increased share in the world market.

The Mission would 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/ zones within selected districts of states having potential for medicinal plants cultivation and to promote such cultivation following Good Agriculture 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.

The institutional arrangement for implementing the major activities under the Mission i.e. technology dissemination, quality planting material, cultivation, post harvest management and marketing will be varied depending upon the organizations/ institutions present in the state covered under the programme and will include cooperatives, incorporated companies, state government undertakings, individual entrepreneurs, associations, producer companies, self help groups, Krishi Vigyan Kendras, etc. for ensuring proper delivery under the scheme. All the activities related to cultivation, processing, marketing, quality assurance and certification will be converged under the Mission for better synergy. State Governments are free to choose their own model, create or orient existing institutions to carry forward the objectives of the Mission in a holistic manner. The experience so far with the implementation of the erstwhile similar scheme has not been very encouraging therefore implementation of the mission activity will have to be very eagerly watched. It is noteworthy that much would depend on the quality of implementation by state governments.

It has been reported that many of the significant Indian plants do not find place in the list of importable herbs in many countries. For example, Bacopa Monnieri (Brahmi) the celebrated brain tonic from India is not in the approved list of European Union importable herbs. Similarly Terminalia Belirica (Baheda) one of the three ingredients in Trifala is not a part of TGA (Australia). Most of the countries have lists of importable herbs as food supplements, flavouring agents, etc. Indian herbs are largely left out for the absence of compiled safety data along with data of their usefulness for healthy living. There is a need to compile such list of non importable herbs which are considered significant for exports and prepare their monographs. It is important that these herbs are not classified as drugs only but where ever applicable also as dietary supplements. A joint effort of the industry and government in a time bound format with dedicated funds is of utmost importance.

Extracts of medicinal plants or phytochemicals constitute the most significant export opportunity in the short run for India. An ABC analysis of the main medicinal plants of India, on a pre established criteria, would help us to pick up 25 odd plants, which can be called 'star' plants, to focus all our attention on them, for export needs in the first phase of three years. This is not to undermine the importance of others but is only a method to focus our attention selectively for better results in short time. The immediate need is to gain a firm ground in the foreign markets explicit in statistics. The Vishesh Krishi Upaj Yojna (VKUY) can come handy in promoting these star plants and their products. The VKUY should also include extracts as well as compounds isolated from the herbs so identified under the star criteria. This will incentivise a gradual move from exports of plants and their parts to their products in the first phase as envisaged in several decisions of the government.

Solvents like ethanol are essential need for processing the herbal products. Various State Governments have very elaborate and restrictive practices in imparting licenses even to the genuine industries. This impedes the growth of the herbal extract industry as some countries do not allow for extracts from other solvents. A special and urgent attention to this road block is needed.

### **9.6 The Manufacturing Process**

In India Schedule M of the Drugs and Cosmetics Act includes the Good Manufacturing Practices that are applicable to the pharmaceutical industry and these have come into effect from the 1<sup>st</sup> of July, 2005. In addition to these it may make sense for the Indian industry to comply with a higher level of GMP's (if possible) as laid out in the two following international sources.

- ❖ A (non-binding) WHO publication called "Quality Control Methods for Medicinal Plant Materials" published in 1998, which has been revised in 2005.
- ❖ WHO technical Report Series 943, which are recommendations of the WHO Expert Committee on Specifications for pharmaceutical preparations.

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Apart from this there are specific EC guidelines, which address Good Manufacturing Practices for medicinal products.

### **9.7 Market Access**

Most industry insiders seem to think that most of the trade barriers in the developed countries can be surmounted with creation of greater awareness and some industry members have been active enough in the identification of these barriers, as well as having been pro-active in trying to get them removed.

Some of the Non Tariff Trade Barriers which have come to light and prevent the free market for AYUSH products and services can be summarized as under:

- ❖ Non recognition of Ayurvedic Practitioners for medical practice abroad
- ❖ Non recognition of Ayurvedic Pharmacopoeia
- ❖ Absence of established norms and procedures for unique requirements of AYUSH products in major markets such as EU, US etc.
- ❖ Absence of GMP standards and therefore dependence on WHO guidelines which may not fully encompass Ayurvedic products
- ❖ Unclear guidelines on gauging Quality and Standardization
- ❖ Absence of clear policies for Educational courses in AYUSH
- ❖ Unsubstantiated fears about IPR with respect to AYUSH medicines

It is widely stated that dissemination and validation of a unique medical system can be best achieved by practitioners of the system. AYUSH has grown over thousands of years through transfer of complex knowledge through ancient and medieval systems of education to finally culminate in present day AYUSH educational institutions. There is a sizeable population in the country which in one way or the other uses AYUSH medical system. Despite a sizeable domestic following we have not been able to assign AYUSH practice a place of dignity and respect in the social ladder of the country. On the one hand, we have eminent practitioners who have acquired respect though may have adopted knowledge through traditional methods, on the other; we have a set of practitioners who are educated in organized institutions. Since, AYUSH system despite its social acceptance has not achieved formal socio-political approval, practitioners associated with the system are still considered less popular.

The first requirement is to elevate the AYUSH system in the formal health care system, not restricting it to a few hospitals and health care institutions, but establish it equally with other systems both in qualitative and quantitative terms. This would necessitate a large number of practitioners and improvement in AYUSH education with better positioning. These two outcomes would lay down the foundations of wide scale acceptance of AYUSH system in India itself. Domestic formal acceptance of the system would generate appropriate environment for these practitioners to go out and carry the wisdom and practice of



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AYUSH. Therefore, the first concentration of the Government should be on enlarging the scope of AYUSH practice and improve AYUSH education both qualitatively and quantitatively. This should be followed with efforts to see how AYUSH practitioners can go abroad and disseminate knowledge and information. To begin with, this could be done in countries where traditional medicine has recognition as a health care system. For example, countries in South Asia, Africa, ASEAN, etc., can be taken in the first instance to develop cooperation programmes.

India is in the process of negotiating preferential trading arrangements with many countries and some groups of countries. It may be a good approach to include Traditional medicine as an important constituent in these agreements. Traditional medicinal products could be kept out of respective negative lists and could be traded duty free. Besides parties may agree to allow practitioners of traditional medicines albeit in limited numbers and cooperate on technical issues such as standards, export certification, technical capacities and human resource development etc. First such agreement could be taken up in the SAARC region due to similarity of our systems of traditional medicines.

Earlier, in this section preparation of monographs for star plants have been recommended. Similarly, there is a strong need to hasten the process of preparing Ayurvedic pharmacopoeia for established drugs and constituents. In absence of GMP standards, WHO guidelines are being followed. However, there is need to develop specific GMP guidelines for AYUSH products. Quality assurance is a significant demand of AYUSH importers and should help in establishing credibility of AYUSH products. Therefore, a quality certification for AYUSH products exported from India would establish quality credentials of these products, and is strongly recommended.

An assessment of AYUSH sector gives the impression of an environment with complexities. This to some extent could be because of the multiple challenges faced by AYUSH and multiple activities taking place to respond to these challenges. In the exclusive context of export promotion of AYUSH products an exclusivist approach is necessary. Once our focus is limited to 25 odd star plants, for each of them a flow chart of activities would be easier to prepare and monitor. This would necessitate a substantial amount of house-keeping in the concerned institutions of Government of India.

In the manner of selecting top 25 plants it is also suggested that we may launch a Focus Products Scheme for Top 50 Ayurvedic formulations. Funds must be provided for compiling internationally acceptable Drug Master Files for these products and there must be a concerted push between various Ministries to ensure that these products are allowed market access in all countries. An internal licensing mechanism for ASU industry will enable more companies who meet the basic criteria of quality and infrastructure to manufacture and export these formulations. This will also mark the beginning of formal and supported commerce for ASU industry. This will also announce the arrival of ASU formulations in

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the global market for natural products and will do to the ASU industry what Ginseng did to traditional Chinese medicine.

### **Promoting AYUSH Education**

**Greater emphasis must be given to AYUSH education as well as infrastructure in institutions imparting AYUSH education.**

**A possible way of facilitating exports could be to create a single window for clearances for companies wishing to export ASU products.**

**There is great potential for AYUSH to flourish regionally i.e., in South Asia where there is an existing culture of AYUSH, as well as South East Asia which also has had traditional medicines of various kinds historically. A great deal, however, depends on private initiative and business methods to create awareness and start marketing in these regions. Negotiations should occur in the services sector with South Asian countries to allow AYUSH doctors from India to practice in these countries.**

A process of certification (internal and voluntary) might go a long way in convincing other countries of the quality of these products.

### **9.8 A Look at China**

By 2050 the herbal market is expected to reach US \$ 5 trillion. China has set up over 15 high quality labs to modernize and develop herbal medicine. It gave focus of researching in specific therapeutic areas like liver disease, diabetes etc. Arsenic trioxide an active ingredient extracted from Chinese medicine is approved by US FDA. Similarly ZT 1 is under clinical trials in Europe. Artemisinin based drug developed by Novartis from Chinese herbal medicine is distributed world over. Several multinationals are attracted to develop herbal medicines.

Departments of Chinese medicines are set up in over 95 percent of general hospitals. Over 500,000 personnel are in Chinese medicine sector. Around 2,500 specialised hospitals, 28 medical colleges focused on Chinese medicine and pharmacology, 57 research institutions in Chinese medicine, over thousand companies producing Chinese medicine, fuel the market. The country has over 70,000 graduates and 1,000 postgraduates with Ph.D. or masters degree. China has established three toxicity evaluation centers and four clinical testing centers. Chinese medicines are available side by side with western medicines in various hospitals across country.

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The direction for the herbal medicine has to be given by government at this point of time. The big manufacturers in herbal area are focused on food products like honey or Chyawanprash etc., and the serious herbal medicine is under attended.

It will be desirable to expand the delivery of Ayush healthcare in Public Health delivery institutions through a tiered approach within a fixed time. This will encourage Ayush education while it expands its practice and increases the consumption of Ayush medicines..

### **Extension of Concessions to AYUSH Products on par with Pharmaceutical Products**

**The Indian Foreign Trade Policy allows some concessions for pharmaceutical products but makes no mention of AYUSH products as a distinct category. Remediying this could have a beneficial effect on the industry, which requires assistance for large scale technical up gradation. Fiscal benefits granted to the industry for such up gradation, could also act as incentives to the industry.**

## **9.9 Promoting Indian AYUSH & Herbal Industry**

In order to promote Ayush industry government could consider the following approaches,

**1. Focus Product Scheme - Select top 25 plants and Top 50 Ayurvedic formulations and Provide thrust**

- 1.1. Funds must be provided for compiling internationally acceptable Drug Master Files for these products and there must be a concerted push between various Ministries to ensure that these products are allowed market access in all countries.**
- 1.2. The Vishesh Krishi and Gram Udyog Yojana (VKGUY) should also include extracts as well as compounds isolated from the herbs so identified under the Focus product scheme.**
- 1.3. These focus products should have a published information on minimum purchase price and minimum quantity for a minimum period of time to encourage reliable cultivation. Produce from both wild sources and cultivated land should be encouraged independently.**
- 1.4. To achieve desired purity level at various micro units spread across the country may not be economically feasible. Hence these have to be bought at a gross level and routed to select central units for purification to bring them to the required quality standards. Processing zones, near important cultivation areas should be developed where the whole process of adding value to the raw medicinal plants takes place.**
- 1.5. Ethanol availability to recognized Ayush industries producing these products should be on a fast track basis.**

- 1.6. These formulations should be given complete tax concession with respect to excise duty/ vat etc. when priced say less than Rs.5/- 'cost of therapy per day' at therapeutic doses and having therapeutic claims.
- 1.7. Identify & promote Agri Export Zones (AEZs) for these plants.
- 1.8. Encourage clinical trial work to establish efficacy/safety and process standardisation of various formulations. Government should conceptualise a project and approach established pharmaceutical companies or established R&D labs, etc. to conduct the necessary research for select Ayurvedic preparations especially the analytical research.
- 1.9. Provide a meaningful financial assistance (for example Rs. 50 lakhs) as a grant if the product satisfies certain parameters such as:
  - 1.9.1. Complies with guidelines on heavy metal/pesticide/mycotoxin/microbial residues
  - 1.9.2. Efficacy is proven by 2 double blind controlled trials
  - 1.9.3. Analytical/chromatographic methods have been developed which facilitate both qualitative and quantitative estimation of ingredients
  - 1.9.4. Is from sustainably usable plant parts for at least 70% of ingredients.
  - 1.9.5. At least 2 publications in reputed journals of pharmaceuticals on the product.

## **2. Creating National Resources in Herbals**

- 2.1. Schedule 1 of Drug & Cosmetics act lists 57 official Ayurvedic books. Many are out of print and these should be made available and digitized. List of Ayurvedic herbs of India as mentioned in these books should also be made available.
- 2.2. Compile a comprehensive national database on the available scientific information about safety efficacy, phytochemistry and clinical data on each Indian medicinal plant. Create a national library of primary phytochemical reference standards and cost effective testing of herbal products.
- 2.3. Government should initiate specific research programs through state agricultural universities aimed at searching, identifying elite species/ varieties/chemotypes of those medicinal plants whose quality assessment criteria have been standardized. Herbal extract/product manufacturers having access to high quality raw material (elite varieties) become very critical for maintaining economic viability/competitiveness in both domestic and international markets. Elite varieties have been identified for some spices but for medicinal plants this work has not been done yet.
- 2.4. Establish a national germplasm & seed bank for medicinal plants. Aggressively develop the seed material and make it available for cultivation. Provide subsidies for the cultivation of red listed plants.
- 2.5. India specific Good Agricultural Practices (GAPs), Good Harvesting Practices (GHPs) could be prepared by National Medicinal Plant Board (NMPB)
- 2.6. In-vitro pharmacology and analytical phyto-chemistry laboratories are very few in India and are crucial for standardization of natural products. A national long term project can give contracts to various laboratories to facilitate the standardization of

natural products. As the labs are very few, the ministry should work with some development bank such as EXIM bank to promote such laboratories in key areas backed up by long term work, which is a national priority.

- 2.7. There exists a need to create competence in the core areas of molecular pharmacology by updating the academic curriculum and upgrading the learning systems. Training on assay systems development, etc., has to be taken up by CSIR laboratories. Several assays that provide higher content information about the drug substance are becoming increasingly unaffordable as several IPR issues are involved. The subject being important, the country needs to achieve some self reliance and hence the national herbal mission should undertake this task.
- 2.8. In key states, Ayurvedic/medicinal plant herbarium should be set up to collect, maintain and supply upon request authentic specimens of medicinal plants/ parts in a systematic manner.
- 2.9. Various government bodies are conducting scores of studies on herbal drugs. The current requirements of international bodies do not accept dated study protocols and demand high standards. Urgent audit is required on all these studies and pursue only such projects which are designed to meet international standards.
- 2.10. NIPER or a national laboratory should undertake special training programmes to SMEs on phytochemical isolation, molecular pharmacology, analytical testing, etc.
- 2.11. Urgent initiative should be taken in training all such clinical investigators and scientists on the design of clinical trials that are acceptable by international regulatory agencies. The current skill set available in modern medicine should be rapidly used in our traditional systems

### 3. Regulatory Issues

- 3.1. A convenient system to register Indian medicinal plants such as Ayurvedic herbs is required. While about 8,000 plant species are said to be medicinal, the medicinal uses of about 1,800 plant species are described in Ayurved. Many are described in folklore and some are in use. However, such plants which are not officially Ayurvedic/Siddha/ or Unani can not obtain manufacturing license as there is no procedure to add new plants/folklore plants.
- 3.2. Many of the significant Indian plants do not find place in the list of importable herbs in many countries. For example TGA Australia does not recognize any of the Indian pharmacopoeias while it recognizes Pharmacopoeia of the PRC of China. US FDA/ MHRA of UK, MCC of South Africa, TGA of Australia etc., have their own list of positive drugs which are safe and effective for permitting imports. We do not have such an official list that clearly states the important Indian medicinal plants that are safe and effective with reliable documentation. An urgent need, therefore, exists to compile the required data to enlist a herb in importable lists in various countries and initiate the registration of these herbs. A concerted effort is needed and the success

has to be monitored. Where applicable they may be classified as dietary supplements and in select cases as drugs.

- 3.3. Pharmexcil should provide a national registration cell which can provide information about the prevailing global rules and regulations governing natural products.
- 3.4. A periodic quality audit for AYUSH products exported from India should be undertaken to assure quality of the products.

#### **4. Excise Issues**

- 4.1. 'The intention of use' of a particular substance should govern the classification of a substance as a drug/health food/food. For example ginger can be a food and in some doses becomes an Ayurvedic drug and in another dose and form becomes a beverage. This has to be clarified with excise department as one of the steps to promote herbal sector.
- 4.2. All herbal raw materials are treated alike at forest check points. There exists a case to treat all cultivated herbal raw material and herbs collected from waste lands with a different perspective. Restrictions should be eased where the collection is from sustainable parts like leaves, flowers, seeds, fruits etc., simplification of transit permit/legal procurement certificate for transportation of raw drugs is essential.
- 4.3. Forest departments should create a list of plants/ trees where the collection is from sustainable parts, and should encourage herbal collectors to undergo proper training. Such training can help improve the overall quality of herbal raw material and reducing wastage.

#### **5. International Opportunity**

The herbal products in demand in various countries have to be researched and suitability & availability of Indian herbals for export production should be assessed. Trends in exports of herbal medicines, classes of herbal products, etc. should be analysed to re-orient Indian production to the requirements of International demand. Similarly, formulations popular in various countries should also be identified for manufacture and export of the same. The exercise would open gates for several opportunities for India in Herbal exports. The exercise requires dedicated and extensive research by various stake holders and initiation may be done in this direction.